Obstructive Sleep Apnea and the Commercial Driver: Understanding the Controversy and Applying Screening Criteria

Scott Levy, MD, MPH, FACOEM

Western Occupational and Environmental Medical Association
CME Webinar - June 16, 2011

Disclosure

I have no conflicts of interest to report. Any products or images shown are for illustrative purposes only.

Objectives

Pathophysiology
Clinical Signs
Treatment
Controversy
Understanding the Available Guidelines
Benefits of Screening
It is estimated that nearly one in three commercial drivers suffers from mild to severe Obstructive Sleep Apnea (OSA).

More prevalent as we age:
- Affects 4% of middle-aged men
- 2% of middle aged women
- 27% of older men
- 19% of older men and women

Characterized by pauses or gaps in breathing due to an obstruction of the airway

Obstructive Sleep Apnea: Physiology
Obstructive Sleep Apnea: Physiology

Partial blockage of airway causing abnormal breathing and sleep disruptions
37 million experience on a regular basis

Sleep Apnea

Predisposing Factors
- Obesity
- Narrow oropharynx
- Large neck size
- Small jaw
- Other

Mallampati Classification
Mallampati Classification

A

B

C

D

Neck Circumference

Jaw Size
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Sleep Apnea Symptoms
- Loud, regular/irregular snoring
- Unrefreshing sleep
- Daytime sleepiness
- Falling asleep in non-stimulating environments
  - Watching TV
  - Long drives

Definitions
- Apnea – airflow ceases for more than 10 seconds.
- Hypopnea – airflow decreases for more than 10 seconds + associated decrease in O2 sats + an arousal from sleep.
- Severity (apnea-hypopnea index):
  - Mild – 5+ episodes/hour.
  - Moderate – 15+ episodes/hour.
  - Severe – 30+ episodes/hour.

Conditions Associated With OSA

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Obstructive Sleep Apnea and Cardiovascular Effects

- Oxygen level drops
- Carbon Dioxide builds

Resumption of breathing
- Elevated blood pressure

Brain arousal
- Nervous system stimulates brain to awaken

The Relationship Between Obstructive Sleep Apnea and Hypertension

Mild OSA
- Odds of having hypertension was 42% greater

Moderate
- Double the risk

Severe
- Almost 3x greater

How Do We Test for Sleep Apnea?

Sleep Studies
- can be performed at home (unsupervised) or in a sleep lab (supervised).
Epworth Sleepiness Scale

Use the following scale to choose the most appropriate number for each situation:

- 0 = Normal ability to resist sleep
- 1 = Severe sleepiness: specifically during the day

<table>
<thead>
<tr>
<th>Situation</th>
<th>Chances of dozing</th>
</tr>
</thead>
<tbody>
<tr>
<td>Waking up</td>
<td></td>
</tr>
<tr>
<td>Shining, 8 a.m.</td>
<td></td>
</tr>
<tr>
<td>As a passenger in a car for an hour without a break</td>
<td></td>
</tr>
<tr>
<td>Sitting in the afternoon when circumstances permit</td>
<td></td>
</tr>
<tr>
<td>Talking to someone</td>
<td></td>
</tr>
<tr>
<td>In the car while stopped for a few minutes in traffic</td>
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</tbody>
</table>

Score:
- 0-9: Normal range
- 10-14: Suggestive
- 15-24: Severe

Treating Obstructive Sleep Apnea

- Constant Positive Airway Pressure (CPAP)
  - Newer machines have “a compliance card” which documents CPAP usage.
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Uvulopalatopharyngoplasty (UPPP)

Mandibular Advancement Device

The Controversy

- Who do we screen?
  - Only those who report symptoms?
  - Only those who look symptomatic?
  - According to what guidelines?
    - FMCSA
    - Current medical literature
    - Other?
Controversy #1 - Regulation or Guideline?

<table>
<thead>
<tr>
<th>Topic</th>
<th>Details</th>
</tr>
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<tbody>
<tr>
<td>1</td>
<td>Has no loss of a foot, leg, hand, or arm</td>
</tr>
<tr>
<td>2</td>
<td>Impairment in a body part that would affect driving, i.e. Inability to grasp</td>
</tr>
<tr>
<td>3</td>
<td>Diabetes must be controlled and not on insulin</td>
</tr>
</tbody>
</table>

391.41 (b)

1 and 2
- Has no loss of a foot, leg, hand, or arm
- Impairment in a body part that would affect driving, i.e. Inability to grasp

3
- Diabetes must be controlled and not on insulin

4
- Has no current clinical diagnosis of myocardial infarction, angina pectoris, coronary insufficiency, thrombosis.

6
- HTN
  - Stage 1-3
  - 140/90
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391.41 (b)

8
- Epilepsy (seizure disorder)
9
- Psychiatric disorder
10
- Visual acuity of at least 20/40

391.41 (b)

11
- Ability to hear
12 and 13
- Drug abuse
- Alcohol abuse

391.41 (b)

5
- Has no established medical history or clinical diagnosis of a respiratory dysfunction likely to interfere with the ability to control and drive a commercial motor vehicle safely.
Controversy #1

Is OSA considered “a respiratory dysfunction likely to interfere with the ability to control and drive a commercial motor vehicle safely”?

