Obstructive Sleep Apnea
in Truck Drivers

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Funding Disclosures

- American College of Occupational and Environmental Medicine (ACOEM)
- Federal Motor Carrier Safety Administration (FMCSA), U.S. Department of Transportation (DOT)
- Harvard School of Public Health, NIOSH Education and Research Center (ERC)
The Federal Motor Carrier Safety Administration (FMCSA) was established as a separate administration within the U.S. Department of Transportation (DOT) on January 1, 2000, pursuant to the Motor Carrier Safety Improvement Act of 1999.

FMCSA’s primary mission is to reduce crashes, injuries, and fatalities involving large trucks and buses.

DOT and FMCSA Rules and Regulations
- Section 49 CFR 391.41(b)(5) of the Federal Motor Carrier Safety Regulations states that the driver must have:

  “no established medical history or clinical diagnosis of respiratory dysfunction likely to interfere with the ability to control and drive a commercial motor vehicle safely.”
Overview

- Introduction
- Obstructive Sleep Apnea and Obesity
- Obesity and Sleepiness
- Obstructive Sleep Apnea and Crash Risk
- Risk Factors in Sleepy Drivers
- Screening for and Detecting OSA
- FMCSA Medical Expert Panel Recommendations
- Challenges
- Medico-legal Considerations
Introduction

- **Commercial Drivers**
  - > 8 million in the U.S.
  - Obesity prevalence ~50% (nearly twice that of the U.S. population)
  - Risk for OSA as high as 50%
  - Motor vehicle crash risk is associated with OSA

- **Barriers**
  - Challenging public policy decision
  - There are limited data that is specific to commercial drivers.
Motor Vehicle Crashes

- 2006: Police reported
  - 368,000 large truck crashes
  - 4,321 fatalities
  - 77,000 injuries.
- 50% of large truck crashes lead to death or incapacitating injury.

National Highway Traffic Safety Administration (NHTSA), Fatality Analysis Reporting System (FARS) and General Estimates System (GES).
Obstructive Sleep Apnea

- U.S. Population
  - As high as 20%
  - 2-10% overall prevalence

- Truck Drivers
  - 17-28% (various studies)
  - Severity of OSA

<table>
<thead>
<tr>
<th>Severity</th>
<th>AHI &lt;5</th>
<th>AHI &gt;5</th>
<th>AHI &gt;15</th>
<th>AHI &gt;30</th>
</tr>
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<tbody>
<tr>
<td>Normal</td>
<td>40.4%</td>
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<tr>
<td>Mild</td>
<td></td>
<td>28.1%</td>
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<tr>
<td>Moderate</td>
<td></td>
<td></td>
<td>24.9%</td>
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<tr>
<td>Severe</td>
<td></td>
<td></td>
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<td>10.6%</td>
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Anatomy of Obstructive Sleep Apnea

FIGURE 1A. Normal airway. The soft palate and uvula are normal in length and total size. The tongue is normal in size and is angled forward. The upper airway at the level of the nasopharynx, oropharynx and hypopharynx is normal in size and contour.

FIGURE 1B. Abnormal airway during sleep. Multiple sites of obstruction often occur in patients with obstructive sleep apnea. An elongated and enlarged soft palate impinges on the posterior airway at the level of the nasopharynx and oral pharynx. In addition, a receding jaw pushes an enlarged tongue posterior to impinge on the hypopharyngeal space.

A Patient with Severe Sleep Apnea

Obesity

- **U.S. Population**
  - Prevalence – 33.8%, 2008

- **Commercial Drivers**
  - Prevalence - 50%*


Source: CDC Behavioral Risk Factor Surveillance System.

N=406
~50% BMI ≥ 30
~38% overweight
Obesity

- Obesity $\rightarrow$ OSA, OSA $\rightarrow$ Obesity
- Obesity $\rightarrow$ Sleepiness, Fatigue
- Obesity (even w/o OSA) $\rightarrow$ Sleepiness
- OSA (+ Obesity) $\rightarrow$ Crash Risk
Obesity & Sleep Apnea

Abdominal Fat and Sleep Apnea
The chicken or the egg? *Diabetes Care* 31 (Suppl. 2):S303–S309, 2008

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**Figure 1**—Potential mechanisms forming a vicious cycle where obesity may result in OSA and OSA may lead to weight gain (see text for details). UAW, upper airway.
Obesity & Sleepiness

Fig. 2. BMI-specific prevalence of EDS.

