



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

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Presented to

Federal Motor Carrier Safety Administration

January 14th, 2008



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Introduction

The primary mission of the U.S. Department of Transportation's (DOT's) Federal Motor Carrier Safety Administration (FMCSA) is to reduce crashes, injuries and fatalities involving commercial motor vehicles (including large trucks and buses). One mechanism used to facilitate this effort is the updating of current, and the development of new, medical fitness standards and guidelines for medical examiners who are responsible for certifying drivers as fit for duty. FMCSA is committed to review and begin updating all of their current standards and guidelines by 2009.

This report serves the purpose of summarizing the considerations and recommendations of a panel of five experts in the field of sleep medicine (henceforth termed the Medical Expert Panel) who examined FMCSA's current guidelines for medical examiners pertaining to obstructive sleep apnea.

Guideline Development Medical Expert Panel

Members of the Medical Expert Panel charged with making recommendations pertaining to whether the current guidelines for obstructive sleep apnea need to be updated are listed in Table 1.

Table 1. Members of the Medical Expert Panel

Name	Current Position
Sonia Ancoli-Israel, PhD	Dr Ancoli-Israel, Ph.D. is Professor of Psychiatry at the University of California San Diego School of Medicine, Director of the Sleep Disorders Clinic at the Veterans Affairs San Diego Healthcare System, Co-Director of the Laboratory for Sleep and Chronobiology at the UCSD GCRC, and Co-Director of the Education and Dissemination Unit of the VA VISN-22 Mental Illness Research, Education and Clinical Center (MIRECC).
Charles Czeisler, PhD MD	Dr Czeisler is the Baldino Professor of Sleep Medicine, Harvard Medical School and Senior Physician for the Division of Sleep Medicine at Brigham and Women's Hospital.
Charles George, MD FRCPC	Dr George is Professor of Medicine at the University of Western Ontario in London, Canada and Director of the LHSC Sleep Disorders Laboratory.
Christian Guilleminault, MD BiolD	Dr Guilleminault is Professor of Psychiatry and Behavioral Sciences at the Stanford School of Medicine.
Allan Pack, MB, ChB, PhD	Dr Pack is Professor of Medicine, and Neurology at the University of Pennsylvania School of Medicine where he is also the chief of the Division of Sleep Medicine and director of the Center for Sleep and Respiratory Neurobiology

Methodology

Brief Overview of Evidence Report Methodology

The recommendations contained in this report are based in part upon the interpretation and assimilation of information presented in a comprehensive systematic review of available literature, prepared by ECRI Institute and Manila, and presented to the Medical Expert Panel on August 13th, 2007. The evidence report was developed following a systematic literature search for evidence accessible from several electronic databases. These databases included (but were not limited to) Medline, PubMed (pre Medline), EMBASE, PSYCH Info, CINAHL, TRIS, and the Cochrane Library (through April 30th, 2007). Additional hand searches of the published literature (i.e., bibliographies of identified relevant articles), and "gray literature" resources (e.g., Web searches) were also performed. Data obtained from these searches were screened against a set of a priori inclusion criteria. Included data were pooled and synthesized, where applicable, using meta-analytic techniques described in detail in the Evidence Report

titled, “Obstructive Sleep Apnea and Commercial Motor Vehicle Driver Safety.” See also Appendix B of this report.

The Medical Expert Panel Meeting and Recommendation Formulation

On August 13th, 2007, FMCSA, Manila Consulting, the ECRI Institute, and the five members of the Medical Expert Panel convened a two-day conference. The purpose of this conference was several-fold:

- To review the existing FMCSA guidelines for medical examiners which pertain to the certification and recertification of individuals who have, or who are suspected of having, obstructive sleep apnea.
- To discuss the available evidence contained in the Evidence Report and other sources pertaining to the consequences to public safety that are associated with certifying individuals with obstructive sleep apnea medically fit to drive a CMV.
- To recommend changes to existing FMCSA guidelines that are deemed necessary following the critical assessment of the available evidence.

In developing recommendations to FMCSA, members of the Medical Expert Panel were guided by three central principles. These principles were as follows:

- Recommended changes to the existing FMCSA guidelines should be based on scientific evidence whenever possible¹.
- Recommended changes to the existing FMCSA guidelines should be concise and explicit.
- Recommended changes to the existing FMCSA guidelines should be actionable.

This document provides a summary of the recommendations derived from this process.

Recommended Changes to Original Guidelines

The Medical Expert Panel recommended that FMCSA make substantial changes to the current guidelines pertaining to obstructive sleep apnea. These recommendations were based on a combination of evidence provided by the Evidence Report titled, “Obstructive Sleep Apnea and Commercial Motor Vehicle Driver Safety” and several other sources. Below we present the recommendations of the Medical Expert Panel and provide justification for these recommendations.

Guideline 1: General Guideline

The Medical Expert Panel recommended that FMCSA’s current guidelines pertaining to individuals who have obstructive sleep apnea (Appendix A) be replaced with the following general guideline statement:

- A diagnosis of obstructive sleep apnea precludes an individual from obtaining unconditional certification to drive a CMV for the purposes of interstate commerce.

¹ Recommendations from the Medical Expert Panel, for which no supporting evidence was identified and which are thus based on expert opinion alone, are identified as such.

- A diagnosis of obstructive sleep apnea, however, should not exclude all individuals with the disorder from driving a CMV; certification may be possible in some instances. An individual with a diagnosis of obstructive sleep apnea may be certified to drive a CMV if that individual meets the following criteria:
 - Has untreated obstructive sleep apnea with an AHI \leq 20, **AND**
 - Has no daytime sleepiness, **OR**
 - Has obstructive sleep apnea that is being effectively treated.
- An individual with OSA who meets the requirements for certification described above should be recertified on an annual basis, based on demonstrating satisfactory compliance with therapy.

Justification

There are now substantial data that OSA is associated with an increased risk of crashes in drivers of passenger cars (Sassani et al. 2004; Tregear et al. 2007). This has been little studied, however, in commercial drivers. Studies in passenger car drivers all show there is an increased risk of crashes in individuals with an apnea/hypopnea index >30 episodes/hour, while some studies show that there is an increased risk in individuals who have less severe sleep apnea. Studies comparing individuals with excessive sleepiness to those who do not have sleepiness find that having an apnea/hypopnea index ≥ 20 episodes/hour is a risk factor for excessive sleepiness (Pack et al. 2006). The expert panel thus believed that individuals with an AHI <20 who were not excessively sleepy could be certified to drive.

Supporting References

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- Sassani, A., Findley, L.J., Kryger, M., Goldlust, E., George, C., Davidson, T.M. (2004). Reducing motor-vehicle collisions, costs, and fatalities by treating obstructive sleep apnea syndrome. *Sleep* 27:453-458.
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Guideline 2: Specific Guideline Statement 1 – Drivers who should be disqualified immediately or denied certification

The Medical Expert Panel identified several populations of individuals who they believe should not be certified or recertified as being medically qualified to drive a commercial motor vehicle. These populations are:

- Individuals that 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 that is 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 CPAP compliance as outlined in Guideline 3 **OR**
- Individuals who have undergone surgery and who are pending the findings of a 3 month post-operative evaluation.
- Individuals who have been found to be non-compliant with their treatment at any point, **OR**
- Individuals who have a BMI of greater than 33 kg/m² (pending evaluation by a sleep study) (80 percent of the panel)

Justification

This guideline is based on identifying individuals who have possible consequences of obstructive sleep apnea (OSA) that are relevant to the driving task, i.e., excessive sleepiness while driving and/or a previous crash due to falling asleep. The expert panel wanted also an objective method for identifying individuals at high risk for OSA. In middle-aged adults, obesity is the largest single risk factor for OSA (Young et al., 1993). Studies in commercial drivers (Gurubhagavatula et al., 2004) have identified that a BMI, a measure of obesity, of 32.7 kg/m² (i.e., rounded to 33.0) is the optimal cut-point to identify, using this information alone (height, weight), who is likely to have OSA. This method for screening for OSA has a sensitivity of 76.9% and a specificity of 70.5%. While this will miss some individuals with OSA, it is a practical approach that can be simply implemented.