Doesn’t this refer more to COPD or other “serious” respiratory problems likely to cause the patient sudden incapacitation such as severe sudden dyspnea?

Federal Motor Carrier Safety Administration (FMCSA)

391.41 (b) 5 FMCSA Medical Advisory Criteria For Evaluation

Since a driver must be alert at all times, any change in his or her mental state is in direct conflict with highway safety.
391.41 (b) 5 FMCSA Medical Advisory Criteria For Evaluation

There are many conditions that interfere with oxygen exchange and may result in incapacitation, including emphysema, chronic asthma, carcinoma, tuberculosis, chronic bronchitis and sleep apnea.

391.41 (b) 5 FMCSA Medical Advisory Criteria For Evaluation

If the medical examiner detects a respiratory dysfunction, that in any way is likely to interfere with the driver's ability to safely control and drive a commercial motor vehicle, the driver must be referred to a specialist for further evaluation and therapy.

National Registry of Certified Medical Examiners
As a medical examiner, it is important for you to distinguish between medical standards and medical guidelines. Regulations/standards are laws and must be followed. Whereas guidelines, such as advisory criteria and medical conference reports are recommendations. While not law, the guidelines are intended as best practices for medical examiners.

Guidelines have been issued by the Federal Motor Carrier Safety Administration (FMCSA) to provide you with additional information and are based on medical literature. If you choose not to follow the guidelines, the reason(s) for the variation should be documented. You are responsible for determining if the commercial motor vehicle (CMV) driver is medically qualified and is safe to drive under the Federal Motor Carrier Safety Regulations (FMCSRs).

Controversy #2

Who do we screen?
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Evolution of Screening Standards for Commercial Drivers

- Brief history of OSA guidelines in commercial drivers.

Pulmonary Conference 5/2001

Operators with suspected sleep apnea (symptoms of snoring and hypersomnolence), or with proven but untreated sleep apnea, not be medically qualified for commercial motor vehicle operation until the diagnosis has been eliminated or adequately treated.

Pulmonary Conference 5/2001 Recommendation
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Joint Task Force (JTF) 2006

Screening Recommendation for Commercial Drivers With Possible or Probable Sleep Apnea

1. Sleep history suggestive of OSA (snoring, excessive daytime sleepiness, witnessed apneas)

2. Two or more of the following:
   a) BMI >35 kg/m2
   b) Neck circumference greater than 17” in men or 16” in women
   c) Hypertension (new, uncontrolled, or unable to control with less than 2 medications)

3. ESS > 10

4. Previously diagnosed OSA: compliance claimed, but no recent medical compliance data available for immediate review

5. AHI >5 but <30 in a prior sleep study and no excessive daytime somnolence (ESS 11), no MVA’s, no hypertension requiring 2 or more agents to control
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March 2009

Key Points

- 456 drivers
- 53 (12%) sent for sleep study using JTF criteria
- 20 studies performed and all 20 confirmed as OSA via Sleep Study
- 33 patients lost to f/u
Key Points

DOT Medical Review Board

Summary of MRB Minutes 1/2008

a) As BMI increases the risk for crash increases
b) Obesity (BMI ≥ 30) is predictor of OSA
c) Commercial Drivers BMI
   • 42 percent of drivers have a BMI of ≥ 30
   • 24 percent of drivers have BMI ≥ 33
Summary of MRB Minutes 1/2008

Medical Expert Panel
- Screen all drivers with BMI ≥ 33. Screening all with a BMI of 30 would be better but infrastructure to screen everyone is not yet available. Symptomatic or high risk should also be screened.

Medical Review Board
- Screen all drivers with BMI ≥ 30

Medical Expert Panel Guidance

- Asymptomatic patients
  - AHI<20- Clear for 1 year, CPAP not mandatory
  - AHI>20- Mandatory treatment
- Symptomatic
  - Require treatment
    - If on CPAP need to demonstrate compliance and effectiveness.
    - If surgery then require repeat AHI<10
    - Consider use of sleep specialist

American Thoracic Society 2004
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ATS 2004

THE PHYSICIAN'S LEGAL OBLIGATIONS
Overview of Current Legal Process
Under general principles of malpractice liability, physicians are obligated to adhere to the prevailing standard of care (58). In regard to the recognition and treatment of sleep apnea, the report from the congressionally mandated National Commission for Sleep Disorders Research concluded that health care practitioners were generally unaware of the hazards that sleepiness and sleep apneas posed to the health and safety of the country (48). Hence, in the opinion of this Committee, it is unreasonable at the present time to hold general or primary care practitioners to a routine standard for recognition of sleep apneas and its consequences. Also, current therapy for severe sleepiness is not in the domain of the general or primary care practitioner. On the other hand, specialists who have, or hold themselves to have, medical training and skills in the recognition and management of sleep apneas are held to a higher standard because clinical management of this condition has been in their domain for at least the past 10 years. Pulmonary specialists, in particular, are expected to be aware of the presentations and complications of excessive sleepiness, of which sleep apnea is a common cause.