Bixler et al. *J Clin Endocrinol Metab* 90: 4510–4515, 2005
Obesity & Sleepiness

ORIGINAL INVESTIGATION

Obesity Without Sleep Apnea Is Associated With Daytime Sleepiness

Alexandros N. Vgontzas, MD; Edward O. Bixler, PhD; Tan MD; Tjiaaw-Ling Tan, MD; Deborah Kantner, BS; Louis F. Martin, MD; Anthony Kales, MD

Conclusions: Daytime sleepiness is a morbid characteristic of obese patients with a potentially significant impact on their lives and public safety. Daytime sleepiness in individuals with obesity appears to be related to a metabolic and/or circadian abnormality of the disorder.

Arch Intern Med. 1998;158:1333-1337

The pathophysiology of daytime sleepiness is complex and multi-factorial.
OSA and Crash Risk

Mean crash risk ratio: 1.21-4.89.

Individuals with OSA have twice the crash compared to individuals without OSA.

Other studies have estimated the odds ratio to be as high as ~11.

Conclusion: Untreated sleep apnea is a significant contributor to motor vehicle crashes.
OSA and Increased Crash Risk

- Does the present of obstructive sleep apnea increase crash risk?
  - Yes – Severe Sleep Apnea
  - Maybe – Mild to Moderate Sleep Apnea; some studies say “yes” others “no”; the evidence is not definite to suggest that greater severity of OSA leads to incrementally increased crash risk.
The Most Definitive Study of the Effect of CPAP Treatment to Reduce Crash Risk

Reduction in motor vehicle collisions following treatment of sleep apnoea with nasal CPAP

Thorax 2001;56:508–512

C F P George

N=210
Mean BMI = 35.5
Mean AHI = 54
Mean age = 52

The risk of MVCs due to OSA is removed when patients are treated with CPAP. As such, any restrictions on driving because of OSA could be safely removed after adequate treatment.
Risk Factors

For OSA
- BMI – Obesity
- Neck Circumference
- Waist Circumference
- Age
- Gender?
- Daytime sleepiness
- Visceral adipose tissue

For Crash
- OSA
- BMI – Obesity
- Apnea + Hypopnea Index (AHI), RDI
- Oxygen (de) Saturation - hypoxemia
- Daytime sleepiness
- Visceral adipose tissue
- Inadequate Sleep

There are limited data on the risk for crashes in commercial truck drivers with OSA.
Various Tests May Not Correlate with Crash Risk

  - Epworth Sleepiness Scale (ESS)
  - Psychomotor Vigilance Test (mean reaction time)
  - Psychomotor Vigilance Test (slope of decline in reaction time)
  - % Errors on Steer Clear

  None of the above correlated with increased crash risk (N=60)
Screening for OSA Using BMI

  - BMI of 32 kg/m$^2$ used as a cut-point to screen
  - 100% denied excessive daytime sleepiness
  - 78% had polysomnography-confirmed OSA or excessive daytime sleepiness by the multiple sleep latency test (MSLT)

  - BMI $\geq 33$ kg/m$^2$, OSA, Sensitivity 0.77, Specificity 0.71.

  - BMI $\geq 35$ kg/m$^2$
  - Talmage et al. 2008. N=1443, 13% screened for OSA, PPV 94.8%
  - Parks et al. 2009. N=456, 12% screened for OSA, PPV 100%
Screening with Subjective Findings

  - Of those with sleep disordered breathing, only 22% of the men and 17% of the women reported excessive daytime sleepiness.

  - *None* of the drivers who were diagnosed with OSA reported a history of snoring or excessive daytime sleepiness.

  - Of drivers with confirmed OSA, mean Epworth Sleepiness Scale score: 3.35
  - >50% of drivers with confirmed OSA denied a history of snoring, excessive daytime sleepiness, or a history of a sleep disorder.
Epworth Sleepiness Scale

The instrument

How likely are you to doze off or fall asleep in the following situations, in contrast to feeling just tired? This refers to your usual way of life in recent times. Even if you have not done some of these things recently try to work out how they would have affected you.[1]

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

- 0 = no chance of dozing
- 1 = slight chance of dozing
- 2 = moderate chance of dozing
- 3 = high chance of dozing

<table>
<thead>
<tr>
<th>Situation</th>
<th>Chance Of Dozing</th>
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<tbody>
<tr>
<td>Sitting and reading</td>
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<tr>
<td>Watching TV</td>
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<tr>
<td>Sitting inactive in a public place (e.g. a theater or a meeting)</td>
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<tr>
<td>As a passenger in a car for an hour without a break</td>
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<tr>
<td>Lying down to rest in the afternoon when circumstances permit</td>
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<tr>
<td>Sitting and talking to someone</td>
<td></td>
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<tr>
<td>Sitting quietly after a lunch without alcohol</td>
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<tr>
<td>In a car, while stopped for a few minutes in traffic</td>
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### Joint Task Force OSA

#### Screening Recommendations

Drivers meeting one or more of the six criteria are considered to have OSA or probable OSA.

