

Expert Panel Recommendations: Obstructive Sleep Apnea and Commercial Motor Vehicle Driver Safety

Medical Expert Panel Members:

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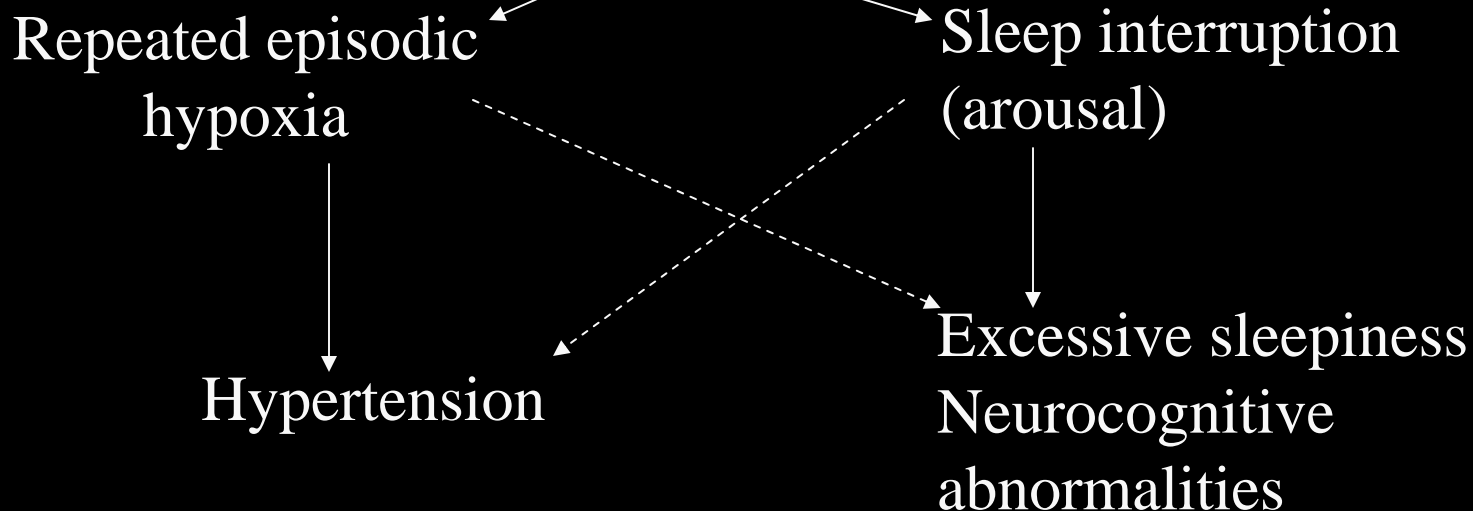