One member of the expert panel was concerned that individuals with BMI between 30 kg/m² and 33 kg/m² were also at increased risk for OSA (Young et al., 1993). Dr Pack proposed that the cut-point for determining who requires a sleep study be a BMI of 30 kg/m². The other members of the panel were concerned about the feasibility of this and noted that according to a recent study (Pack et al., 2006), 41.9% of truck drivers would have to be given only temporary certification, pending a sleep apnea evaluation, based on this recommendation. If 33 kg/m² is used, this number of drivers to be studied drops substantially since 24.0% of drivers have a BMI greater than 33 kg/m². Moreover, by focusing on this group, the majority of the panel believed that we would identify the vast majority of commercial drivers with severe sleep apnea.

Supporting References

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- Ellen, R. L., S. C. Marshall, et al. (2006). "Systematic review of motor vehicle crash risk in persons with sleep apnea." *J Clin Sleep Med* 2(2): 193-200.
- Gurubhagavatula I, Maislin G, Nkwuo JE, Pack AI. (2004). Occupational screening for obstructive sleep apnea in commercial drivers. *Am J Respir Crit Care Med* 170(4):371-6.
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Guideline 3: Specific Guidance – Conditional Certification

The Medical Expert Panel recommended that the following groups of individuals with obstructive sleep apnea be allowed to conditionally drive a CMV:

- Individuals with a BMI ≥ 33 kg/m² may be conditionally certified for one month pending the findings of a sleep study. The panel noted that this period should be less than one week. However, given the current infrastructure for sleep studies in the United States, obtaining a sleep study within one week is unlikely to be feasible in many cases. Consequently, the panel recommended that a transition period of two years be allowed during which time efforts should be made to improve the infrastructure so that the period between requesting a sleep study and obtaining that study can be reduced to one week for certification purposes.
- Individuals recently diagnosed with OSA may be conditionally certified for one month during which time they will be started on CPAP therapy. At the end of this month, they can be conditionally certified for 3 months if compliance to CPAP is documented in the two previous weeks. Compliance should be reassessed at 3 months. If at the three month assessment such an individual demonstrates treatment compliance, that individual may be certified for a period of one year. The commercial driver needs to receive information that if they stop using their CPAP during this one year period, they should stop driving a commercial vehicle. They should be warned that if they stop using their CPAP and are involved in a crash, then it is likely that they will be considered liable by the legal community. At one year, future recertification should be dependent upon proof of continued compliance with treatment. At the end of one year the certifying physician should review all compliance data for that year. Ideally, in time, with newer CPAP machines, these data will include not only compliance but information about efficacy of treatment. It is conceivable that, if at the end of one year the individual is no longer compliant with therapy, certification may not be renewed or only renewed for a brief period to allow compliance with therapy to be re-established.
- Minimally acceptable compliance is defined here as greater than 4 hours of use for at least 70% of the days, based on current standards of practice (Gay P, Weaver T, Loube D, Iber C. Evaluation of positive airway pressure treatment for sleep related breathing disorders in adults. Positive Airway Pressure Task Force; Standards of Practice Committee; American Academy of Sleep Medicine. *Sleep* 29:381-401, 2006).

Justification

The expert panel appreciated that the recommendation that all commercial drivers with a BMI ≥ 33 kg/m² will require a sleep apnea evaluation will affect a large number of drivers, i.e., 24.0%. They thus proposed that such individuals should receive conditional certification for one month during which time a sleep apnea evaluation could be performed. For public safety reasons, this evaluation should occur

sooner, but there is a concern that the diagnostic infrastructure is not in place to make this feasible. This issue should be revisited in two years to reconsider whether the time for conditional certification could be shortened if the relevant diagnostic infrastructure is more developed.

Once diagnosed, certification is dependent on demonstrating compliance with therapy. The expert panel believed that compliance should initially be assessed at one month. If this is satisfactory, then for 3 months, and if acceptable, for one year. Some members of the expert panel were concerned that one year was a long time between assessments and considered recommending much more regular assessments of compliance. To offset this concern, the expert panel recommends counseling of the driver about the need for continued CPAP use and also about their potential liability if the driver stops using CPAP.

A threshold for CPAP adherence is difficult to define. There is a dose-response relationship between hours of use of CPAP and benefit with some individuals obtaining benefit from more limited use (Weaver et al. 2007). The current standard of practice is to define acceptable compliance as at least 4 hours/day on at least 70% of days (Gay et al., 2006). CPAP adherence is bimodal, i.e., there are regular and irregular users (Weaver et al., 1997) such that the majority of individuals meeting this minimal goal will have greater CPAP use.

Supporting References

- Gay, P., Weaver, T., Loube, D., Iber, C. (2006) Evaluation of positive airway pressure treatment for sleep related breathing disorders in adults. Positive Airway Pressure Task Force; Standards of Practice Committee; American Academy of Sleep Medicine. *Sleep* 29:381-401.
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Guideline 4: Referral for Confirmation of Diagnosis and/or Stratification of Severity

The Medical Expert Panel recommended that FMCSA consider adopting the following guidelines pertaining to the confirmation of a diagnosis of OSA and its stratification by 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 objective obstructive sleep apnea:

- Those categorized as high risk for obstructive sleep apnea according to the Berlin Questionnaire (Appendix C), **OR**
- Those with a BMI ≥ 33 kg/m², **OR**
- Those judged to be at risk for obstructive sleep apnea based on a clinical evaluation (see Guideline 5)

Justification

The rationale for choosing the threshold of a BMI ≥ 33 kg/m² was described under Guideline 2. The expert panel also believed that use could be made of a symptom questionnaire for identifying individuals at high risk for obstructive sleep apnea—the Berlin Questionnaire. This has been validated in different populations.

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- Sharma, S. K., C. Vasudev, et al. (2006). "Validation of the modified Berlin questionnaire to identify patients at risk for the obstructive sleep apnoea syndrome." *Indian J Med Res* 124(3): 281-90.
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Guideline 5: Clinical Evaluation-Identification of Individuals with Undiagnosed Obstructive Sleep Apnea

The Medical Expert Panel opined that they believe it to be one of the roles of the medical examiner to identify individuals who may have undiagnosed obstructive sleep apnea. Consequently, the Medical Expert Panel proposed the following guideline:

- Medical examiners should actively screen for obstructive sleep apnea in all individuals who request fitness-for-duty certification for the purposes of driving a CMV for the purposes of interstate commerce
- Symptoms suggestive of obstructive sleep apnea include the following:
 - Chronic loud snoring
 - Witnessed apneas or breathing pauses during sleep
 - Daytime sleepiness
- Risk factors for obstructive sleep apnea 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
- Conditions known to be associated with a high risk of obstructive sleep apnea include the following:
 - Hypertension (treated or untreated)
 - Type 2 diabetes (treated or untreated)
 - Hypothyroidism (untreated)

Justification

There are a number of symptoms of obstructive sleep apnea. In patients with obstructive sleep apnea, loud snoring during every sleep period is common, although not specific, i.e., some individuals with this complaint do not have OSA. Witnessed apneas are a less common complaint, but more specific, i.e., most individuals with this will have OSA (Young et al., 2002a; Young et al., 2002b). Studies in various epidemiological projects have identified the risk factors for OSA and it is known that it aggregates in families, i.e., there is a genetic component (Strohl et al., 1996). Assessing neck size should be part of the routine evaluation of commercial drivers.

There is an association between obstructive sleep apnea, hypertension and diabetes. These all occur together as part of the metabolic syndrome (Vgontzas et al., 2005).

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Guideline 6: Specific Guideline-Method of Diagnosis and Severity

The Medical Expert Panel recommended that FMCSA consider adopting the following guidelines pertaining to the appropriate methods used to confirm a diagnosis of OSA and stratify its 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 5 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.

