

**Topic: Management of OSA in commercial vehicle operators (CMVOs)**

**Audience:** Can have sub-menus for PCPs, Sleep medicine physicians, occupational medicine physicians

**Key questions:**

**1) How can we screen for OSA in CMVOs?**

A variety of tools are available to screen CMVOs who are at higher risk for OSA.

In general, objective measures tend to be more reliable than self-reported symptoms.

Because obesity is a powerful risk factor for OSA, body mass index (BMI; a proxy variable for obesity) or neck circumference (indicative of central obesity) tend to be more reliable estimates for identifying those at high risk for OSA.

Varying BMI thresholds have been suggested to indicate high risk. These range from 30 kg/m<sup>2</sup> (recommended by the Medical Review Board of the FMCSA); 33 kg/m<sup>2</sup> (recommended by a Medical Expert Panel commissioned by the FMCSA, based on prior work<sup>i</sup>); or 35 kg/m<sup>2</sup> (recommended by a 2012 joint commission of the Motor Carrier Safety Advisory Committee and Medical Review Board, a 2016 FMCSA Medical Review Board; and a Tri-Society Task Force).<sup>ii</sup>

Physical examination findings of a neck circumference larger than 17 inches in a man or 15.5 inches in a woman, a high modified Mallampati class airway (class III or IV), enlarged tonsils, or retrognathia on physical exam also indicate high OSA risk.

In general, symptoms such as loud habitual snoring, choking or gasping during sleep, breathing stops witnessed by others during sleep, unrefreshing sleep, and excessive daytime sleepiness can suggest the presence of OSA. The lack of these and other symptoms does not exclude the possibility of OSA.

**2) What is the prevalence of OSA in CMVOs?**

Obesity, male gender, and middle age are among the most common risk factors for OSA. Because all three conditions exist commonly among CMVOs, the prevalence of OSA in this population tends to be high with estimates ranging from 28%<sup>iii</sup> to 60%.<sup>iv,v,vi</sup> One of the largest studies assessed 19,371 employees of a single trucking company and found that ~21% of drivers overall had at least 10 breathing pauses or reductions in airflow per hour. Among those at high risk based on a screening questionnaire, 80% had some degree of OSA, defined as at least 5 breathing pauses or reductions in airflow per hour.

### 3) Can home sleep apnea testing (HSAT) be used for OSA diagnosis?

The topic of HSAT in CMVOs has been reviewed previously.<sup>vii</sup> HSAT can be used in the diagnosis of OSA provided the CMVO achieves sleep the night of the recording, the HSAT chain of custody is secure, and OSA is at least moderate in severity. A positive test is useful, but a negative test does not exclude the possibility of OSA because HSAT can miss milder forms of the disease. Indeed, data loss occurs 10% of the time because HSATs are not monitored by a technologist. Programming the HSAT device to start automatically (rather than manually by the patient) can reduce data loss.

HSAT technologies vary widely in signals monitored, sampling rates, and scoring and analysis including automation for some manufacturers. In general, they use total monitoring time as a surrogate for total sleep time thereby systematically overestimating sleep duration. Some use actigraphy to estimate movement time to indicate wake time which increases the accuracy of total sleep time estimations.

The AASM has offered guidelines<sup>viii</sup> regarding these technologies including: specific signals and their sampling frequency, manual scoring and review for devices with automated scoring algorithms, confirmatory in-laboratory polysomnography following negative HSAT results in patients with a high pre-test probability of OSA, and follow up care and management recommendations.