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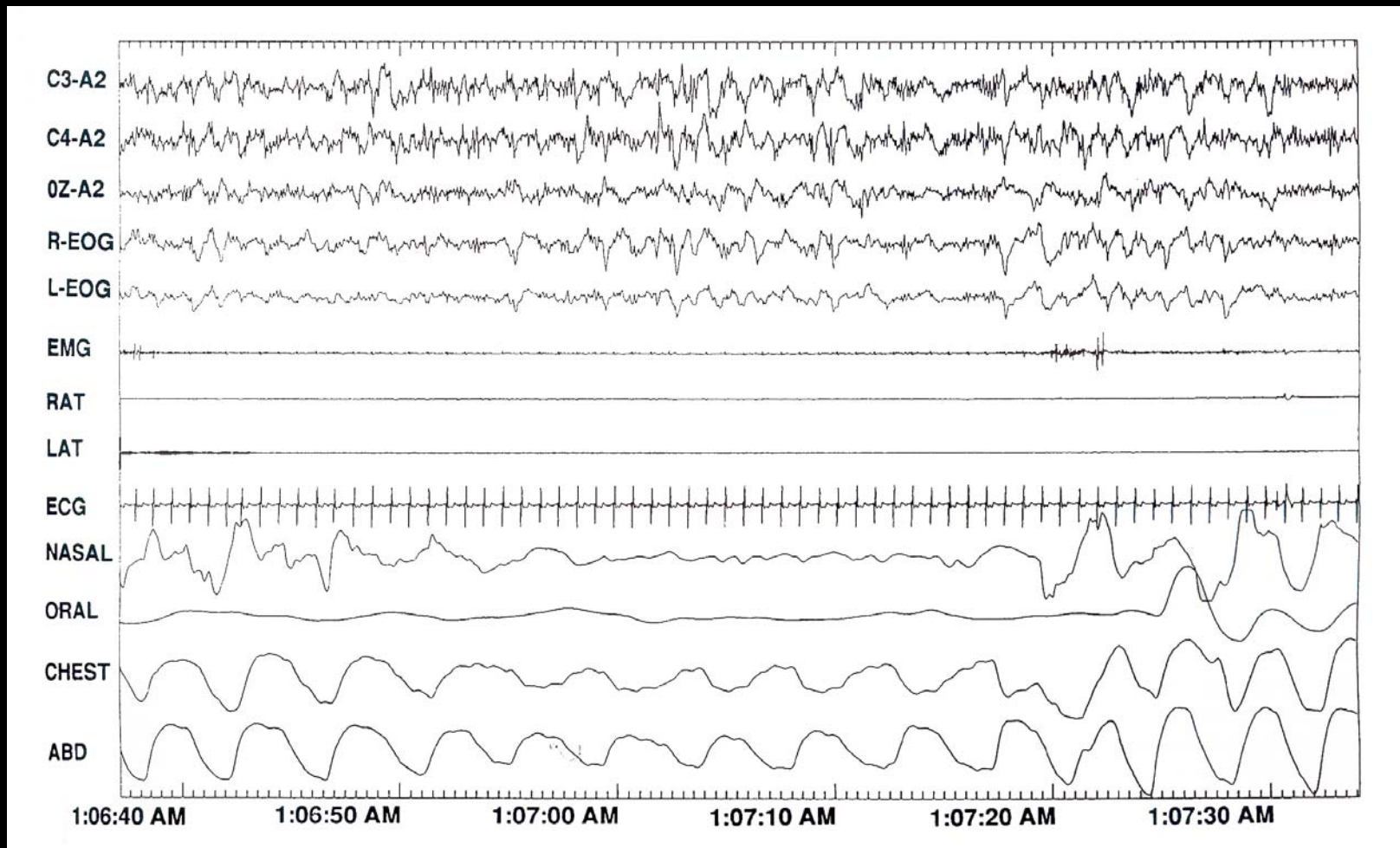
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SLEEP APNEA: Major Facts