Justification

Currently the standards for diagnosis of OSA is a full in-laboratory sleep study—polysomnography. This includes assessment of breathing, oxygen level and electroencephalogram (EEG) to stage sleep. New technology is now available to assess sleep-disordered breathing without the need for the EEG. Use of this new technology has now been suggested to be covered and an acceptable way to diagnose OSA in Medicare recipients. This recommendation is in the comment stage. It is somewhat controversial with different professional societies having different opinions on the topic. This new technology will be useful

for assessing sleep-disordered breathing in commercial drivers given the large number who will need this evaluation based on these recommendations. This guideline was unanimously approved by the expert panel.

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Guideline 7: Treatment of Obstructive Sleep Apnea – PAP

The Medical Expert Panel recommended that FMCSA consider adopting the following guidelines pertaining to the appropriate treatment of individuals with moderate-to-severe OSA:

- All Individuals with obstructive sleep apnea who require treatment should be referred to a clinician with relevant expertise.
- Positive airway pressure (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
- Individuals with OSA who have been treated with PAP may be certified if they have been successfully treated for a minimum of 1 week
 - Successful PAP treatment is defined as follows:
 - Demonstration of good compliance with treatment (see below)
 - Resolution of excessive sleepiness when driving

- 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 4 hours of use per night on at least 70% of nights.

Justification

As outlined in previous Guidelines, there can be substantial variation between patients in their patterns of use of PAP, i.e., number of hours/night and number of days/week in which the device is used. Some patients benefit from more limited use while others still show residual sleepiness even with quite substantial use of PAP. Assessment of the current literature by experts on this topic led the American Academy of Sleep Medicine to recommend at least 4 hours of use/day on at least 70% of nights as an acceptable standard (Gay et al., 2006). This group also recommended improvement in symptoms as an appropriate end-point but this will be difficult to assess in commercial drivers.

Supporting References

- Alajmi, M., A. T. Mulgrew, et al. (2007). "Impact of continuous positive airway pressure therapy on blood pressure in patients with obstructive sleep apnea hypopnea: a meta-analysis of randomized controlled trials." *Lung* 185(2): 67-72.
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Guideline 8: Specific Guideline-Treatment of Obstructive Sleep Apnea – Alternatives to PAP

The Medical Expert Panel recommended that FMCSA consider adopting the following guidelines pertaining to the appropriate treatment of individuals with moderate-to-severe OSA who require a treatment other than PAP:

- Dental appliances and surgery are considered to be potential alternatives to PAP for the treatment of obstructive sleep apnea.
 - 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 commercial motor vehicle for the purposes of interstate commerce.
 - Compliance among individuals who have undergone surgical treatment for obstructive sleep apnea 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).

Justification

An alternative therapy to nasal positive airway pressure is use of intra-oral devices worn during sleep. These devices reposition the mandible thereby increasing the size of the upper airway. The benefit of these devices has been shown in randomized trials (Chan et al., 2007). However, not all individuals benefit from this therapy and in some subjects OSA may get worse (Henke et al., 2000). There is, moreover, no method currently available to monitor compliance with this form of therapy. Given this, and the variable efficacy with this treatment, the expert panel took the view that this form of therapy could not be recommended for use in commercial drivers as an acceptable treatment for OSA.

Supporting References

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Guideline 9: Treatment of Obstructive Sleep Apnea - Bariatric Surgery

The Medical Expert Panel recommended that FMCSA consider adopting the following guidelines pertaining to obese individuals with moderate-to-severe OSA who undergo 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 clinician **AND**
 - Sleep exam indicates that $AHI \leq 10$ **AND**
 - No longer excessively sleepy
- For individuals who are certified based on these criteria, re-evaluation by sleep evaluation 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%) and/or their symptoms of OSA recur.

Justification

Given that a major risk factor for OSA is obesity, bariatric surgery in morbidly obese patients usually results in substantial weight loss, marked improvement in degree of OSA and, in many patients, actually cure OSA. Patients with OSA having bariatric surgery will typically be on PAP therapy. In many patients, but not all, this therapy may no longer be required after substantial weight loss. For such individuals, a re-evaluation by a sleep study at six months following surgery is recommended. There are very limited long-term follow-up data on patients after bariatric surgery with most studies reporting data up to two years of follow-up. Thus, certification for such individuals should be for two years at a maximum with a requirement for a repeat sleep study evaluation at that time.

Supporting References

- Buchwald, H., Y. Avidor, et al. (2004). "Bariatric surgery: a systematic review and meta-analysis." *Jama* 292(14): 1724-37.
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- Verse, T. (2005). "Bariatric surgery for obstructive sleep apnea." *Chest* 128(2): 485-7.

Guideline 10: Treatment of Obstructive Sleep Apnea - Oropharyngeal Surgery

The Medical Expert Panel recommended that FMCSA consider adopting the following guidelines pertaining to individuals with moderate-to-severe OSA who undergo 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 clinician AND
 - Do not experience daytime sleepiness AND
 - Have an AHI \leq 10
- Annual Recertification required
 - Annual objective testing with AHI \leq 10 AND
 - No daytime sleepiness

Justification

There are no data showing benefit of this form of surgery in randomized controlled trials. There are a large number of soft tissue procedures to the oropharynx that are used. Most data are for the uvulopalatopharyngoplasty. There are data to support that a large number of subjects having this surgery get side effects in the form of difficulty swallowing. The surgery is, however, still frequently performed. Even in individuals who are improved by this type of surgery, recurrence of OSA over time is recognized. Thus, the maximum period of certification in individuals who benefit from this surgery is one year, at which time there is a need for re-evaluation by objective assessment of degree of sleep-disordered breathing.

Supporting References

- Sundaram, S., S. A. Bridgman, et al. (2005). "Surgery for obstructive sleep apnoea." Cochrane Database Syst Rev(4): CD001004.
- Tregear, S.J., et al. (2007) "Obstructive Sleep Apnea and Commercial Motor Vehicle Driver Safety – Evidence Report." Prepared by Manila Consulting Incorporated and the ECRI Institute for FMCSA.

Guideline 11: Treatment of Obstructive Sleep Apnea – Facial Bone Surgery

The Medical Expert Panel recommended that FMCSA consider adopting the following guidelines pertaining to individuals with moderate-to-severe OSA who undergo 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 clinician AND
 - Do not experience daytime sleepiness AND
 - Have an AHI \leq 10
- Annual Recertification required
 - Annual objective testing with AHI \leq 10 AND
 - No daytime sleepiness

Justification

Surgery to reconfigure the facial bones—mandible (jaw) and maxilla—can increase the size of the upper airway and, in appropriate individuals, be effective in treating OSA. The benefit of the surgery has not been demonstrated, however, in randomized controlled trials unlike the benefit demonstrated by PAP. There are, moreover, limited data as to long-term benefit. In the absence of such data, a reasonable approach is to re-evaluate such subjects annually by objective sleep testing.

Supporting References

- Sundaram, S., S. A. Bridgman, et al. (2005). "Surgery for obstructive sleep apnoea." Cochrane Database Syst Rev(4): CD001004.

- Tregear, S.J., et al. (2007) “Obstructive Sleep Apnea and Commercial Motor Vehicle Driver Safety – Evidence Report.” Prepared by Manila Consulting Incorporated and the ECRI Institute for FMCSA.

Guideline 12: Specific Guideline - Treatment of Obstructive Sleep Apnea – Tracheostomy

The Medical Expert Panel recommended that FMCSA consider adopting the following guidelines pertaining to individuals with moderate-to-severe OSA who undergo 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 clinician AND
 - Do not experience daytime sleepiness AND
 - Have an AHI \leq 10
- Annual Recertification required
 - Annual objective testing with AHI \leq 10 AND
 - No daytime sleepiness

Justification

Tracheostomy is a definitive procedure for OSA since it allows individuals to open their tracheal opening at night and to breathe directly through this, thereby bypassing the obstructed upper airway. It was frequently used before PAP became available, but is now rarely used to treat OSA because of side effects of this form of therapy. Individuals who have had a tracheostomy to treat OSA need to be re-evaluated on an annual basis.

Supporting References

- Sundaram, S., S. A. Bridgman, et al. (2005). "Surgery for obstructive sleep apnoea." Cochrane Database Syst Rev(4): CD001004.
- Tregear, S.J., et al. (2007) “Obstructive Sleep Apnea and Commercial Motor Vehicle Driver Safety – Evidence Report.” Prepared by Manila Consulting Incorporated and the ECRI Institute for FMCSA.