### 4) What are the limitations of using HSAT?

While HSAT offers lower cost, greater convenience, and the comfort of testing in one's own home, this testing modality has limitations. HSAT is not as sensitive as in-lab testing with a false negative rate as high as 17%.<sup>ix</sup> Thus, a negative HSAT does not rule out the possibility of OSA. Also, HSAT only assesses for sleep-disordered breathing and not other sleep disorders such as periodic limb movement disorder, parasomnias, nocturnal seizures, bruxism, or narcolepsy. In general, HSAT does not record wake versus sleep, so total monitoring time is used as a proxy for total sleep time leading to systematic underestimation of sleep-disordered breathing. Because of this limitation, the test does not generate an AHI, but rather a Respiratory Event Index (REI). Also, sleep fragmentation (i.e., arousals from sleep) related to OSA, which is an important contributor to daytime sleepiness, is not routinely measured by HSAT. As such, HSAT can miss or underdiagnose patients and therefore is recommended for use in those with a high pretest probability of moderate to severe OSA. Patients with complicated medical or neurocognitive conditions such as neuromuscular disease, severe pulmonary disease, congestive heart failure, dementia, or other conditions are not appropriate candidates for HSAT.

Since HSATs are not monitored by a technologist, signal loss or artifact may limit the usefulness of the recording and chain of custody can be an issue. Testing failure requiring repeat testing can occur if a lead becomes displaced, disconnected, or falls off entirely while the patient is sleeping. Technical failures have been reported to occur about 10% of the time.<sup>x</sup> Devices that auto-start

using a pre-programmed timer are less likely to fail than those that have a manual start feature, in which the patient is required to initiate the recording at bedtime.

## 5) What are the limitations of using PSG?

In-laboratory polysomnography is the gold-standard measure to detect OSA, but certain limitations exist. First, this test is more expensive than HSAT and patients may have higher out-of-pocket costs. More and more third party payers are requiring prior authorization before testing, and, sometimes, such authorization for in-laboratory PSG is not given if sleep apnea is the suspected diagnosis; payers instead require HSAT as the initial diagnostic test.

Second, access to such testing may be limited, with waits in the U.S. reported to be 2-10 months.<sup>xi</sup>

Third, PSG requires the patient to sleep in an atypical environment which is problematic for several reasons:

- The laboratory setting and monitoring equipment interferes with sleep.
- Bedtime activities which influence breathing during sleep, such as alcohol intake or smoking, may be curtailed in the lab setting.
- Allergens present at home that influence breathing may not be present in the laboratory.
- Noise, lighting, temperature, and comfort level of the bedding in the laboratory may differ from those at home.

## 6) When should PAP therapy be offered?

The FMCSA Medical Review Board recommended in 2016 that PAP be offered for all patients who have  $AHI \geq 20$  events/hour on in-laboratory polysomnography.<sup>xii</sup>

Be aware this AHI threshold is not interchangeable with the REI obtained on HSAT, since the latter is not expected to capture hypopneas that result in arousals, and total monitoring time, rather than total sleep time, is used in calculating the frequency of sleep-disordered breathing events during HSAT.

Additionally, lower AHI values on in-laboratory PSG or lower REI values on HSAT do not necessarily indicate milder disease. Patients with lower values of AHI or REI should still be offered PAP therapy if they are deemed to have at least moderate disease, which may be suggested by significant symptoms impacting daytime functioning, or by high levels of oxyhemoglobin desaturation during sleep, or the presence of co-morbid medical conditions.

## 7) What are the indications and limitations for PAP, oral appliance, or surgery?

Positive airway pressure (PAP) therapy is the most effective and reliable treatment for OSA of all severities. Many insurance providers require a trial of PAP therapy prior to consideration of

coverage of alternate forms of treatment. PAP therapy is advantageous due to the ability to monitor treatment adherence on a daily basis. Some patients have difficulty tolerating PAP treatment for a variety of reasons. However, usage and tolerance are improved when therapy is supervised by sleep specialty providers.

Oral appliances are alternatives for patients with milder degrees of apnea that do not tolerate PAP therapy or prefer an alternative treatment.<sup>xiii</sup> Historically, the disadvantage of oral appliances was the lack of adherence tracking. If electronic adherence monitoring is validated in oral appliance therapies, they may become acceptable alternatives for transportation workers in the future.