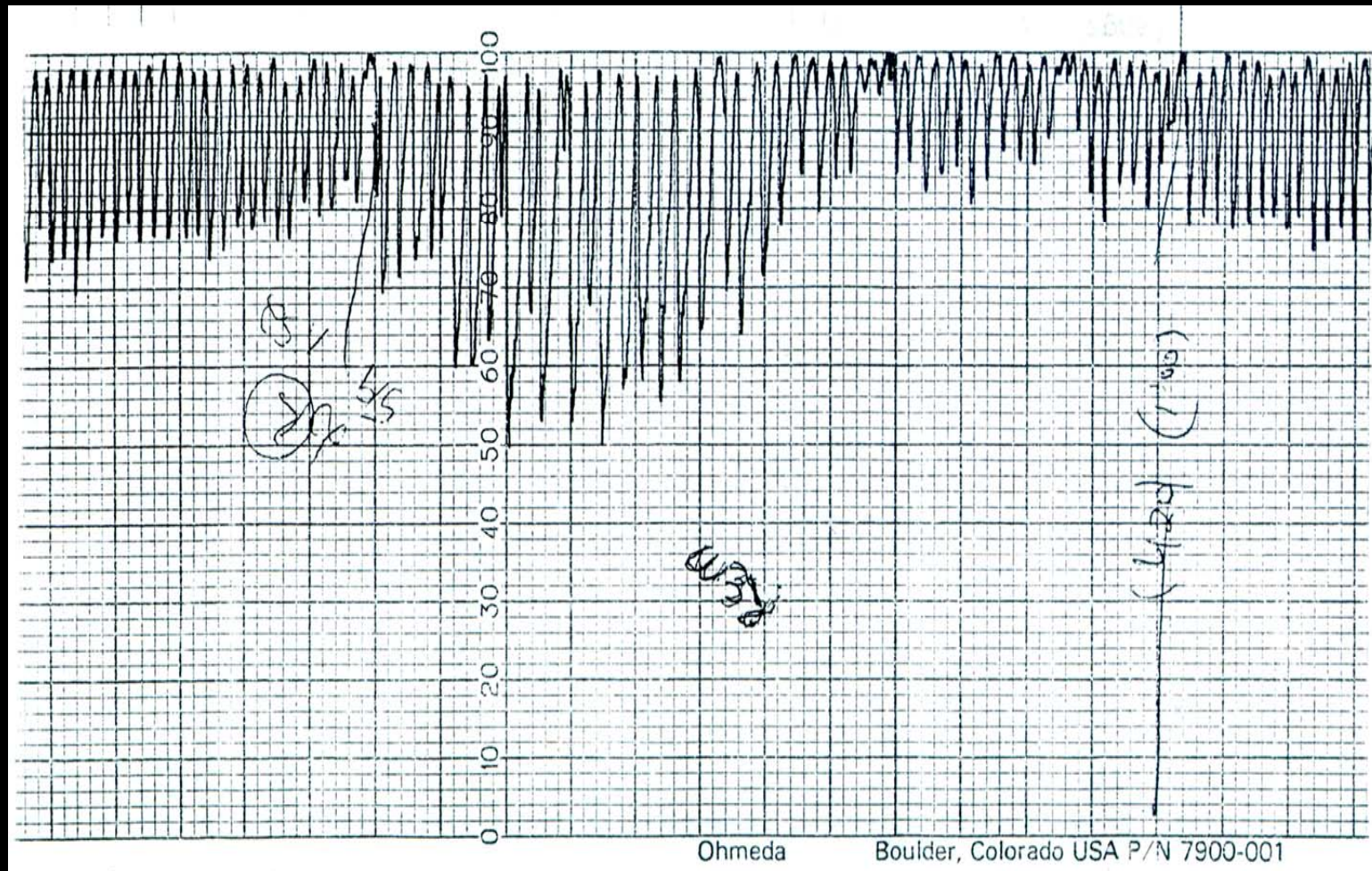
- Symptomatic sleep apnea - 4% of middle-aged males, 2% of middle-aged females (Young et al, 1993)
- Recurrent pauses (apnea) or decrements in breathing (hypopneas)
- Breathing pauses lead to



