Alliance of Sleep Apnea Partners (ASAP)
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Established: March 12, 2018
MA ID: 001316962 IRS ID: 82-5078693 DINS: 00576197

April 23, 2021

Elise Berliner, PhD.
Task Order Officer
Center for Evidence and Practice Improvement
Agency for Health Care Policy Research and Quality
5600 Fishers Lane
Rockville, MD 20857
SENT VIA EMAIL TO: epc@ahrq.hhs.gov

Re: Draft Technology Assessment – "Continuous Positive Airway Pressure Treatment for Obstructive Sleep Apnea"

Dear Dr. Berliner:

The Alliance of Sleep Apnea Partners (ASAP), a 501c3 organization founded by Sleep Apnea patients and patient caregivers, offers the following in support of much-needed research leading to therapeutic benefit for patients. ASAP appreciates the resources and time the AHRQ has invested in reviewing evidence from research studying the impact of Positive Air Pressure (PAP), the most common Sleep Apnea treatment.

A large part of the U.S. population suffers from Sleep Apnea, with a majority undiagnosed and untreated. Recent research has determined that Sleep Apnea is as much as five times more prevalent in the minority population than it is in the general population. Sleep Apnea patients often present with major co-morbidities (e.g., CVD, DM2, HBP, AFIB, stroke, CHF, etc.). Those who also contract COVID have negative outcomes estimated to be 70% higher than that of the general population, with underserved groups showing the worst outcomes.

While we appreciate that the meta study performed by the AHRQ is constrained by rigorous scientific methodology and procedures and must be conducted with great attention to study assessment protocols, we are concerned that the AHRQ conclusions to the effect that there is weak support in the studies for the effectiveness of PAP could be easily misinterpreted to mean that you have concluded that PAP is ineffective. Sentences such as "RCTs provide low strength of evidence (SoE) that CPAP does not affect the risk of all-cause mortality…" (incorporating as it does, an implied double negative) seem particularly likely to cause confusion outside the ranks of medical research professionals.

Those of us who have used PAP all night, every night, for many years *know* the benefits of PAP therapy. PAP has enabled us (and many family members) to keep our jobs, careers and marriages. PAP helps us to stay alive and out of the dementia wards of nursing homes. PAP has reduced or eliminated our severe O2 desaturations, stopped the TIAs and absence seizures, the premature bigeminy, PVCs and AFIB, raised HDL significantly and stopped the gout. In many cases, PAP has helped us lose the weight which Sleep Apnea made us gain. PAP has stopped our zombie-like fatigue.

For some of us, unable to sustain REM sleep since childhood, PAP has restored our dreams-- in every sense.

We hasten to note that those of us experiencing the greatest improvements in health from PAP treatment continue to be excluded from studies for ethical reasons (O2 desat too great, AHI too high, etc.) We, the sickest patients and the most likely to show benefit, are *never* represented in the studies. This exclusion badly undermines the statistical significance of the evidence that can be ethically gathered in the studies.

For many of us, PAP treatment ended decades of expensive (in terms of both financial costs and adverse health consequences) misdiagnoses and mistreatments by numerous specialists, all to try to determine what was wrong with us, before we were ever successfully diagnosed and treated. A Sleep Apnea patient, once correctly diagnosed and appropriately treated, costs the health care system <u>far</u> less. Unfortunately, for both the individual and the system, that often doesn't happen until we are in our 50's, 60's or later.

ASAP Alliance of Sleep Apnea Partners
ApneaPartners.Org
Designed with Patients in Mind

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Recently there has been a trend in the direction of tightening the criteria for various Sleep Apnea related treatment and support. While the AHRQ report has focused on specific criteria for hypopnea scoring and definitions of the AHI, the findings of the study suggest that there is not a direct association between AHI (regardless of scoring criteria) and several health outcomes. We do not feel this diminishes the importance of treating patients who have symptoms -including snoring and apneas at night, disrupted sleep, and daytime fatigue and sleepiness, and poor quality of life. We urge that the report does not use the review of AHI values to restrict treatment, but rather balances the importance of symptoms and quality of life to patients rather than a single number from a single study on a night that may or may not be representative of their typical sleep.

ASAP is most concerned that the AHRQ report, as currently worded could easily be misunderstood by payers (CMS and insurers), further eroding the already limited and much needed treatment and support options available to Sleep Apnea patients, especially in underserved minority populations.

We understand that weak evidence of benefit is not evidence of weak benefit and that ineffective studies of PAP are not probative evidence that PAP is ineffective.

But we hasten to ask:

> Will all those reading this review of studies appreciate and understand those logical and scientific points? Will the press understand it?
>
> Will patients, especially those struggling with adherence, reading a journalist's synopsis which references the AHRQ report, understand that?

ASAP trusts that it is part of your Agency mission and responsibility to assure that your findings are stated in the way least likely to be misunderstood, misinterpreted or misapplied. Accordingly, please consider prominently and expressly advising at appropriate points, (possibly the Conclusion, Abstract and/or Main Points?) that:

"The findings reviewed are inconclusive for use in evaluating therapeutic benefit of PAP."

And perhaps that:

"The lack of strong evidence underscores the need for more inclusive additional research".

We hope that the result of the publication of this study will be a renewed impetus supporting better, more conclusive research relative to Sleep Apnea, and NOT the further erosion of treatment and support for Sleep Apnea patients.

Sincerely,
Sarah E. Gorman
President, Alliance of Sleep Apnea Partners
sarah.gorman@me.com

CC: ASAP Board of Directors, ASAP Scientific Advisory Panel