Consensus Criteria for Screening Commercial Drivers for Obstructive Sleep Apnea: Evidence of Efficacy

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Objective: *To validate the recently published consensus criteria for screening commercial drivers for obstructive sleep apnea (OSA).* ***Methods:*** *A large, consecutive case series of commercial drivers was screened for OSA at a single occupational medicine clinic and those screening positive were referred for overnight polysomnography.* ***Results:*** *One hundred ninety (13%) of 1443 individuals having commercial motor vehicle driver examinations screened positive for OSA. None of these would have been detected if the only screening were the questions on the current Commercial Driver Medical examination form. One hundred thirty-four underwent polysomnography, and of those 94.8% had OSA, which is the best estimate of the positive predictive value of these consensus criteria in a population of truck drivers.* ***Conclusion:*** *The proposed screening criteria have a high positive predictive value in this population. This study lends support for the requirement to screen for OSA in commercial drivers.* (J Occup Environ Med. *2008;50: 324–329*)

Truck driving is a hazardous occupation, with the third highest fatality rate among common occupations in the United States.[1] Thus, operating commercial motor vehicles for interstate commerce or operating large trucks (>26,000 pounds gross vehicle weight) for intrastate commerce is considered a "safety sensitive position" and requires a commercial driver's license and certification of medical fitness through a Commercial Driver Medical Examination (CDME). These examinations are often called a "DOT examination" for Department of Transportation, since the Federal Motor Carrier Safety Administration is one of the DOT agencies, though that acronym is inaccurate as these examinations do not involve certification for airlines, railroads, or other modes of transportation.

Large truck crashes are potentially severe due to the size, weight, and speed of these vehicles. The Federal Motor Carrier Administration's (FMCSA) Large Truck Crash Study found that half of such crashes result in fatal or incapacitating injuries.[2] The truck driver was judged to be at fault in 87% of these crashes. In 7% of these crashes, the driver at fault admitted to falling asleep while driving.[3] Probably more of the accidents occurred because the driver fell asleep, but this could not be documented due either to the driver's death or due to the driver's unwillingness to admit falling asleep for fear of disciplinary consequences. Only 4% occurred because the driver was medically incapacitated by a

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heart attack, stroke, hypoglycemic coma etc, yet, these medical conditions are the primary foci of the CDME medical examination form.

Obstructive sleep apnea (OSA) is a common condition that is known to cause excessive sleepiness. OSA is common in commercial drivers, and untreated it is associated with a 2- to 7-fold increased risk of motor vehicle crashes.[4] A study by Pack et al[5] found that 28% of commercial drivers had some degree of OSA. Although the FMCSA has not issued clear criteria to guide health care providers who perform CDMEs, a consensus conference has recently published criteria.[6,7] This consensus document was published by the American College of Chest Physicians, the American College of Occupational and Environmental Medicine, and the National Sleep Foundation. These criteria were proposed based on a thorough literature review to assist medical examiners in detecting drivers who might have OSA, and thus who may require polysomnogram (PSG) testing, both to protect the long-term health of the driver and to ensure public safety on the highways.

These criteria have not been field tested in a population of commercial drivers. This large case series represents the experience of one Occupational Medicine clinic in implementing and attempting to partially validate these consensus conference criteria.

Materials and Methods

The criteria proposed by this joint task force were implemented in a two-physician clinic beginning October 1, 2007. From October 1, 2006 through February 28, 2007 this clinic performed 1443 CDMEs. Each driver completed the history section of the Federal CDME form. All drivers also completed a questionnaire about factors, which would suggest that sleep apnea might be present (developed from reference 6-Appendix) and an Epworth Sleepiness Scale score. During the physical examination each driver's blood pressure, Body Mass Index (BMI), and neck circumference (in inches) were measured. If the driver met the consensus conference criteria for the 3-month certification, he was so informed. In addition, drivers meeting these criteria were told in writing they would be required to have a PSG performed in a sleep laboratory. The drivers were instructed to forward the results of the PSG to the clinic, to permit evaluation for longer certification intervals.

The PSGs were performed in multiple community and hospital-associated sleep laboratories. There was no requirement that they be performed only in laboratories with a particular accreditation. The PSG reports were formatted differently for each sleep laboratory. Nevertheless, all contained the same information on key variables that are used to indicate the presence and severity of OSA.

Statistical analyses were performed using SAS 9.1.3.[8] Test for trend for binary or multilevel responses were done using the Jonckheere-Terpstra test, a nonparametric test for ordered differences among strata. Tests for trends for continuous variables, including BMI and neck circumference were done using the Kendall Tau β correlation coefficients and corresponding probability values. All *P* values reported are two sided.