Example of Obstructive Sleep Apnea:



Nocturnal O₂ Saturation in a Patient with Sleep Apnea:

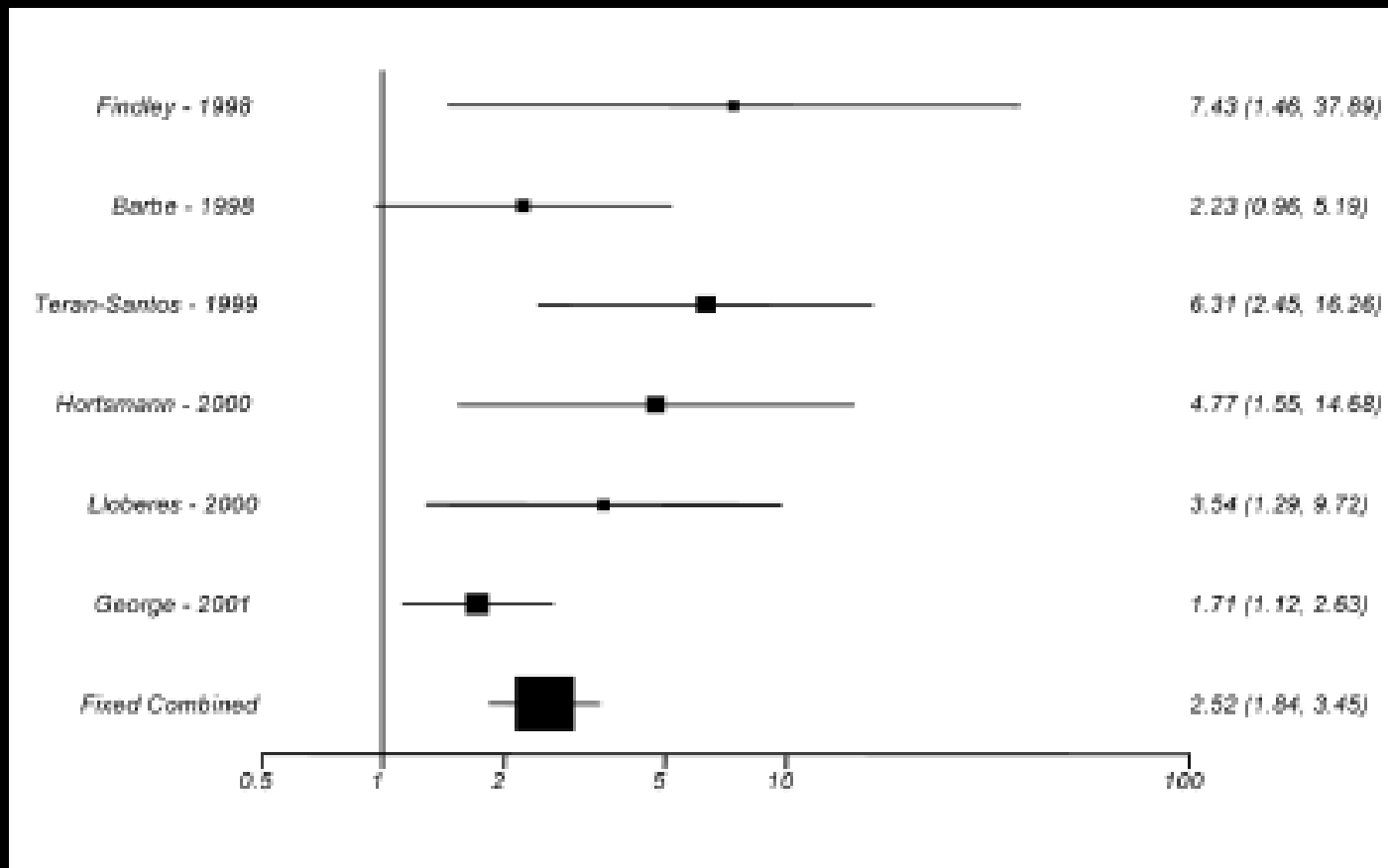


Risk Factors for Obstructive Sleep Apnea:

- Obesity
- Obesity
- Obesity
- Ethnic background
- Upper airway anatomy
- Endocrine abnormalities
- Menopausal status
- Genetic factors