<table>
<thead>
<tr>
<th>Historical Findings</th>
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<tbody>
<tr>
<td>1. Snoring, excessive daytime sleepiness, witnessed apneas</td>
</tr>
<tr>
<td>2. MVA likely related to sleep disturbance (run off road, at-fault, rear-end collision)</td>
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<tr>
<td>3. Previous OSA diagnosis</td>
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<table>
<thead>
<tr>
<th>Epworth Sleepiness Scale</th>
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<tr>
<td>4. ESS score &gt; 10</td>
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<table>
<thead>
<tr>
<th>Physical Examination Findings</th>
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<tr>
<td>5. Sleeping in examination or waiting room</td>
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<tr>
<td>6. Two or more of the following</td>
</tr>
<tr>
<td>a. BMI $\geq 35$ kg/m$^2$</td>
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<tr>
<td>b. NC &gt; 17 inches in men, 16 inches in women</td>
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<tr>
<td>c. Hypertension (new, uncontrolled, or unable to control with &lt; 2 medications)</td>
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</tbody>
</table>

*Adapted from *Screening Recommendations for Commercial Drivers With Possible or Probable Sleep Apnea* from Hartenbaum et al. *J Occup Environ Med.* 2006;48(9 Suppl):S4-S37.*
Identifying a “high” risk driver

- What about BMI? Uncertain if recommendations will identify a specific BMI (without other factors present) to trigger out-of-service evaluation.
- A recent fall-asleep crash
- Recent “near miss” episodes of “micro-sleep” while driving
- Driver falls asleep during meals or conversation
- Prior diagnosis and lack of CPAP compliance
- Recent surgery without documented follow-up
- High Epworth Sleepiness Scale score.
  - Joint Task Force ESS >16.

A “high” risk driver should be evaluated for the etiology of sleepiness and should not drive.
## Joint Task Force Guidelines

### Screening Recommendations for Commercial Drivers With Possible or Probable Sleep Apnea

**Medically Qualified to Drive Commercial Vehicles If Driver Meets Either of the Following**

1. No positive findings or any of the numbered in-service evaluation factors
2. Diagnosis of OSA with CPAP compliance documented

**In-Service Evaluation (ISE) Recommended If Driver Falls Into Any One of the Following Five Major Categories (3 mo maximum certification)**

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 inches in men, 16 inches in women;
   c) Hypertension (new, uncontrolled, or unable to control with less than 2 medications).
3. ESS >10
4. Previously diagnosed sleep disorder; compliance claimed, but no recent medical visits/compliance data available for immediate review (must be reviewed within 3-mo period); if found not to be compliant, should be removed from service (includes surgical treatment)
5. AHI >5 but <30 in a prior sleep study or polysomnogram and no excessive daytime somnolence (ESS <11), no motor vehicle accidents, no hypertension requiring 2 or more agents to control

**Out-of-Service Immediate Evaluation Recommended If Driver Meets Any One of the Following Factors**

1. Observed unexplained excessive daytime sleepiness (sleeping in examination or waiting room) or confessed excessive sleepiness
2. Motor vehicle accident (run off road, at-fault, rear-end collision) likely related to sleep disturbance, unless evaluated for sleep disorder in the interim
3. ESS ≥16 or FOSQ <18
4. Previously diagnosed sleep disorder:
   d) Noncompliant (CPAP treatment not tolerated);
   e) No recent follow up (within recommended time frame);
   f) Any surgical approach with no objective follow up.
5. AHI >30

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AHI indicates apnea-hypopnea index; BMI, body mass index; CPAP, continuous positive airway pressure; ESS, Epworth Sleepiness Scale; FOSQ, Functional Outcomes of Sleep Questionnaire; OSA, obstructive sleep apnea.
An individual with a diagnosis of OSA may be certified for year to drive a CMV if that individual meets the following criteria:

- Has untreated OSA with an apnea-hypopnea index (AHI) \( \leq 20 \),
  - **AND**
  - Has no daytime sleepiness, **OR**
  - Has OSA that is being effectively treated.