Results

From October 1, 2006 through February 28, 2007 this clinic performed 1443 consecutive CDMEs. Of these, 190, or 13% of the drivers, met the consensus criteria[4,5] for a limited 3-month certification, to permit time for the driver to be scheduled for a PSG. None of these 1443 drivers checked "yes" to the question on the CDME medical examination form "Sleep disorders, pauses in breathing while asleep, daytime sleepiness, loud snoring". Thus, if screening for OSA were done relying only on the "yes" or "no" question on the federal CDME examination form, no cases of OSA would have been detected. The only drivers who answered this question "yes" were some of (but not all) those who already had a continuous positive airway pressure (CPAP) machine for OSA.

Of the 190 drivers who "screened positive" for OSA by the consensus conference criteria, 56 were drivers applying for employment with a new motor carrier, who rather than be tested for OSA, declined employment with that prospective employer. They may have sought employment with another carrier, or had CDMEs with different health care provider(s) who do not screen for sleep apnea, and they may be driving for other carriers with untreated OSA.

Table 1 shows the results of the first 134 PSGs received since implementation of this screening program in October 2006. These tests were all accomplished in drivers who had never been tested before.

Only seven of these 134 drivers (5.2%) did not have OSA. The vast majority (94.8%) of the drivers were diagnosed with OSA, suggesting that the consensus conference criteria are very specific, but probably are not sensitive enough to screen for OSA. Since all 1443 drivers did not have PSGs, the screening consensus criteria sensitivity and specificity and the negative predictive value in our population cannot be calculated. Nevertheless, we are able to infer a range of positive predictive values of these screening criteria in this population. Assuming a worst case scenario, that all 56 who declined polysomnography did not have OSA, the positive

TABLE 1
Categorization of Drivers by Screening Criteria

Total Drivers Screened	1443
Drivers screen positive	190
Drivers refusing polysomnography	56
No OSA	7
Mild OSA	40
Moderate OSA	34
Severe OSA	53

predictive value of the screening criteria is 49.6%. Assuming that all in fact had OSA, the positive predictive value would be 96.2%. Perhaps the most realistic estimate for positive predictive value is to exclude them from the analyses, in which case the positive predictive value is 94.8%. Table 2 shows that there were no significant demographic differences between the drivers refusing to be tested and those who did have PSGs.

Of the 127 drivers who had OSA, 31.5% had mild disease (with an Apnea-Hypopnea index [AHI] of 5 to 14.9), 26.8% had moderate disease (with an AHI of 15 to 29.9), and 41.7% had severe disease (with an AHI of ≥30).

The Epworth Sleepiness Scale, which is a validated instrument in populations seeking treatment for symptoms, is not predictive in this population of drivers, as it decreased progressively in the more severe grades of OSA.

Statistical analyses found that there was a statistically significant trend for higher BMI ($P = 0.010$), larger neck circumference ($P = 0.001$), lower Epworth Sleepiness Scale ($P = 0.012$), lower minimum O_2 saturation ($P < 0.001$), and proportion of subjects with a minimum O_2 saturation ≤84% ($P = 0.006$) with increasing severity of OSA.

Discussion

This prospective case series was intended to evaluate the effectiveness of the recently published consensus criteria for screening commercial drivers for OSA. Some of those who screen positive (require a PSG) at a preemployment examination have chosen to resign and seek employment elsewhere. Of the first 134 PSG results obtained because of the consensus criteria, 94.8% of the drivers had OSA. This is also the best estimate of the positive predictive value of these consensus criteria in this population. None of these drivers would have been tested or discovered if screening for OSA had been based solely on the "yes" or "no" question on the federal CDME examination form. This suggests that reluctance to admit problems or denial seriously limit the usefulness of this question on the CDME form.

Thus, the consensus criteria clearly permit detection of a group of drivers with a high probability of having OSA. It appears either a regulation or guidance for medical examiners at least as stringent as these consensus criteria is needed. Lowering the criteria to require obtaining PSGs in a larger group of drivers is an option. The study by Hartenbaum et al[4] found 28% of commercial drivers had some degree of OSA. In this study's population, the consensus criteria resulted in 13% of the drivers being required to obtain PSG testing. Hopefully, these consensus criteria select those drivers most in need of testing and diagnosis. This has yet to be proven, and studies from additional centers may help answer this question.