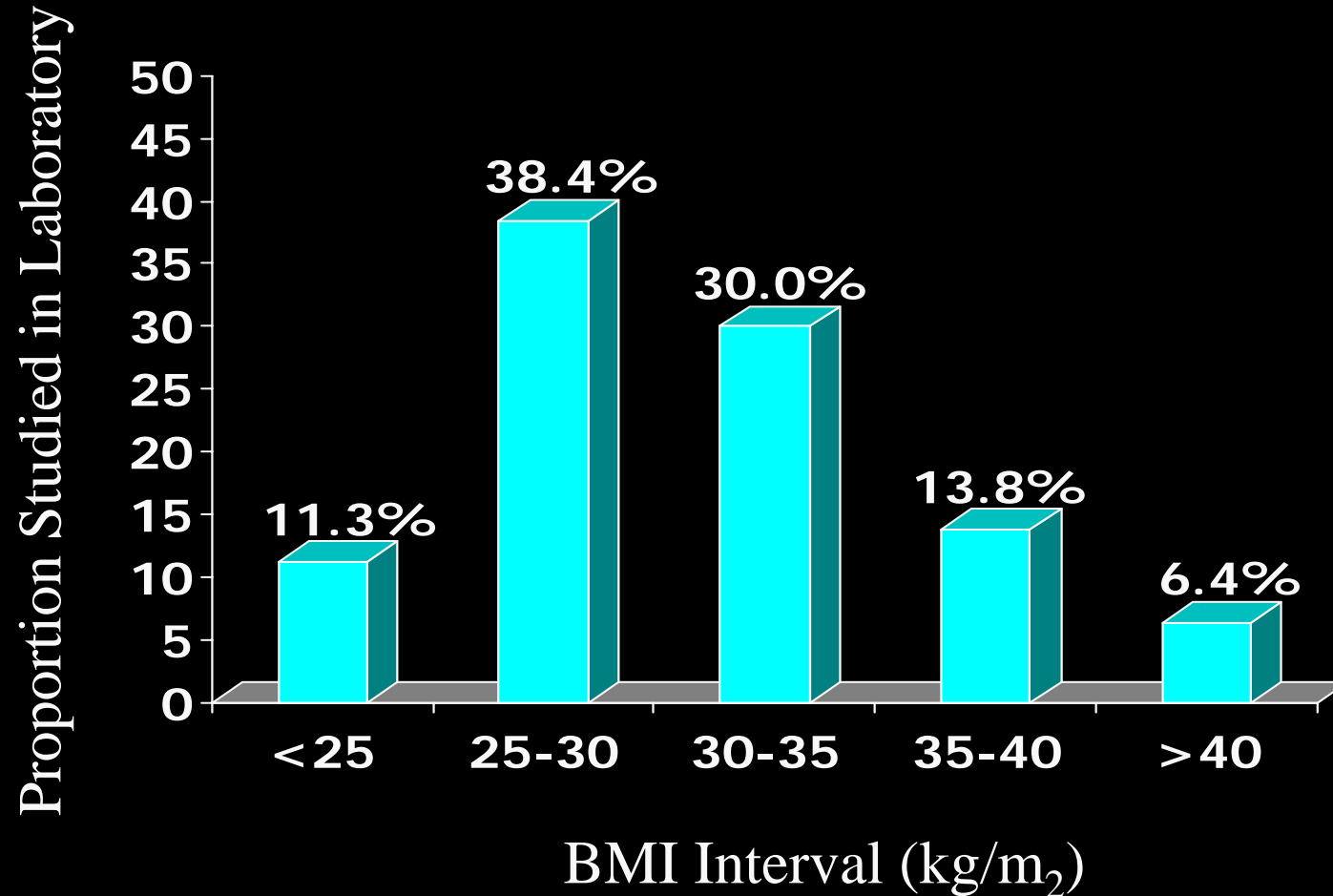
Meta Analysis- Increased Risk of Car Crashes in Subjects with Obstructive Sleep Apnea

(Sassani et al. Sleep, 27:453, 2004)