Disqualification for:

- Driver status post surgery for OSA without a PSG to confirm AHI \( \leq 20 \).
- Driver with AHI > 20, until CPAP is initiated.
- Driver with admitted crash due to sleepiness.
- Driver who reports sleepiness while driving.
Conditional Certification

- Diagnosed with OSA - one month conditional certification
  - If compliant with CPAP at one month, three month certification.
  - If compliant with CPAP at three months, 1 year certification.
- Warn driver about the danger of stopping CPAP
- Warn driver they could be liable if not using CPAP and involved in crash
- Recheck compliance in one year (all data)
- Minimal CPAP compliance >4 hours/day, 70% of days
Use of overnight PSG is the preferred method of diagnosis, but acceptance of portable testing that includes **at least five hours of oxygen saturation, nasal pressure, and sleep wake time**.

Required evaluation for the presence of OSA in drivers who have a high risk score on the Berlin Questionnaire, BMI $\geq 33$, or high risk based on clinical evaluation.
Treatment, Access, Costs

Pulmonary Perspective

Sleep Apnea, Alertness, and Motor Vehicle Crashes

Charles F. P. George

1University of Western Ontario, London Health Sciences Centre, South Street Hospital, London, Ontario, Canada


“Treatment with nasal CPAP reduces crash risk to levels seen in the population at large. This, of course, applies only when patients are compliant with treatment.”

“Yet, access to care is far from being readily available.”

“And, even when the diagnosis is established and treatment available, insurance companies may not universally pay the up-front costs for CPAP, even though they continue to pay overall much greater ongoing monthly costs for many secondary preventive drug therapies.”
Can it be done?

Schneider National Reports Benefits of Their Sleep Apnea Screening Program

Schneider National, Inc., a provider of truckload, logistics and intermodal services headquartered in Green Bay, Wis., reported significant savings in their medical costs as well as accident reduction, reduced turnover, and increased productivity due to their sleep apnea screening program. During the first phase of the study, 547 drivers were tested and 445 (80 percent) were identified as suffering from a sleep disorder. During the three-year pilot program, 11,000 drivers were screened, and 778 cases of obstructive sleep apnea (OSA) were identified. Drivers who were found to be at increased risk for OSA underwent overnight sleep studies and, if diagnosed with OSA, were immediately provided with continuous positive airway pressure (CPAP) machines and permitted to return to work. The company provided free CPAP machines where indicated; treatment was monitored by an outside organization.

It was reported that in drivers with sleep disordered breathing who were treated, medical costs were reduced an average of 58%. It was estimated that the company saved an average of $578 per driver per month for each case of sleep apnea treated. They also found the rate of accidents due to fatigue reduced by 30% in drivers treated with continuous positive airway pressure (CPAP) machines. The driver retention rate of CPAP-treated individuals was 2.29 times greater than the total company driver population in 2004.

Schneider National was awarded the National Sleep Foundation’s (NSF’s) 2007 Healthy Sleep Community Award for Innovative Sleep Apnea Screening Program in March 2007 for their OSA detection and treatment program. Schneider National is the ninth recipient of the Award which recognizes businesses that initiate activities or programs based on sleep science with the goal of providing long-lasting results to benefit a significant portion of a particular community.
Point of Care
Medico-legal Considerations

- Document recommendations after dispositioning the driver.
- Document that you warned the driver of risk.
- High risk drivers should be advised to not drive a commercial vehicle.
- High risk drivers should have an early diagnostic study/then, treatment
Challenges

- Practical Screening
  - Which guidelines?
  - Which criteria?
- “Doctor Shopping” (GAO report)
- Access to care
- Access treatment
- Compliance & Adherence
  - Referral recommendations, treatment (CPAP)
  - Adequate use (time on CPAP)
  - Measurement
  - Enforcement
What to expect?

- Practice and Practical Solutions

- Policy
  - FMCSA
    - Guidelines to replace or build upon Joint Task Force recommendations. Pending...
    - Proposed registry of examiners. Pending ...
      - Periodicity certification of examiners. Pending decision...
    - FMCSA Medical Review Board, Medical Advisory Board
  - Medical Expert Panel on OSA
    - January 2008 Recommendations
      [Link to PDF](http://www.mrb.fmcsa.dot.gov/documents/PPP/Expert_Pan_Rec_Sleep_Apnea_12508.pdf)
Questions & Comments

Thank you!

Contact information:
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+1 617-678-9007
What is the evidence on performance testing?

- Maintenance of wakefulness Test (MWT)
  - No definitive evidence that the MWT is predictive of crash risk.
  - No normative data is available for the general population.
  - No basis for evidence-based reliable application in the clinical setting.
  - Not recommended by the FMCSA Expert Panel