

Executive Summary

Obstructive Sleep Apnea and Commercial Motor Vehicle Driver Safety

Presented to

Federal Motor Carrier Safety Administration

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Prepared for



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FMCSA will consider all MRB and MEP recommendations, however, all proposed changes to current standards and guidance (guidelines) will be subject to public-notice-and-comment and relevant rulemaking processes.

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Policy Statement

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Purpose of Evidence Report

Of all occupations in the United States, workers in the trucking industry experience the third highest fatality rate, accounting for 12 percent of all worker deaths. About two-thirds of fatally injured truck workers were involved in highway crashes. According to statistics from the United States Department of Transportation (DOT), there were 4,932 fatal crashes involving a large truck in 2005 for a total of 5,212 fatalities. In addition, there were 137,144 non-fatal crashes; 59,405 of these were crashes that resulted in an injury to at least one individual (for a total of 89,681 injuries).

The purpose of this evidence report is to address several key questions posed by Federal Motor Carrier Safety Administration (FMCSA). Each of these key questions was developed by FMCSA such that the answers to these questions provided information that would be useful in updating their current medical examination guidelines. The seven key questions addressed in this evidence report are as follows:

<u>Key Question 1:</u> 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?

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

<u>Key Question 3:</u> 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?

<u>Key Question 4:</u> 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?

<u>Key Question 5:</u> 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)

<u>Key Question 6:</u> 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 measures¹ of crash risk)?

¹ Indirect measures of driver safety include the following: simulated driving, closed course driving, measures of cognitive function, measures of psychomotor function, and daytime sleepiness.

<u>Key Question 7:</u> 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 this evidence report were identified using a process consisting of a comprehensive search of the literature, examination of abstracts of 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, we examined the reference lists of all obtained articles with the aim of identifying relevant articles not identified by our electronic searches. 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

Our assessment of the quality 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 this evidence report was extensive. Random- and fixed-effects meta-analyses were used to pool data from different studies.(1-5) Differences in the findings of studies (heterogeneity) were identified using the Q-statistic and I².(6-8) Sensitivity analyses, aimed at testing the robustness of our findings, included the use of cumulative fixed- and random-effects meta-analysis.(9-11) The presence of publication bias was tested for using the "trim and fill" method.(12-14)

Presentation of Findings

In presenting our findings we made a clear distinction between qualitative and quantitative conclusions and we assigned a separate "strength of evidence" rating to each of conclusion format. The strength of evidence ratings assigned to these different types of conclusion are defined in Table 1.

Table 1. 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 Cond	clusion (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 $\geq 30 \text{ kg/m}^2$ also presented a two-fold higher crash rate than nonobese 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-CMVs

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 inlaboratory, 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.(23-25) 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 2.

Table 2. Summary of Findings – Key Question 5

	Behavioral modification (weight loss)		Dental Appliances	Medications				Surgery		
		CPAP	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
АНІ	*	•**	•	?	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

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- 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-tosevere 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 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 cash 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 require 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 effects²
 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).

² Assuming that other treatment options do have a positive impact on crash risk (an assumtption that is as yet unproven).