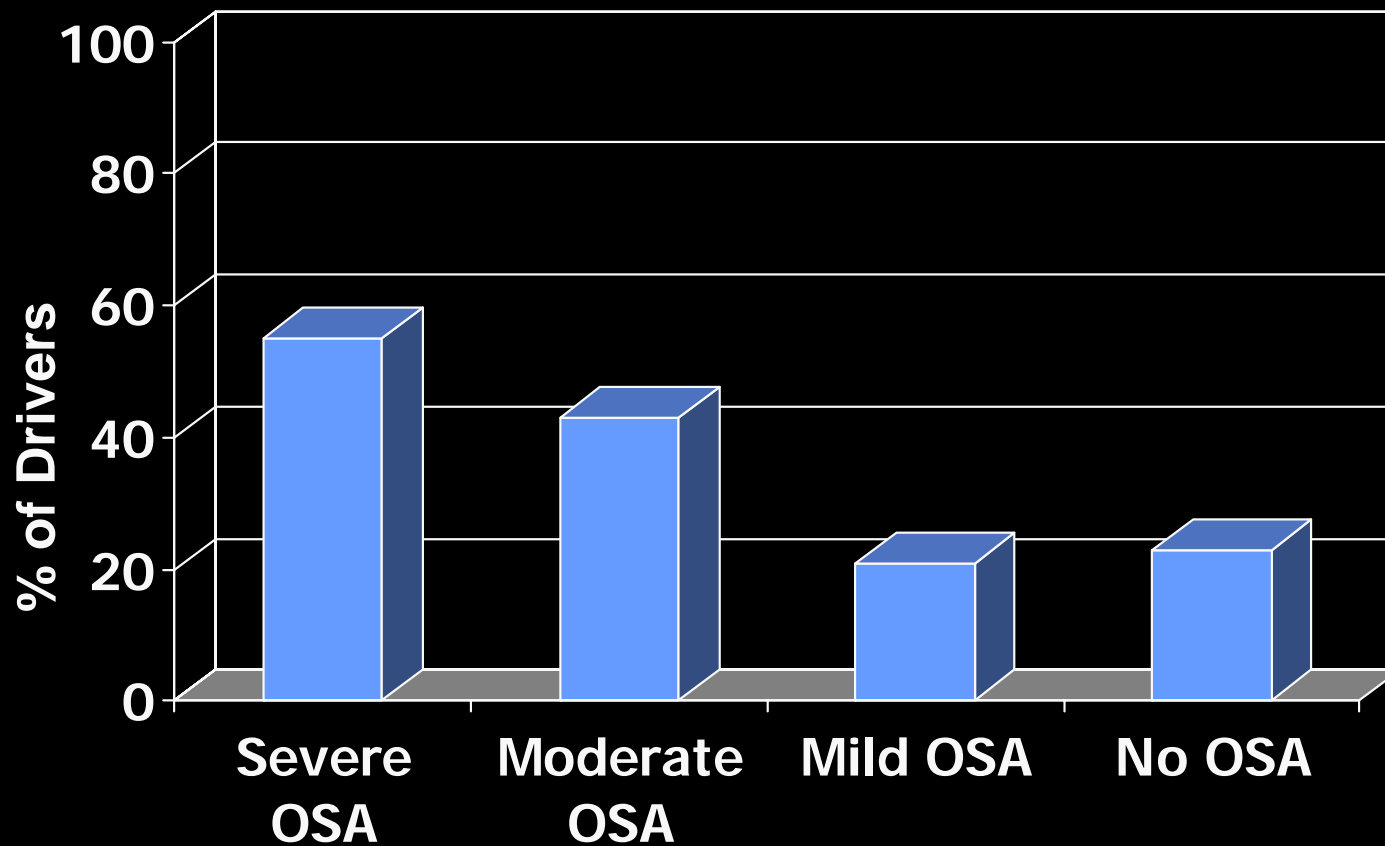
Distribution of Body Mass Index in Commercial Drivers

(Gurubhagavatula et al. AJRCCM, 170: 371, 2004)



Pathological Sleepiness in Commercial Drivers with Different Degrees of Obstructive Sleep Apnea (OSA)

(Pack et al. AJRCCM, 174:446,2006)



Using BMI as a Screen for OSA

(Gurubhagavatula et al, AJRCCM, 170: 371, 2004)

- Best cut-point $\geq 33\text{kg/m}_2$
- Sensitivity – 0.77
Specificity – 0.71
- AUC under receiver operating curve = 0.80
(perfect = 1.0)

Recommendation 1: General Guidance

- A diagnosis of OSA precludes an individual from obtaining unconditional certification to drive a CMV for the purposes of interstate commerce.
- A diagnosis of OSA, however, should not exclude all individuals with the disorder from driving a CMV; certification may be possible in some instances.

Recommendation 1: General Guidance

- An individual with a diagnosis of OSA may be certified 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.
- An individual with OSA who meets the requirements for certification described above should be recertified annually, based on demonstrating satisfactory compliance with therapy.

Recommendation 2: Specific Guidance—Drivers who should be disqualified immediately or denied certification

- Individuals who report that they have experienced excessive sleepiness while driving, **OR**
- Individuals who have experienced a crash associated with falling asleep, **OR**
- Individuals with an AHI greater than 20, until such an individual has been adherent to Positive Airway Pressure (PAP). They can be conditionally certified based on the criteria for Continuous Positive Airway Pressure (CPAP) compliance as outlined in Guideline 3

Recommendation 2:

Specific Guidance—Drivers who should be disqualified immediately or denied certification

- Individuals who have undergone surgery and who are pending the findings of a three-month post-operative evaluation.
- Individuals who have been found to be non-compliant with their CPAP treatment *at any point*

Recommendation 3: Conditional Certification

- BMI \geq 33 kg/m² – one month pending sleep study evaluation. (80% of the panel)
- Ideally should be one week- revisit in two years.