The weaknesses of this study include the inability to assess the 56 drivers who declined PSG evaluation. This is also a case series from a single Occupational Medicine clinic, although with a sizable number of CDMEs performed. These results need to be replicated by other sites, to insure reproducibility and generalizability to other populations. Since the PSGs were done in many different sleep laboratories, there may be some modest differences in the accuracy with which apneas and hypopneas were recognized.

The Epworth Sleepiness Scale is a widely used instrument that has been validated in symptomatic populations seeking help or treatment. In this population of drivers, who in general wish to minimize their ad-

TABLE 2
Results of 134 Polysomnograms

Item	Drivers Refusing Polysomnography	No OSA	Mild OSA	Moderate OSA	Severe OSA	*P* for Two Sided Test for Trend
Number	56	7	40	34	53	
Mean Age (yr) (±SD)	42.8 (11.8)	39.3 (10.7)	43.5 (11.8)	38.8 (10.7)	42.8 (10.3)	0.616
Mean body mass index (kg/m^2) (±SD)	39.2 (6.1)	35.9 (2.6)	39.7 (5.1)	40.1 (6.8)	41.6 (5.9)	0.010
Mean neck circumference (in) (±SD)	*	17.0 (1.1)	17.7 (0.8)	17.9 (1.0)	18.1 (0.9)	0.001
% With hypertension	*	28.6	47.5	38.2	58.5	0.207
Mean Epworth Sleepiness Score (range)	3.40 (2.57)	5.57 (2–11)	3.78 (0–10)	3.32 (0–8)	2.68 (0–9)	0.012
Mean Apnea Hypopnea Index (range)	*	2.0 (0.4–4.5)	9.3 (5.0–14.9)	22.4 (15.0–29.4)	59.6 (30.7–119.2)	†
Mean Minimum O_2 Saturation (%) (range)	*	90.0 (85–94)	85.6 (75–94)	83.9 (57–92)	78.8 (40–90)	<0.001
% of subjects with O_2 saturation ≤84%	*	28.6	32.5	44.1	66.0	0.006

*Data not collected on drivers not receiving polysomnography.
†No test for statistical significance as OSA category is determined by Apnea Hypopnea Index.

missions of health problems, the Epworth appears to be a less reliable screening instrument. The inverse association of the Epworth with the severity of the OSA is counterintuitive and suggests potential denial or deception. In this group of drivers, 1 of the 134 who had PSGs had an Epworth of >10, which is one of the consensus document criteria for requiring OSA testing. This driver had an Epworth of 11, and on testing did not have OSA. Decisions on whom to test for OSA in this population appear to require objective criteria, and not subjective admission of symptoms (questionnaires).

One factor limiting the number of PSGs obtained was the cost of the testing. Most of the drivers receiving preplacement examinations did not have health insurance, and the cost of testing was clearly the reason many chose not to be tested, and to seek alternative employment. It is unfortunate that the consensus criteria recommend certification of at risk drivers for no more than 3 months, while most employers offer their newly hired drivers medical insurance that becomes effective after 3 months of employment. Thus, lack of medical insurance coverage for PSG testing is clearly a barrier to identification and treatment of drivers at risk.

In the medical literature it is not clear what level of severity of OSA predicts a significant increase in driving risk such that employers, or regulations should insist on treatment. The consensus criteria state that drivers with severe OSA (AHI ≥30/hr) must be successfully treated to be certifiable, and successfully treated to an AHI of <5/hr, but without exception <10/hr. When these criteria for treatment were discussed with the employers and carriers involved in this population of commercial drivers, the carriers all chose to require their employee-drivers with moderate OSA, and those with mild OSA with an AHI >10 to accept treatment (usually CPAP). If treatment to an AHI of <10 is the minimally acceptable standard for drivers with severe OSA (by the consensus criteria), and if Teran-Santos et al[9] found an increased risk of motor vehicle crashes at an AHI of >10, these employers may believe the appropriate ethical and legal risk standard is to require all drivers with OSA to achieve an AHI <10 with treatment. Hopefully this case series report can begin a discussion about the appropriate level of OSA disease severity to require treatment, both to protect the public and to protect the health of the driver.

Anecdotally, we are aware of 10 large truck crashes resulting from driver loss of vehicle control for which the carrier is being sued for at least 1 million dollars. Of these 10, our review of the CDME medical examinations before the crash suggests that at least four out of the 10 would have been required to be tested for OSA by the consensus criteria, had they been in use at the examination facility. We are also aware of an additional driver with newly diagnosed sleep apnea who was suboptimally compliant with CPAP therapy who fell asleep while driving and whose truck became stuck in the interstate highway median, avoiding a serious accident.