Multilevel or stepwise surgical approaches can be considered for patients intolerant or unwilling to use PAP or oral appliance as long as patients are aware of the limitations and risks.<sup>xiv</sup>

Whichever form of therapy is chosen - PAP, oral appliance or surgical therapies -- the treating physician should document objective improvement of OSA with a target AHI or REI of less than 5 events/hour. This is best accomplished by in-laboratory PSG, though in the case of milder OSA, auto-adjusting PAP devices in an unattended setting or HSAT may be a reasonable alternative.<sup>xv</sup> One should note that measurement of residual sleep-disordered breathing events using auto-adjusting PAP devices is heterogeneous (i.e., manufacturer-specific) and may or may not reflect laboratory-based measurements.

Patients effectively treated surgically should be regularly screened for recurrent disease. Ongoing follow up for all treated patients is necessary to ensure adequacy of therapy, to document adherence, and to address any barriers to adherence or side-effects of therapy.

## **8) When should a CMVO be immediately disqualified from operating a commercial vehicle?**

Drivers should be disqualified immediately or denied certification if they meet any of the following criteria:

- Report EDS during the major wake period, while driving, OR
- Experienced a crash that is thought to be due to drowsiness, OR
- Fell asleep while driving
- Have AHI  $\geq 20$  events/hour until treatment efficacy is established
  - for those on PAP, this means a download that shows effective therapy for one week
  - for those who have undergone surgery, a 3-month post-op re-evaluation with AHI  $< 20$
- Non-adherence with treatment at any point

## **9) When should a CMVO have conditional certification?**

In the absence of reasons for immediate disqualification:

- An operator with BMI  $\geq 33$  kg/m<sup>2</sup> may be certified for 2 months, pending sleep study and establishment of adherence with therapy
- An operator with OSA may be certified for 1 month after starting PAP therapy, then certified for 3 months if adherence and efficacy are demonstrated. If adherence and efficacy are shown at 3 months, the driver may be certified for 1 year. Future certification depends on continued adherence and efficacy
- Minimal acceptable adherence consists of using PAP for  $\geq 4$  hours/day on  $\geq 70\%$  of days
- The clinician should use his or her judgment to determine whether more frequent visits or assessments may be required, based on the operator's disease severity, adherence and individual response to therapy.

### 10) When can a CMVO have unconditional certification?

All individuals with OSA must be referred to a clinician with relevant expertise. A CMVO should be re-evaluated by the medical examiner at least yearly.

PAP is the preferred, first-line therapy.

Unconditional certification may be issued if:

The CMVO has AHI  $\leq 20$ , and does not report excessive daytime sleepiness during the major wake period, OR The CMVO has OSA (any AHI) which is being effectively treated. The worker does not report experiencing excessive sleepiness during the major wake period, AND meets minimal acceptable adherence levels with treatment (average of  $\geq 4$  hours of use per day on  $\geq 70\%$  of days). Adequate PAP pressure should be established through one of the following: In-laboratory titration study, Auto-adjusting system

CMVOs should be informed that optimal benefits occur with at least 7 hours of daily use.

Following bariatric surgery, a CMVO may be certified if:

- Effective treatment with PAP is established, OR
- Re-evaluation (with sleep study) shows AHI  $< 10$ /hour at least 6-months post operatively (i.e., once weight nadir is reached), and the treating physician finds that OSA is effectively resolved, AND
- Cleared by the treating surgeon, AND
- Excessive daytime sleepiness is resolved

Patients who have an OSA diagnosis should be recertified annually. The CMVO should be advised to have more frequent reevaluation if he/she gains weight ( $\geq 5\%$ ) or if symptoms recur or worsen.

With oropharyngeal surgery, facial bone surgery, or tracheostomy recertification to operate a motor vehicle may occur if the following criteria are met:

- At least 1 month elapses after surgery, to allow tissue edema to resolve, AND
- The CMVO is cleared by the treating physician, AND
- A sleep study shows AHI < 10, AND
- Excessive daytime sleepiness is resolved

Annual recertification should be done in all patients who have had non-PAP therapies for OSA. If needed on the basis of symptoms, exam, or weight gain, a repeat sleep study should be done, to confirm that AHI < 10/hour; in addition, excessive daytime sleepiness should be resolved.