Recommendation 3: Conditional Certification

- Diagnosed with OSA → one month certification
- If compliant with CPAP at one month → three month certification
- If compliant with CPAP at three months → 1 year certification
 - Warn driver about danger of stopping therapy
 - Warn driver they could be liable if not using therapy and involved in crash
- Recheck compliance in one year (all data)
- Minimal CPAP compliance > 4 hours/day, 70% of days

Recommendation 4: Specific Guidance—Referral for Confirmation of Diagnosis or Stratification of Severity

- Individuals who meet the following criteria should be required to undergo an evaluation to confirm the diagnosis of, and, if necessary, stratify the severity of OSA:
 - Those categorized as high risk for OSA according to the Berlin Questionnaire, *OR*
 - Those with a BMI ≥ 33 kg/m², *OR*
 - Those judged to be at risk for OSA based on a clinical evaluation (see Guideline 5)

Recommendation 5: Specific Guidance—Identification of Individuals with Undiagnosed OSA

- Symptoms suggestive of OSA include:
 - Chronic loud snoring
 - Witnessed apneas or breathing pauses during sleep
 - Daytime sleepiness
- Risk factors for OSA are:
 - Advancing age
 - BMI ≥ 28 kg/m²
 - Small jaw
 - Large neck size (≥ 17 inches (male) ≥ 15.5 (female))
 - Small airway (a narrow or edematous oropharynx)
 - Family history of sleep apnea

Recommendation 6: Specific Guidance—Method of Diagnosis and Severity

- The preferred method of diagnosis and assessment of disease severity is overnight polysomnography (PSG)
- Acceptable alternative methods for assessment of risk in CMV drivers include objective recording devices validated against PSG that include at least five hours of measurements of:
 - oxygen saturation, **AND**
 - nasal pressure, **AND**
 - sleep/wake time.
- Regardless of the type of study performed, individuals should be tested while on their usual chronic medication regime.

Recommendation 7: Specific Guidance—Treatment of OSA— Positive Airway Pressure (PAP)

- The Medical Expert Panel recommends that the FMCSA consider adopting the following guidelines on the appropriate treatment of individuals with moderate-to-severe OSA:
- All Individuals with OSA who require treatment should be referred to a physician with particular expertise in management of patients with OSA.
- PAP is the preferred method of therapy
- Adequate PAP pressure should be established through one of the following means:
 - an in-laboratory titration study
 - an auto-titration system without an in-laboratory titration

Recommendation 7: Specific Guidance—Treatment of OSA— Positive Airway Pressure (PAP)

- Individuals with OSA who have been treated with PAP may be certified if they have been successfully treated for a minimum of one week
 - Successful PAP treatment is defined as follows:
 - Demonstration of good compliance with treatment (see below)

Recommendation 7: Specific Guidance—Treatment of OSA— Positive Airway Pressure (PAP)

- Individuals with OSA who are treated with PAP must demonstrate compliance with treatment and this must be documented objectively
 - Compliance is defined as using PAP for the duration of total sleep time.
 - Optimal treatment efficacy occurs with seven hours or more of use during sleep; however, four hours of documented time at pressure per major sleep episode is minimally acceptable.
 - Based on current standards of practice, an acceptable CPAP use is at least four hours of use per night on at least 70 percent of nights.

Recommendation 8: Specific Guidance—Treatment of OSA— Alternatives to PAP

- Dental appliances and surgery are considered to be potential alternatives to PAP for the treatment of OSA.
 - Currently there is no method of measuring compliance among individuals treated with dental appliances. Consequently, use of dental appliances cannot be considered an acceptable alternative to PAP in individuals who require certification to drive a CMV in interstate commerce.
 - Compliance among individuals who have undergone surgical treatment for OSA is less of an issue. Consequently, surgical treatment (bariatric, upper airway soft tissue, facial bone, and tracheostomy) is deemed an acceptable alternative to PAP (see later guidelines).