Guideline 13: Patient Education

The Medical Expert Panel recommended that FMCSA consider adopting the following guidelines pertaining to the education of individuals who meet the criteria for certification to drive a commercial motor vehicle:

- 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, etc)

- Weight loss
- Smoking cessation
- Exercise
- Reduced alcohol intake
- The importance of treatment compliance (if relevant)
- 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
- Effects of respiratory or CNS depressants on OSA

Comments

The expert panel believed that OSA is a relatively complex condition which can be affected by a number of factors, e.g., drugs and alcohol, and it can produce not only excessive sleepiness but also acid reflux (GE reflux), hypertension and is a risk factor for cardiovascular disease and diabetes. It would be helpful to commercial drivers with OSA to have complete information on these aspects and the Federal Motor Carrier Safety Administration should consider developing specific educational materials for commercial drivers with OSA.

Recommendations for Future Guidelines

The Medical Expert Panel made several recommendations pertaining to the need for the development of further guidelines. The areas for which the panel considers the production of guidelines to be necessary include the following:

- 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
- Hours of service
- Obesity/hypoventilation Syndrome
- Side effects of medication
- Development of a national registry of certified drivers to include:
 - Full medical history
 - It is envisioned that medical examiners will be responsible for populating the registry
- 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 CMV's
 - Evaluation of alternatives to PSG in CMV drivers

Comments

While the expert panel was charged with developing guidelines specifically for obstructive sleep apnea, they noted that there were a number of other sleep disorders which resulted in excessive daytime sleepiness. Disorders such as restless legs syndrome are common. Moreover, a vitally important issue for commercial drivers is insufficient sleep. A recent study of commercial drivers (Pack et al., 2006) found that 13.5% slept on average less than 5 hours/day. Short sleep duration had an equal impact to severe OSA on daytime performance and is more common. The expert panel believed that there was a compelling rationale to develop additional guidelines in this area.

Additional Recommendations

The medical Expert Panel made the following additional recommendations:

- Panel recommends that FMCSA consider creating incentives for large trucking companies to develop fatigue management models (e.g. Schneider Model)
- A dissemination program should be coupled with these models

Notes

Obstructive sleep apnea is only **one** cause for excessive daytime sleepiness in commercial drivers. Commercial vehicle companies should consider implementing a comprehensive approach to the issue of driver sleepiness (fatigue) that would include screening of its drivers for obstructive sleep apnea, altering the drivers' schedules to maximize alertness, and ensuring that drivers get sufficient sleep. Such programs might include fitness-for-duty testing and/or on-board detection of drowsiness of the driver. The Federal Motor Carrier Safety Administration should develop a program that stimulates individual companies to develop novel, comprehensive programs in this area. The content of such programs would need to be approved by the FMCSA and there would be a requirement for dissemination of the results to the rest of the industry. The program developed by the trucking company—Schneider—to assess OSA in its drivers is a model in this regard.

Relevant References

1. http://www.schneider.com/news/Final_NSF_Award_Release.html
2. Pack, A.I., Staley, B., Pack, F.M., Rogers, W.C., George, C.F.P., Dinges, D.F., and Maislin, G. Impaired performance in commercial drivers: role of sleep apnea and short sleep duration. *Am. J. Respir. Crit. Care Med.* 174:446-454, 2006

APPENDIX A: Current FMCSA Standards and Guidelines for Medical Examiners Pertaining to Seizure Disorders

Appendix A summarizes the FMCSA's current standards and guidelines pertaining to individuals with seizure disorders.

Current Medical Fitness Standards and Guidelines for CMV drivers in the United States

Current Medical Fitness Standards

The current medical qualification standard for fitness to drive a CMV (49 CFR 391.41(b) subpart 5) states the following (see: <http://www.fmcsa.dot.gov/rules-regulations/administration/fmcsr/fmcsrruletext.asp?section=391.41>):

A person is physically qualified to drive a commercial motor vehicle if that person —

- Has no established medical history or clinical diagnosis of a respiratory dysfunction likely to interfere with his/her ability to control and drive a commercial motor vehicle safely.

Current Medical Qualification Guidelines

Unlike standards which are regulations that a medical examiner must follow, these guidelines are recommendations that the medical examiner should follow. While not law, the guidelines are intended as standards of practice for medical examiners. Currently, guidance from FMCSA on the certification of individuals with obstructive sleep apnea come from two separate conference sources; a 1988 conference report from a medical expert panel that focused on neurological disorders and a 1991 conference report from a medical expert panel that focused on pulmonary disorders.

In 1988, FMCSA published the outcome of a conference aimed at reviewing the current medical standards covering neurological disease (see: <http://www.fmcsa.dot.gov/facts-research/research-technology/publications/medreports.htm>) and providing guidance to medical examiners on the certification of individuals with obstructive sleep apnea. Relevant guidance from this conference is as follows:

“Patients with sleep apnea syndrome having symptoms of excessive daytime somnolence cannot take part in interstate driving, because they likely will be involved in hazardous driving and crashes resulting from sleepiness. Even if these patients do not have the sleep attacks, they suffer from daytime fatigue and tiredness. These symptoms will be compounded by the natural fatigue and monotony associated with the long hours of driving, thus causing increased vulnerability to crashes. Therefore, those patients who are not on any treatment and are suffering from symptoms related to EDS should not be allowed to participate in interstate driving. Those patients with sleep apnea syndrome whose symptoms (e.g., EDS, fatigue etc.) can be controlled by surgical treatment, e.g., permanent tracheostomy, may be permitted to drive after 3 month period free of symptoms, provided there is constant medical supervision. Laboratory studies (e.g.

polysomnographic and multiple sleep latency tests) must be performed to document absence of EDS and sleep apnea.”

In 1991, FMCSA published the outcome of another medical expert conference aimed at reviewing the current medical standards covering pulmonary disease (see: <http://www.fmcsa.dot.gov/facts-research/research-technology/publications/medreports.htm>) and again providing guidance to medical examiners on the certification of individuals with obstructive sleep apnea. Relevant guidance extracted from this report is as follows:

“Individuals with suspected or untreated sleep apnea (symptoms of snoring and hypersomnolence) should be considered medically unqualified to operate a commercial vehicle until the diagnosis has been dispelled or the condition has been treated successfully. In addition, as a condition of continuing qualification, commercial drivers who are being treated for sleep apnea should agree to continue uninterrupted therapy as long as they maintain their commercial driver’s license. They should also undergo yearly multiple sleep latency testing (MSLT).”

Medical Fitness Standards and Guidelines for Individuals Performing Transportation Safety in the United States

Current medical fitness standards and guidelines for individuals performing transportation safety in the United States are summarized in Table 2. Included in the table are pertinent rules and guidance for pilots, railroad workers, and merchant mariners.

Table 2. Standards and Guidelines for Sleep Apnea from other U.S. Government Transportation Safety Agencies

FAA ¹ (all classes of airmen)	Railroad ¹	Merchant Mariner ¹
<p>Examiners may re-issue an airman medical certificate under the provisions of an Authorization, if the applicant provides the following:</p> <ul style="list-style-type: none"> • An Authorization granted by the FAA; and • A current report (performed within last 90 days) from the treating physician that references the present treatment, whether this has eliminated any symptoms and with specific comments regarding daytime sleepiness. If there is any question about response to or compliance with treatment, then a Maintenance of Wakefulness Test (MWT) will be required. <p>The Examiner must defer to the AMCD or Region if:</p> <ul style="list-style-type: none"> • There is any question concerning the adequacy of therapy; • The applicant appears to be non-compliant with therapy; • The MWT demonstrates sleep deficiency; or • The applicant has developed some associated illness, such as right-sided heart failure. 	<p>No specific standards or guidelines</p>	<p>Sleep disorders which would result in gradual deterioration of performance of duties, sudden incapacitation or otherwise compromise shipboard safety, including required response in an emergency situation may be disqualifying.</p>

*Source of information for FAA Regulations and Guidelines:

http://www.faa.gov/about/office_org/headquarters_offices/avs/offices/aam/ame/guide/special_iss/all_classes/sleep_apnea/

‡Source of information for Federal Railroad Administration Guidelines: <http://www.fra.dot.gov/us/content/1586>

‡Source of information for Merchant Mariner Guidelines: http://www.uscg.mil/hq/g-m/nvic/2_98/n2-98.pdf

Regulatory Medical Fitness Standards in Australia, Canada, the United Kingdom, New Zealand, and Sweden

Regulatory standards and guidance pertaining to sleep apnea and commercial motor vehicle driving in Australia, Canada, the United Kingdom, New Zealand, and Sweden are presented in [Table 3](#).