Because treatment efficacy cannot be ascertained on an ongoing basis, oral appliances are not acceptable for those in whom AHI is  $\geq 20$  events/hour.

### **11) When can a CMVO return to work?**

A CMVO who has been disqualified from operating a motor vehicle due to untreated OSA or suspicion of OSA, may resume operating a vehicle if the operator meets the criteria outlined in items #9 and 10 above, such that the CMVO has been evaluated by a sleep specialist and shown to demonstrate objective evidence of adherence to PAP and efficacy of therapy.

### **12) How can we address treatment efficacy?**

The primary goal of OSA treatment is to demonstrate improvement of OSA severity, adherence to therapy, and improved patient symptoms.<sup>xvi</sup> Specific measures include a combination of physician judgement, symptom surveys, objective testing, and adherence data.

Employees in safety-sensitive positions pose unique challenges which include time limitations, concerns regarding employment, and treatment that is compatible with their job duties.

Improvement in OSA severity can be determined by either a sleep study while on the specific OSA therapy or a sleep study after corrective treatments such as weight loss (through lifestyle changes or bariatric surgery) or upper airway surgeries. However, one should note that these assessments do not provide ongoing evaluation of daytime function in “real time.” Therefore, all patients should be counseled that it is their responsibility to adhere to the prescribed therapy and to avoid drowsy driving. If they feel their OSA is not effectively treated they should alert their health care provider.

For PAP therapies, built-in technologies allow tracking of hours of use, pressure settings, mask leak, and residual AHI. Mask leak is useful in assessing efficacy because leak disrupts sleep quality and may impact the control of sleep-disordered breathing events. Efficacious treatment should also address and resolve mask leak.

Adherence tracking for oral appliances is under investigation. Currently these therapies do not monitor residual events. Body weight should also be monitored. Weight increases of 5% or more in those receiving non-PAP therapies should be re-evaluated to ensure treatment is efficacious. In patients receiving auto-adjusting PAP therapy, review of adherence data is necessary to ensure the device is adjusting adequately to increasing pressure requirements from weight gain and that the residual AHI remains low.

No specific measure alone is adequate to ascertain treatment efficacy. Rather, a comprehensive evaluation by a clinician with experience in sleep medicine is advised. Such evaluation may include a review of sleep hygiene and sleep schedule to ensure adequate sleep quality and sleep duration. Additionally, subjective measures such as the Epworth Sleepiness Scale, or objective measures such as the MSLT or MWT, should be considered, when appropriate.

Of note, subjective symptoms have been shown to be unreliable in employment settings, and MSLT/MWT data provide only a single “snapshot” of the point in time the test was completed. Such studies, though objectively measured (rather than subjectively reported), have not yet been shown to correlate with on-the-road performance.

### **13) When and how should I report a driver whom I think is unfit?**

In conditions in which public health and safety are at risk, reporting requirements generally supersede a patient’s right to privacy. Patients who are deemed to be at high risk for a crash, and who indicate an unwillingness to adhere to treatment recommendations at any time should be reported to state licensing agencies, medical examiners, employers, or the referring entity as appropriate. Reports should be directed to the state DOT. If possible, the referring medical examiner should also be notified. The patient should be informed of the physician’s requirement to report, that a report is being made, and the reason for reporting. This communication should be documented in the medical record.

### **14) Links to useful references**

[Sleepeducation.org](http://Sleepeducation.org)

[NIOSH](#)

[NIOSH Center for Motor Vehicle Safety](#)

[FMCSA](#)

[NHTSA](#)

[NTSB](#)

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<sup>i</sup> Ancoli-Israel S, Czeisler CA, Georgo CFP, Guilleminault C, Pack AI. Expert Panel Recommendations; Obstructive Sleep Apnea and Commercial Motor Vehicle Driver Safety. <https://www.fmcsa.dot.gov/sites/fmcsa.dot.gov/files/docs/Sleep-MEP-Panel-Recommendations-508.pdf>. Published January 14, 2008. Accessed February 10, 2017.

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