In reviewing PSGs from a large number of sleep laboratories, a consistent finding is that the interpreting physician will recommend a trial of CPAP treatment if the minimum oxygen saturation during the PSG drops below 85% (equivalent to an arterial pO_2 of 50 mm Hg) regardless of the severity of OSA as determined by the AHI. This level of hypoxia is probably deleterious to the driver's long-term health. In our population, 64% of the drivers with severe OSA had this level of nocturnal hypoxia. The consensus criteria for treatment would require all the drivers with severe OSA (as defined by the AHI) to accept treatment, but make no comment on how medical examiners are to evaluate the PSG data on oxygen saturation.

In this study's population, 41% of the drivers with moderate OSA, and 29% of the drivers with mild OSA (as defined only by the AHI) had this level of hypoxia. These drivers would not require treatment by the consensus conference criteria, and yet if untreated they may have a serious health problem. They have fewer apnea spells per hour, but their apneas last longer, leading to significant nocturnal hypoxia. One of this study's drivers with "only" moderate sleep apnea had a minimum oxygen saturation of 57% (equivalent to an arterial pO_2 of 30 mm Hg). This driver by the consensus criteria would not be required to accept treatment.

Some of the drivers with "only" mild or moderate OSA had very short sleep latencies on their PSGs, strongly suggesting they have a serious risk of being in a motor vehicle crash. It would appear that CDME criteria for minimum O_2 saturation and for sleep latency measurements on PSGs are needed for drivers with OSA. Until there is FMCSA guidance, one option is for medical examiners to require all commercial drivers with sleep apnea (AHI >10) to be treated. Another option is to require treatment for those with severe OSA (AHI >30), for those with significant hypoxia (pO_2 ≤84 mm Hg), and for those with a short sleep onset latency (<5, or perhaps 8 minutes).

The results of this study would also appear to have implications for the evaluation of others in safety sensitive positions (eg, aircraft and boat pilots, railroad engineers, forklift operators, crane operators etc).

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Appendix

Name _____ **SSN** ____-___-_____
Date _____/_____/_____ **Age** _____ **Sex M** ____ **F** ____

Questions:

Do you use, or are you supposed to use a breathing machine (CPAP or BiPAP) while you sleep? Yes _____ No _____

Have you ever had a sleep study or polysomnogram (in which you slept overnight in a sleep lab while connected to test equipment) to determine if you have a sleep disorder? Yes _____ No _____

In the last 5 years, has any spouse or bed partner commented that you snore? Yes _____ No _____

In the last 5 years, has any spouse or bed partner commented that you make noises (gasps or snorts) when you are sleeping? Yes _____ No _____

In the last 5 years, has any spouse or bed partner commented that you stop breathing or pause in breathing for 10 or more seconds at a time? Yes _____ No _____

Compared to others you know who are commercial drivers, do you feel that you are **much** more sleepy in the daytime than they are? Yes _____ No _____

Do any of your blood relatives (NOT those who married into your family) have obstructive sleep apnea or use a breathing machine while they sleep at night? Yes _____ No _____

Have you had any motor vehicle accidents as a commercial driver in which you were determined to be "AT FAULT"? Yes _____ No _____

Driver Signature: _____ Date ____/___/_____

Page 2:
Name _____ Date ____/___/_____

Epworth Sleepiness Scale:
How likely are you to doze off or fall asleep in the following situations, in contrast to just feeling tired? This refers to your usual way of life in recent times. Even if you have not done some of these things recently, try to work out how they would have affected you. Use the following scale to choose the *most appropriate number* for each situation:

0 = would *never* doze
1 = s*light* chance of dozing
2 = *moderate* chance of dozing
3 = *high* chance of dozing

Situation	**Chance of dozing**
Sitting and reading	_____
Watching TV	_____
Sitting inactive in a public place (for example a theatre or a meeting)	_____
As a passenger in a car for an hour without a break	_____
Lying down to rest in the afternoon when circumstances permit	_____
Sitting and talking to someone	_____
Sitting quietly after a lunch without alcohol	_____
In a car, while stopped for a few minutes in traffic	_____

Total score: Epworth Sleepiness Scale _____

Measurements by Physician:

Body Mass Index (BMI) _____ kg/m^2
Neck circumference _____ inches
Hypertension: Absent _____ or Present _____ Controlled ____
_____ New _____ Requires only 1 drug
_____ Uncontrolled
_____ Requires ≥ 2 meds for control

Conclusion: **___ No significant OSA Risk** **___ 3 month card** **___ No card**

_____
☐ Physician A ☐ Physician B