Table 3. Regulations Pertaining to Sleep Apnea and CMV driving from Selected Countries

Country	Regulation
Australia*	<p>The criteria for an unconditional license are NOT met:</p> <ul style="list-style-type: none"> • If the person has established sleep apnea syndrome (sleep apnea on a diagnostic sleep study and excessive daytime sleepiness), with moderate to severe sleepiness, until treatment is effective. Consideration should be given to how long-distance drivers will comply with treatment such as CPAP. • If there is a history suggestive of sleep apnea in association with severe daytime sleepiness, until investigated and treated. Severe sleepiness is indicated by frequent self-reported sleepiness while driving, motor vehicle crashes caused by inattention or sleepiness or an Epworth Sleepiness Scale Score of 16 to 24. <p>A <i>conditional license</i> may be granted by the Driver Licensing Authority, taking into account the opinion of a specialist in sleep disorders, and the nature of the driving task, and subject to annual review:</p> <ul style="list-style-type: none"> • For those with established sleep apnea syndrome (sleep apnea on a diagnostic sleep study and excessive daytime sleepiness) who are on satisfactory treatment.
Canada†	<p>The following recommendations should only be made by physicians familiar with the interpretation of sleep studies.</p> <ul style="list-style-type: none"> • Regardless of apnea severity, all patients with OSA are subject to sleep schedule irregularities and subsequent sleepiness. Because impairment from sleep apnea, sleep restriction and irregular sleep schedules may be interactive, all patients should be advised about the dangers of driving when drowsy. • Patients with mild OSA without daytime somnolence who report no difficulty with driving are at low risk for motor vehicle crashes and should be safe to drive any type of motor vehicle. • Patients with OSA, documented by a sleep study, who are compliant with CPAP or who have had successful UPPP treatment, should be safe to drive any type of motor vehicle. • Patients with moderate to severe OSA, documented by sleep study, who are <i>not</i> compliant with treatment and are considered at increased risk for motor vehicle crashes by the treating physician, should not drive any type of motor vehicle. • Patients with a high apnea-hypopnea index, especially if associated with right heart failure or excessive daytime somnolence, should be considered at high risk for motor vehicle crashes. • Patients with OSA who are believed to be compliant with treatment but who are subsequently involved in a motor vehicle crash in which they were at fault should not drive for at least 1 month. During this period, their compliance with therapy must be reassessed. After the 1-month period, they may or may not drive depending on the results of the reassessment.
United Kingdom‡	<p>Driving must cease until satisfactory control of symptoms has been attained, with ongoing compliance with treatment, confirmed by consultant /specialist opinion. Regular, normally annual, licensing review required.</p>
New Zealand**	<p>Driving should cease for individuals who meet the high-risk driver profile as follows:</p> <ul style="list-style-type: none"> • are suspected of having OSA syndrome where there is a high level of concern regarding the risk of excessive sleepiness while driving while the individual is waiting for the diagnosis to be confirmed by a sleep study • complain of severe daytime sleepiness and a history of sleep-related motor vehicle crashes or equivalent level of concern • have a sleep study that demonstrates severe OSA syndrome and either it is untreatable or the individual is unwilling or unable to accept treatment <p>Individuals may resume driving or can drive if their OSA syndrome is adequately treated under specialist supervision with satisfactory control of symptoms. Consideration should be given to the type of driving and hours of driving an individual undertakes. If there is any residual risk of daytime sleepiness medical practitioners should recommend a restriction in working hours or shift work. The Director of Land Transport Safety or the Director's delegate may impose license conditions for regular medical assessment. Medical follow-up may be delegated to the General Practitioner.</p>
Sweden††	<p>Possession (holding a driving license, tractor license or taxi driver license)</p> <ul style="list-style-type: none"> • OSA syndrome constitutes grounds for denial of possession. This, however, does not apply in the case of successful treatment.

Country	Regulation
	<ul style="list-style-type: none"> • Regarding possession in Groups II and III, due consideration shall be given to the additional risks and dangers to traffic safety involved in such possession. <p>Reappraisal (Reappraisal of possession through the requirement on a medical certificate or other medical statement)</p> <ul style="list-style-type: none"> • A reappraisal shall occur at intervals considered suitable in each individual case.

*Source of information for Australia: <http://www.austroads.com.au/afid/index.html>

†Source of information for Canada: http://www.cma.ca/index.cfm/ci_id/18223/la_id/1.htm

‡Source of information for the United Kingdom: <http://www.dvla.gov.uk/medical.aspx?keywords=medical>

**Source of information for New Zealand: <http://www.landtransport.govt.nz/licensing/docs/ltsa-medical-aspects.pdf>

††Source of information for Sweden: <http://www.vv.se/filer/4796/9889eng000915.pdf>

APPENDIX B: Findings of Evidence Report

This appendix summarizes the findings of the Evidence Report titled, “Obstructive Sleep Apnea and Commercial Motor Vehicle Safety.” The purpose of this evidence report was to address several key questions posed by Federal Motor Carrier Safety Administration. Each of these key questions was developed by FMCSA such that the answers to these questions provided information that the Agency believed would be useful in updating their current medical examination guidelines. The seven key questions addressed in the evidence report were:

Key Question 1: Are individuals with obstructive sleep apnea (OSA) at an increased risk for a motor vehicle crash when compared to comparable individuals who do not have the disorder?

Key Question 2: What disease-related factors are associated with an increased motor vehicle crash risk among individuals with OSA?

Key Question 3: Given the findings of Key Question 2, are individuals with OSA unaware of the presence of the factors that appear to be associated with an increased motor vehicle crash risk?

Key Question 4: Are there screening/diagnostic tests available that will enable examiners to identify those individuals with OSA who are at an increased risk for a motor vehicle crash?

Key Question 5: Which treatments have been shown to effectively reduce crash risk among individuals with OSA? Where reductions in crash risk have been assessed:

- i. directly (crash risk)
- ii. quasi-directly (simulated driving performance)
- iii. indirectly (OSA severity, excessive daytime sleepiness, cognitive and psychomotor function, blood pressure, oxygen saturation)

Key Question 6: What is the length of time required following initiation of an effective treatment (determined by Key Question 5), for patients with OSA to reach a degree of improvement that would permit safe driving (as determined by crash rates or through indirect measures² of crash risk)?

Key Question 7: How soon, following cessation of treatment (e.g., as a consequence of non-compliance), will individuals with OSA demonstrate reduced driver safety (as determined by crash rates or through indirect measures of crash risk)?

Identification of Evidence Bases

Separate evidence bases for each of the key questions addressed by the evidence report were identified using a process consisting of a comprehensive search of the literature, examination of abstracts of

² Indirect measures of driver safety include the following: simulated driving, closed course driving, measures of cognitive function, measures of psychomotor function, and daytime sleepiness.

identified studies in order to determine which articles would be retrieved, and the selection of the actual articles that would be included in each evidence base.

A total of seven electronic databases (Medline, PubMed (pre Medline), EMBASE, PSYCH Info, CINAHL, TRIS, the Cochrane library) were searched (through April 30th, 2007). In addition, the reference lists of all obtained articles with the aim of identifying relevant articles not identified by our electronic searches were examined. Hand searches of the “gray literature” were also performed. Admission of an article into an evidence base was determined by formal retrieval and inclusion criteria that were determined *a priori*.

Grading the Strength of Evidence

Quality assessment of the evidence took into account not only the quality of the individual studies that comprise the evidence base for each key question; we also considered the interplay between the quality, quantity, robustness, and consistency of the overall body of evidence.