Physician’s Legal Obligations

- Healthcare practitioners are generally unaware of the hazards that OSA pose.
- It is unreasonable at the present time (1994) to hold general PCP’s to a routine standard for recognition of OSA and its consequences.

“On the other hand specialists who have, or hold themselves to have, medical training and skills in the recognition and management of OSA, are held to a higher standard…”
ATS 2004

“Liability to third parties has also clearly been established in connection with impairments in driving performance…”

ATS 2004

“Thus, a Physician who fails to adhere to the prevailing standard of care of a patient with profound sleepiness is liable to any person injured as a result of the patients impaired driving”

Schneider National Trucking
Schneider Study

- Average cost per large truck crash involving a fatality in 1999 was $3.54 million, and involving an injury was $217,005.

Schneider Study

- Accident rate in treated individuals dropped 73%
- 129% greater retention rate in terms of driver turnover

Schneider Study

- After CPAP intervention
  - _ as many hospital admissions
  - _ the health care dollars compared with the period prior to intervention.
- Per member per month (PMPM) health care costs improved from $433.59 - $666.53 per month.
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Summary

- OSA
  - Well-known and common condition which is caused by several factors of which BMI and age appear to be strong predictors.
  - Leads to an increased risk of
    - Motor vehicle accidents
    - A variety of negative health outcomes.
  - Is easily detectable and treatable

Summary

- Although the FMCSA has not formally adopted a set of screening guidelines, the medical literature is clear.
- For providers to not follow the current clinical guidelines, can bring significant risk.
- The medical community and the public would benefit from having the FMCSA adopt 1 set of guidelines to use as a gold standard.

FAQ’s
FAQ’s

1) If a driver has a BMI greater than or equal to 33 how long should the patient be cleared for?
   ▪ Medical Expert Panel
   ▪ 1 month clearance to obtain sleep study. MEP preferred 1 week but recognized logistical problems

FAQ’s

2) How compliant on CPAP does the patient have to be?
   ▪ Minimum of 4 hour use per night for 70% of nights and AHI must be under 20, preferably under 5.

FAQ’s

3) What is a compliance card?
   ▪ Data card attached to the newer machines which record the patients usage and AHI.
   ▪ Data from the compliance card should be reviewed prior to any further certifications.
FAQ’s

4) If a driver has OSA and starts CPAP treatment, when can he/she be cleared?
   • FMCSA
   • Successful treatment for 1 month
   • Medical Review Board
   • Can receive temporary clearance after 1 week.
   • Need to document compliance
   • If compliant, then 1 and 3 month extension
   • Yearly clearances thereafter if compliant

FAQ from Employers

5) As an employer, how can I afford to have all of my drivers taken out of service during this testing?
   A) Only those drivers deemed to be at significant risk by the medical examiners will need to undergo a sleep study.
   B) Only in rare circumstances are the drivers removed from service as the majority are given temporary clearances which are long enough for them to be tested.

FAQ from Employers

6) This all seems very complicated. Wouldn’t it seem a lot easier to send all of our drivers out to other providers?
   As an employer I would be very careful about purposely choosing providers who ignore the latest medical guidance.
FAQ from Employers

7) Does a driver with OSA need restrictions?
   Not if they are adequately treated.

FAQ from Employers

8) Who pays for the testing and treatment.
   Most health insurances will cover the cost of both as it is medically indicated.

FAQ from Employers

9) Once the driver receives his CPAP, is he automatically given his 2 year clearance?
   No. In order to be medically cleared, the driver needs to demonstrate compliance with the treatment. Once he is deemed compliant and adequately treated he would then receive a 1 year clearance, barring any other issues.
FAQ from Employers

10) If this updated medical guidance is not regulation, why do we have to follow it? This is not any different than failing to screen a patient for cancer. If the latest medical guidelines recommend screening for colon cancer at age 50, failing to do so is considered malpractice. As an employer, you can be held liable for the contractors you use.

FAQ from Patients

11) If I wear CPAP do I need a sleep study every year?

- If your CPAP machine has a compliance card, simply reviewing the data from the card would be all that is needed in most cases.
- If your CPAP device does not have a compliance card, repeat sleep studies may be indicated.

12) Last year I had a sleep study and my provider told me that I did not HAVE to wear CPAP, but this year I am being sent again for another test. Can you explain this?

- The DOT MRB made specific recommendation in terms of ability to drive with OSA. If your AHI was 19 last year and you gained weight, developed HTN or became symptomatic, a repeat PSG (polysomnogram) would be indicated. Age is also a risk factor.
FAQ from Patients

13) As weight seems to be a big risk factor, can someone be treated by simply losing weight?
   Absolutely. Unfortunately a patient can not be allowed to drive until their OSA is controlled. So a reasonable path would be CPAP plus diet until enough weight is lost to improve the condition.

Questions?

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THANK YOU!