



Listening to the Patient Voice in Sleep Apnea: Daytime Functioning and Experience With Therapy

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Introduction

Objective

- Understanding the patient voice and experience is an integral part of clinical care. The American Sleep Apnea Association (ASAA) organized and hosted a Patient-Focused Medical Product Development (PFMPD) meeting for the FDA in June 2018.
- The PFMPD meeting was the first of its kind, focused on medical products in addition to medications. Prior to the PFMPD, similar Patient-Focused Drug Development (PFDD) meetings were held by the FDA beginning in 2012 as a forum for patient communities about their experiences living with their respective conditions and the treatments

Methods

Overview

- A national survey was conducted. It was comprised of 32 items that were a combination of multiple choice and open text fields.
- Sections included diagnosis, symptoms, impact of sleep apnea on daily living, treatments and impact of treatments.
- The survey was developed as a “fit-for-purpose” instrument for use in conjunction with the FDA’s PFDD initiative and was therefore informed by the focus of past PFDD meeting surveys and related medical literature.
- The survey was tested and refined by project staff and in a group of patients. It was deployed by the ASAA (via Survey Monkey) and Evidation Health. It took an average of 17 minutes to complete. The survey was widely publicized, sent to email lists and promoted within social media. All

Results

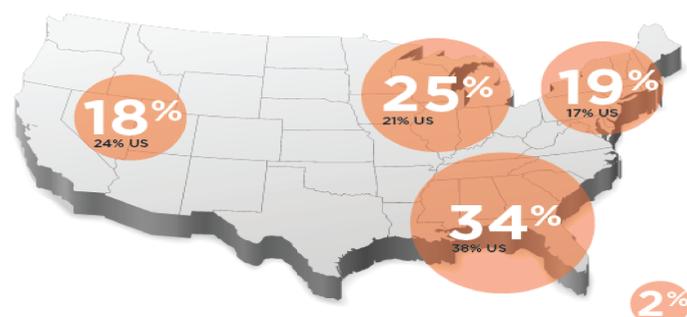


Figure 1. Responses came from across the United States and 2% from other countries. There was slight over-representation from the NE and Midwest regions, and under-representation from the South and West.

Results (continued)

Overview

- The survey was available for completion for the meeting in April and May 2018 and attracted a total of 5,630 responses. 85% of respondents were sleep apnea patients and 14% of respondents were family or friends of a patient.

Participants

- 70% reported using CPAP, and of those 82% reported using it 7 nights per week and 6.2 hours per night.
- 34% of respondents on CPAP continued to report moderate to severe daytime symptoms.
- 53% identified potential long-term consequences of OSA on

| | 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%) |

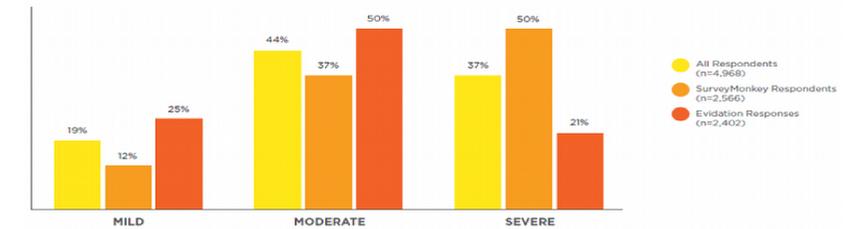
Figure 2. Participant demographics and OSA diagnostic information. 85% of respondents were OSA patients, 57% of respondents were female, and 86% of respondents had received a diagnosis from a physician.

| | 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%) |

Figure 3. Specific activities that were reported as being important to patients but that they could not do at all or do as fully as they would like as a result of sleep apnea.

Results (continued)

SYMPTOM SEVERITY: WITHOUT TREATMENT



SYMPTOM SEVERITY: WITH TREATMENT

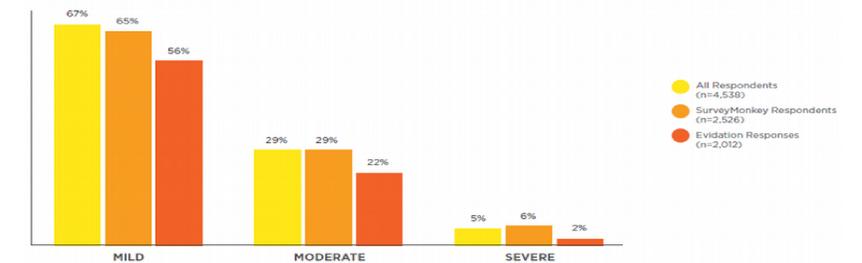


Figure 4. Symptom severity with and without treatment. Mild OSA patients reported higher symptom severity on treatment relative to off. Moderate and severe patients reported higher symptom severity off treatment relative to on, with the biggest difference being in severe OSA patients.

Discussion

Conclusions

- The PFMPD survey conducted by the ASAA is a rich source of the sleep apnea patient’s experience encompassing recognition, diagnosis, symptoms and treatment. For the full report, please visit www.awakesleepapnea.org
- The large total number of respondents provides confidence that these findings reflect a wide continuum of the sleep-apnea-aware community.
- The burden of OSA as well as its current treatments were widely endorsed by study respondents.

Future Directions

- Future research will more closely examine differences by age (current age and age at onset of OSA), gender, and experience with treatment.

Support: The FDA AWAKE meeting was hosted by the ASAA.

References

Maski K, Steinhart E, Williams D, Scammell T, Flygare J, McCleary K, Gow M. Listening to the patient voice in narcolepsy: diagnostic delay, disease burden and treatment efficacy. J Clin Sleep Med. 2017; 13(3):419-425.