Analytic Methods

The set of analytic techniques used in the evidence report was extensive. Random- and fixed-effects meta-analyses were used to pool data from different studies. Differences in the findings of studies (heterogeneity) were identified using the Q-statistic and I^2 . Sensitivity analyses, aimed at testing the robustness of our findings, included the use of cumulative fixed- and random-effects meta-analysis. The presence of publication bias was tested for using the “trim and fill” method.

Presentation of Findings

In presenting the findings of the evidence synthesis, a clear distinction was made between qualitative and quantitative conclusions and a separate “strength of evidence” rating was assigned to each of conclusion format. The strength of evidence ratings assigned to these different types of conclusion are defined in Table 4.

Table 4. Strength of Evidence Ratings for Qualitative and Quantitative Conclusions

Strength of Evidence	Interpretation
Qualitative Conclusion	
Strong	Evidence supporting the qualitative conclusion is convincing. It is highly unlikely that new evidence will lead to a change in this conclusion.
Moderate	Evidence supporting the qualitative conclusion is somewhat convincing. There is a small chance that new evidence will overturn or strengthen our conclusion. ECRI recommends regular monitoring of the relevant literature for moderate-strength conclusions.
Minimally acceptable	Although some evidence exists to support the qualitative conclusion, this evidence is tentative and perishable. There is a reasonable chance that new evidence will either overturn or strengthen our conclusions. ECRI recommends frequent monitoring of the relevant literature.
Unacceptable	Although some evidence exists, the evidence is insufficient to warrant drawing an evidence-based conclusion. ECRI recommends frequent monitoring of the relevant literature.
Quantitative Conclusion (Stability of Effect Size Estimate)	
High	The estimate of treatment effect in the conclusion is stable. It is highly unlikely that the magnitude of this estimate will change substantially as a result of the publication of new evidence.
Moderate	The estimate of treatment effect the conclusion is somewhat stable. There is a small chance that the magnitude of this estimate will change substantially as a result of the publication of new evidence. ECRI recommends regular monitoring of the relevant literature.

Low	The estimate of treatment effect included in the conclusion is likely to be unstable. There is a reasonable chance that the magnitude of this estimate will change substantially as a result of the publication of new evidence. ECRI recommends frequent monitoring of the relevant literature.
Unstable	Estimates of the treatment effect are too unstable to allow a quantitative conclusion to be drawn at this time. ECRI recommends frequent monitoring of the relevant literature.

Evidence-Based Conclusions

Key Question 1: Are individuals with OSA at an increased risk for a motor vehicle crash when compared to comparable individuals who do not have the disorder?

Seventeen articles describing seventeen unique studies met the inclusion criteria for Key Question 1. Four of the 17 included studies were graded as being moderate quality. The remaining 11 studies were graded as low quality. Two included studies enrolled distinct populations of commercial motor vehicle (CMV) drivers. The remainder of the studies included private motor vehicle license holders, an unknown number of whom may have held commercial driver licenses.

A number of evidence-based conclusions were drawn from the findings of our analyses of the data extracted from the 17 included studies. These conclusions are presented below:

Drivers of CMVs

- **CMV drivers with OSA are at an increased risk for a crash when compared to their counterparts who do not have the disorder (Strength of Evidence: Minimal Acceptable).**
 - **A precise estimate of the magnitude of this increased risk cannot be determined at this time.**

Two studies presented data directly relevant to the question of whether obstructive sleep apnea has an impact on CMV driver safety. One study compared crash risk among drivers with sleep apnea syndrome (symptom diagnosis) and drivers not diagnosed with sleep apnea syndrome (controls). Drivers diagnosed with sleep apnea syndrome (Multivariable Apnea Prediction Score ≥ 0.5 and Epworth Sleepiness Scale (ESS) score ≥ 11) were found to be at an increased risk for motor vehicle crash (OR = 1.3, 95% 1.00-1.69). The value of the findings of this study is weakened somewhat by the fact that individuals enrolled in the study were diagnosed with sleep apnea using questionnaires only.

The second study found that truck drivers identified with sleep-disordered breathing (SDB) had a two-fold higher crash rate per mile than drivers without sleep-disordered breathing. Crash frequency was not dependent on the severity of the sleep-related breathing disorder. Obese drivers with a body mass ≥ 30 kg/m² also presented a two-fold higher crash rate than non-obese drivers. In addition, the authors found that a complaint of excessive daytime sleepiness was related to a significantly higher automotive crash rate in long-haul commercial truck drivers. Sleep-disordered breathing with hypoxemia and obesity are risk factors for automotive crashes.

Drivers of Non-CMV

Because data from studies of CMV drivers with OSA is scarce we deemed it worthwhile to examine relevant data from studies that investigated crash risk associated with OSA among more general driver populations. While the generalizability of the findings of these studies to CMV drivers may not be clear,

such findings do at the very least allow one the opportunity to draw evidence-based conclusions about the relationship between OSA and motor vehicle crash risk in general.

- **As a group, drivers with OSA are at an increased risk for a motor vehicle crash when compared with comparable drivers who do not have the disorder (Strength of Evidence: Strong).**
 - **A precise estimate of the magnitude of this increased risk cannot be determined at the present time.**

Nine studies (Quality Rating: Low) provided data on the relative incidence of crash among individuals who have obstructive sleep apnea and comparable individuals without the disorder. Pooling of these data using a random-effects meta-analysis revealed that the mean crash rate ratio associated with OSA is likely to fall within the range 1.30 to 5.72 (95% CI of random effects summary effect size estimate). Thus, if the underlying crash risk for a CMV driver is 0.08 crashes per person-year, the crash risk for a CMV driver with OSA can be expected to be in the range of 0.10 to 0.46 crashes per person-year. A series of sensitivity analyses found that the estimate was robust. While the quality of the studies was not high, the data were qualitatively consistent, making it unlikely that future studies will overturn our finding that individuals with OSA are at increased risk for a motor vehicle crash.

Key Question 2: What disease-related factors are associated with an increased motor vehicle crash risk among individuals with OSA?

Our assessment of the evidence pertaining to Key Question 1 found that drivers with OSA (both commercial and non-commercial) are at a significantly increased risk for a motor vehicle crash when compared with comparable drivers who do not have the disorder. Not all individuals with OSA, however, appear to be at increased risk and many individuals with the disorder do not pose an additional threat to public safety. The aim of Key Question 2 was to determine whether there are specific risk factors that are predictive of which individuals with OSA are at the greatest risk for a crash. The identification of such risk factors is important because it will enable medical examiners to differentiate high risk individuals from low risk individuals when making decisions about fitness-to-drive certification.

Ten articles describing 10 unique studies met the inclusion criteria for Key Question 2. The quality of the included studies, all of which utilized a case-control design, was not high. One of the 10 included studies was graded as being of moderate quality. The remaining nine studies were graded as being of low quality. One of the studies assessed the factors predictive of crash among CMV drivers with OSA.

The findings of our analyses of the data extracted from the 10 included studies that addressed Key Question 2 are as follows:

- **No evidence-based conclusion pertaining to the risk factors for crash among CMV drivers with OSA can be drawn at the present time.**

A single study examined the relationship between several potential risk factors for crash in CMV drivers. Potential risk factors assessed included the presence of excessive daytime sleepiness (measured using a non-validated instrument), severity of sleep disordered breathing (as

measured using the Oxygen Desaturation Index [ODI]] and body mass index (BMI). The study investigators found that the presence of excessive daytime sleepiness was associated with an increased crash risk. However, neither the severity of sleep disordered breathing nor BMI were found to be significantly associated with crash risk. Because of the low power of this study to detect the presence of these latter associations, and the fact that an underlying trend suggesting that these factors are associated with crash risk, it cannot be concluded that no association exists (a potential type-II statistical error) based on the findings of this study alone.