Recommendation 9: Specific Guidance—Treatment of OSA— Bariatric Surgery

- Individuals who have undergone bariatric surgery may be certified if they are:
 - Compliant with PAP (see guideline for PAP requirements) **OR**
 - Six months post-operative (to allow time for weight loss) **AND**
 - Cleared by treating physician with particular expertise in management of patients with OSA **AND**
 - Sleep exam indicates that $AHI \leq 10$ **AND**
 - No longer excessively sleepy

Recommendation 9: Specific Guidance—Treatment of OSA— Bariatric Surgery

- For individuals certified based on these criteria, re-evaluation by sleep study within two years if they are not on PAP therapy
- Individuals who are off PAP therapy should be given information that they need to seek re-evaluation if they gain significant weight (>5%) or their symptoms of OSA recur.

Recommendation 10: Specific Guidance—Treatment of OSA— Oropharyngeal Surgery

- Individuals with OSA who have been treated with oropharyngeal surgery may be certified if they:
 - Are > 1 month post surgery **AND**
 - Are cleared by treating physician with particular expertise in management of patients with OSA **AND**
 - Do not experience daytime sleepiness **AND**
 - Have an AHI \leq 10

Recommendation 10: Specific Guidance—Treatment of OSA— Oropharyngeal Surgery

- Annual recertification required
 - Annual objective testing with $AHI \leq 10$ **AND**
 - No daytime sleepiness

Recommendation 11: Specific Guidance—Treatment of OSA— Facial Bone Surgery

- Individuals with OSA who have been treated with facial bone surgery may be certified if they:
 - Are >1 month post surgery **AND**
 - Are cleared by treating physician with particular expertise in management of patients with OSA **AND**
 - Do not experience daytime sleepiness **AND**
 - Have an AHI ≤ 10

Recommendation 11: Specific Guidance—Treatment of OSA— Facial Bone Surgery

- Annual Recertification required
 - Annual objective testing with $AHI \leq 10$
AND
 - No daytime sleepiness

Recommendation 12: Specific Guidance—Treatment of OSA— Tracheostomy

- Individuals with OSA who have been treated with oropharyngeal surgery may be certified if they:
 - Are > 1 month post surgery **AND**
 - Are cleared by treating physician with particular expertise in management of patients with OSA **AND**
 - Do not experience daytime sleepiness **AND**
 - Have an AHI ≤ 10

Recommendation 12: Specific Guidance—Treatment of OSA— Tracheostomy

- Annual recertification required
 - Annual objective testing with $AHI \leq 10$ AND
 - No daytime sleepiness

Recommendation 13: Patient Education

- Individuals with OSA who meet the criteria for certification should be provided with education on the following:
 - The importance of adequate sleep
 - Lifestyle changes
 - Weight loss
 - Smoking cessation
 - Exercise
 - Reduced alcohol intake
 - The importance of treatment compliance (if relevant)

Recommendation 13: Patient Education

- The consequences of untreated OSA include:
 - Loss of certification
 - Crash
 - Hypertension
 - Cognitive dysfunction
 - Heart disease
 - Reduced quality of life
 - Reflux
 - Headaches
 - Shorter survival
 - Sleep disruption

Recommendation 14:

Areas Requiring Development of Guidance

- Other causes of excessive daytime sleepiness
 - Insufficient sleep
 - Insufficient time in bed/sleep deprivation
 - Medical illnesses
 - e.g. chronic pain syndromes
 - Other primary sleep disorders
 - Narcolepsy
 - idiopathic hypersomnia
 - Restless Legs Syndrome
 - Shift work sleep disorder

Recommendation 14: Areas Requiring Development of Guidance

- Development of a national registry of certified drivers to include:
 - Full medical history
 - Medical examiners would be responsible for populating the registry

Recommendation 14: Areas Requiring Development of Guidance

- Further research is required in the following areas:
 - Effects of OSA on crash risk among CMV drivers
 - Effects of different treatments of OSA on crash risk among CMV drivers
 - Risk factors for crash among individuals with OSA and other sleep problems
 - Improved risk stratification and prediction in CMVs
 - Evaluation of alternatives to polysomnography in CMV drivers

Additional Recommendations

- The Medical Expert Panel made the following additional recommendations:
- The FMCSA consider creating incentives for large trucking companies to develop management models to address sleep problems in their work-force
- The FMCSA should couple a dissemination program with these models