- **Four factors have been shown to be associated with crash risk among the general driver population. These factors are the presence and degree of daytime sleepiness (as measured using the ESS, but not Multiple Sleep Latency Test [MSLT] or Maintenance of Wakefulness Test[MWT]), severity of disordered respiration during sleep (as measured by the Apnea-Hypopnea Index [AHI] or the Respiratory Disturbance Index[RDI]), blood oxygen saturation levels, and BMI (Strength of Evidence: Minimally Acceptable) .**

A total of 9 included studies that enrolled drivers with private motor vehicles addressed Key Question 2. Potential risk factors examined by these studies included BMI, the presence and severity of daytime sleepiness, the severity of disordered respiration, oxygen saturation, various measures of cognitive and psychomotor function, and measures of depression. Taking the data from all nine studies into account, four factors were found to be associated with crash risk. These factors were the presence and degree of daytime sleepiness (as measured using the ESS but not the MSLT or MWT), severity of disordered respiration during sleep (as measured by the AHI or the RDI), blood oxygen saturation levels, and the BMI. The remaining potential risk factors were not assessed by more than one included study. Consequently, we refrain from drawing evidence based conclusions about the relationship between cognitive and psychomotor function and measures of depression at this time.

Key Question 3: Given the findings of Key Question 2, are individuals with OSA unaware of the presence of the factors that appear to be associated with an increased motor vehicle crash risk?

Our aim in addressing Key Question 3 was to determine whether individuals with OSA are aware of the presence and/or severity of factors that have been shown to be associated with an increased risk for a motor vehicle crash in this population. Our analyses for Key Question 2 identified four such risk factors: BMI; the severity of apnea and hypopnea (as measured using HDI or RDI); the presence and severity of oxygen desaturation; the presence and severity of excessive daytime sleepiness (as measured by the ESS, MWLT, or MWT)

Key Question 3 is only relevant to one of these four risk factors; it is unrealistic to posit that an obese individual may be unaware of their condition. Also, it is highly likely that an individual with OSA will be unaware of the number of apneic and hypopneic events that they experience during the night and their oxygen saturation levels. Consequently, we confined this question to one risk factor; daytime sleepiness.

Three articles describing three unique studies met the inclusion criteria for Key Question 3. None of the three studies, all of which were case series, was of high quality and none attempted to determine whether CMV drivers are aware of the extent to which they are affected by daytime sleepiness.

The finding of our analysis of the data extracted from the three included studies that addressed Key Question 3 is as follows:

- **Individuals with OSA may not be aware of the extent to which they are affected by daytime sleepiness (Strength of Evidence: Minimally Acceptable).**

Three included studies addressed Key Question 3. One included study found that individuals with moderate-to-severe OSA re-evaluated the degree of sleepiness they had experienced prior to the onset of treatment measured using the ESS: the pre-treatment level of sleepiness was reassessed as being much higher than originally reported. Another included study found no correlation between ESS and MSLT scores suggesting a disconnect between subjective and objective measures of sleepiness. However, the final included study compared ESS scores from individuals with OSA with that estimated by their partner.

Key Question 4: Are there screening/diagnostic tests available that will enable examiners to identify those individuals with OSA who are at an increased risk for a motor vehicle crash?

The current reference standard study for diagnosing and determining the severity of OSA is in-laboratory, technician-attended polysomnography (PSG). Among other physiological parameters such as air flow, heart rate and rhythm, and respiratory effort, PSG assesses all four of the known risk factors for crash listed above. This has led to suggestions that all individuals who wish to be certified to drive a CMV and are suspected of, or diagnosed with, OSA, should undergo overnight PSG at a specialist sleep center. For example, the September 2006 recommendations regarding the evaluation for fitness-for-duty from the Joint Task Force of the American College of Chest Physicians, American College of Occupational Health and Environmental Medicine, and the National Sleep Foundation state that all those wishing to drive a CMV who are suspected of having sleep apnea should be assessed by a sleep physician and have any diagnosis confirmed by overnight PSG.

Coupled with these recommendations is a growing awareness among physicians and medical examiners of the danger that OSA poses to transportation safety. Together, these factors will increase the demand for access to sleep labs which will be difficult to satisfy in the face of an acknowledged shortage of testing facilities. This shortfall may lead to delays in diagnosis and treatment initiation. In addition to the deficit in sleep labs, the cost for a PSG is high and may limit access to appropriate testing. Consequently, alternative strategies to PSG that can detect and measure the severity of the known risk factors for a crash are actively being considered.

Our aim in addressing Key Question 4 then was to determine whether alternative, low cost technologies are available that can effectively detect and measure the severity of the known risk factors for a crash among individuals with OSA.

Forty-three articles describing 43 unique studies met the inclusion criteria for Key Question 4. All but one of these studies assessed the diagnostic performance of a portable sleep monitoring system. One study assessed the effectiveness of a clinical model in addition to a portable sleep monitoring system. This study was also the only study to have enrolled only CMV drivers.

The findings of our analyses of the data extracted from the 43 included studies that addressed Key Question 4 are as follows:

- **To date, no model or psychometric instrument has been shown to accurately stratify individuals with OSA by disease severity (a surrogate marker for crash risk).**
- **A number of portable sleep monitoring systems, though not as accurate as the current reference standard (a sleep study in a specialized sleep lab) do offer an alternative method by which the severity of OSA may be assessed in a large number of individuals at a relatively low cost.**
 - **Whether these systems are accurate enough to be considered as acceptable alternatives to the current reference standard for stratifying individuals by OSA severity for the purposes of making decisions about the fitness of an individual to drive a CMV is not clear. Addressing this issue requires that a formal decision and cost-effectiveness analyses be performed. Such analyses are beyond the scope of this evidence report.**

To date, no randomized controlled trial has been published that compares OSA-related outcomes known to be associated with driver safety among individuals with OSA who were stratified into risk groups using PSG or an alternative diagnostic test. Consequently, one must attempt to estimate the likely consequences of replacing standard PSG with cheaper, more easily accessible portable sleep monitoring systems using indirect methods. The first stage in this process is to obtain accurate estimates of the diagnostic performance characteristics of available systems. Once such estimates are identified, a decision model needs to be developed into which these diagnostic performance data can be integrated along with other necessary data (e.g. the costs associated with each diagnostic decision option, the prevalence of severe OSA in the United States CMV driver population, etc).

While no portable sleep monitoring system was as accurate as the reference standard (none had a sensitivity and specificity of 100%, our analyses found that the diagnostic performance characteristics of most portable systems were reasonable. That is, the vast majority of available systems could differentiate individuals with OSA from those without and they could differentiate individuals with severe OSA from those with mild-to-moderate disease better than would be expected by chance alone.

Although we have synthesized the diagnostic performance characteristics of Level II, Level III and Level IV sleep monitors; we caution the reader that the precision of these estimates is low. While the quality of the included studies was moderate-to-high and the quantity of available evidence was reasonably large, a great deal of heterogeneity in the findings of different studies was observed, even when the tests were performed at the same threshold of OSA severity. Attempts to model this heterogeneity were unsuccessful, and none of the more obvious covariates such as differences in the device used, the setting in which the study was performed (lab or at home), or the availability of a technician appeared to be associated with diagnostic performance differences. Indeed, homogeneity testing of diagnostic performance data extracted from studies that used the same device at the same threshold was also found to be heterogeneous.

Whether currently available portable sleep monitoring systems are accurate enough to be considered as acceptable alternatives to the current reference standard for stratifying individuals by OSA severity for

the purposes of making decisions about the fitness of an individual to drive a CMV is not clear. Addressing this issue require that a formal decision and cost-effectiveness analyses be performed. Such analyses, though time consuming and expensive, are central to any decision or policy-making program and fall within the purview of FMCSA's Analysis Division.

Key Question 5: Which treatments have been shown to effectively reduce crash risk among individuals with OSA (as determined by crash rates or through indirect measures of crash risk)?

The overall findings of all of our analyses for Key Question 5 are summarized in [Table 5](#).

Table 5. Summary of Findings – Key Question 5

	Behavioral modification (weight loss)	CPAP	Dental Appliances	Medications				Surgery		
			Mandibular advancement splints	Theophylline	Modafinil (or armodafinil) as adjunct to CPAP	Mirtazepine	Salmeterol	UPPP	LAUP	TCRFTA
Crash	No evidence	***	No evidence	No evidence	No evidence	No evidence	No evidence	No evidence	No evidence	No evidence
Simulated Driving	No evidence	**	*	*	No evidence	No evidence	No evidence	*	No evidence	No evidence
AHI	*	***	*	?	No evidence	*	?	No evidence	?	?
Cognitive/ Psychomotor Function	No evidence	?	?	No evidence	No evidence	No evidence	No evidence	?	?	No evidence
Daytime sleepiness (ESS)	No evidence	***	?	No evidence	?	No evidence	No evidence	*	?	?
Daytime sleepiness (MSLT)	No evidence	?	No evidence	No evidence	?	No evidence				
Daytime sleepiness (MWT)	No evidence	No evidence	?	No evidence	*	No evidence				
Oxygen Saturation	?	***	*	?	No evidence	?	?	?	No evidence	?
24-hour systolic BP	No evidence	**	No evidence	No evidence	No evidence	No evidence	No evidence	?	No evidence	No evidence
24-hour diastolic BP	No evidence	**	No evidence	No evidence	No evidence	No evidence	No evidence	?	No evidence	No evidence

Technology has a positive impact on this outcome such that crash risk is reduced



Technology has a negative impact on this outcome such that crash risk is increased

 Neither a positive nor a negative impact on this outcome has been demonstrated

*** Strength of Evidence = Strong

** Strength of Evidence = Moderate

* Strength of Evidence = Minimally acceptable

? Results equivocal – strength of evidence too weak at present time to draw an evidence-based conclusion (see text for details)

BP=blood pressure; CPAP =continuous positive airway pressure; LAUP=Laser-assisted uvula palatoplasty; TCRFTA=temperature-controlled radiofrequency tissue ablation; UPPP=uvulopalatopharyngoplasty

Taking all of the findings summarized in the table above into account, we draw the following evidence-based conclusions:

- **CPAP reduces crash risk among individuals with moderate-to-severe OSA (Strength of Evidence: Strong).**
- **While several other technologies may reduce crash risk among individuals with moderate-to-severe OSA, the available evidence to support this is not convincing. Consequently, we refrain from drawing further evidence-based conclusions pertaining to other available technologies at this time.**

Key Question 6: What is the length of time required following initiation of an effective treatment (determined by Key Question 5), for patients with OSA to reach a degree of improvement that would permit safe driving (as determined by crash rates or through indirect measures of crash risk)?

Our assessment of the evidence pertaining to Key Question 5 demonstrated that the average driver with OSA is at a significantly increased risk for a motor vehicle crash when compared with comparable drivers who do not have the disorder. Our assessment of the evidence pertaining to Key Question 5 found that CPAP (and perhaps some other technologies) can reduce the increased crash risk associated with OSA. Currently it is understood that there is little evidence to help advise individuals with OSA when driving can be safely restarted after beginning treatment, or whether it is safe to continue driving if treatment is missed for a few nights.

In addressing Key Question 6, we attempted to identify the length of time required following initiation of an effective treatment for individuals with OSA to reach a degree of improvement that would permit safe driving (as determined through indirect measures of crash risk, i.e. driving simulators or cognitive/psychomotor functioning) or to show improvement in the risk factors associated with OSA (i.e. disease severity, daytime sleepiness, oxygen saturation, blood pressure).

Twenty-four articles describing 24 unique studies met the inclusion criteria for Key Question 6. The findings of our analyses of the data extracted from these studies are as follows:

- **The impact that CPAP has on crash risk reduction among individuals with OSA can be seen after as little as one night of treatment (Strength of Evidence: Minimally Acceptable).**

Studies have shown that improvements in simulated driving performance, the severity of disordered respiration, blood oxygen saturation, and some (but not all) measures of cognitive and psychomotor performance improve significantly following a single night of treatment. Exactly how many nights of treatment are required until CPAP exerts its maximum benefit is not known but evidence suggests that this point has been reached prior to two weeks.

- **It is not clear how long it takes for other available treatments to exert their maximum effects³ at this time.**

Key Question 7: How soon, following cessation of an effective treatment (e.g., as a consequence of non-compliance), will individuals with OSA demonstrate reduced driver safety (as determined by crash rates or through indirect measures of crash risk)?

Four articles describing four unique studies met the inclusion criteria for Key Question 7. All four included studies assessed the effects of withdrawal from CPAP. The finding of our analysis of the data extracted from these studies is as follows:

- **Cessation of CPAP leads to a decrease in simulated driving ability and increases in both OSA severity and daytime sleepiness. The rate at which this deterioration occurs cannot be determined; however, this deterioration may occur as soon as 24 hours following cessation of treatment (Strength of Evidence: Minimally Acceptable).**

³ Assuming that other treatment options do have a positive impact on crash risk (an assumption that is as yet unproven).

APPENDIX C: The Berlin Questionnaire

Height (m) _____ Weight (kg) _____ Age _____ Male / Female

Please choose the correct response to each question.

CATEGORY 1

1. **Do you snore?**

- a. Yes
- b. No
- c. Don't know

If you snore:

2. **Your snoring is:**

- a. Slightly louder than breathing
- b. As loud as talking
- c. Louder than talking
- d. Very loud – can be heard in adjacent rooms

3. **How often do you snore**

- a. Nearly every day
- b. 3-4 times a week
- c. 1-2 times a week
- d. 1-2 times a month
- e. Never or nearly never

4. **Has your snoring ever bothered other people?**

- a. Yes
- b. No
- c. Don't Know

5. **Has anyone noticed that you quit breathing during your sleep?**

- a. Nearly every day
- b. 3-4 times a week
- c. 1-2 times a week
- d. 1-2 times a month
- e. Never or nearly never

CATEGORY 2

6. **How often do you feel tired or fatigued after your sleep?**

- a. Nearly every day
- b. 3-4 times a week
- c. 1-2 times a week
- d. 1-2 times a month
- e. Never or nearly never

7. **During your waking time, do you feel tired, fatigued or not up to par?**

- a. Nearly every day
- b. 3-4 times a week
- c. 1-2 times a week
- d. 1-2 times a month
- e. Never or nearly never

8. **Have you ever nodded off or fallen asleep while driving a vehicle?**

- a. Yes
- b. No

If yes:

9. **How often does this occur?**

- a. Nearly every day
- b. 3-4 times a week
- c. 1-2 times a week
- d. 1-2 times a month
- e. Never or nearly never

CATEGORY 3

10. **Do you have high blood pressure?**

- Yes
- No
- Don't know

Scoring the Berlin Questionnaire

The questionnaire consists of 3 categories related to the risk of having sleep apnea. Patients can be classified into High Risk or Low Risk based on their responses to the individual items and their overall scores in the symptom categories.

Categories and scoring:

Category 1: items 1, 2, 3, 4, 5.

Item 1: if 'Yes', assign 1 point

Item 2: if 'c' or 'd' is the response, assign 1 point

Item 3: if 'a' or 'b' is the response, assign 1 point

Item 4: if 'a' is the response, assign 1 point

Item 5: if 'a' or 'b' is the response, assign 2 points

Add points. Category 1 is positive if the total score is 2 or more points

Category 2: items 6, 7, 8 (item 9 should be noted separately).

Item 6: if 'a' or 'b' is the response, assign 1 point

Item 7: if 'a' or 'b' is the response, assign 1 point

Item 8: if 'a' is the response, assign 1 point

Add points. Category 2 is positive if the total score is 2 or more points

Category 3: Item 10

Category 3 is positive if the answer to item 10 is 'Yes' OR if the BMI of the patient is greater than 30kg/m² (BMI must be calculated. BMI is defined as weight (kg) divided by height (m) squared, i.e., kg/m²).

Risk Strata

High Risk: if there are 2 or more Categories where the score is positive

Low Risk: if there is only 1 or no Categories where the score is positive

Additional question: Item 9 should be noted separately.

Relevant References

Netzer NC, Stoohs RA, Netzer CM, Clark K, Strohl KP. Using the Berlin Questionnaire to identify patients at risk for the sleep apnea syndrome. *Ann Intern Med.* 1999 Oct 5;131(7):485-91).