American Thoracic Society Documents

An Official American Thoracic Society Clinical Practice Guideline: Sleep Apnea, Sleepiness, and Driving Risk in Noncommercial Drivers

An Update of a 1994 Statement

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***Background*: Sleepiness may account for up to 20% of crashes on monotonous roads, especially highways. Obstructive sleep apnea (OSA) is the most common medical disorder that causes excessive daytime sleepiness, increasing the risk for drowsy driving two to three times. The purpose of these guidelines is to update the 1994 American Thoracic Society Statement that described the relationships among sleepiness, sleep apnea, and driving risk.**

***Methods*: A multidisciplinary panel was convened to develop evidence-based clinical practice guidelines for the management of sleepy driving due to OSA. Pragmatic systematic reviews were performed, and the Grading of Recommendations, Assessment, Development, and Evaluation approach was used to formulate and grade the recommendations. Critical outcomes included crash-related mortality and real crashes, whereas important outcomes included near-miss crashes and driving performance.**

***Results*: A strong recommendation was made for treatment of confirmed OSA with continuous positive airway pressure to reduce driving risk, rather than no treatment, which was supported by moderate-quality evidence. Weak recommendations were made for expeditious diagnostic evaluation and initiation of treatment and against the use of stimulant medications or empiric continuous positive airway pressure to reduce driving risk. The weak recommendations were supported by very low–quality evidence. Additional suggestions included routinely determining the driving risk, inquiring about additional causes of sleepiness, educating patients about the risks of excessive sleepiness, and encouraging clinicians to become familiar with relevant laws.**

***Discussion*: The recommendations presented in this guideline are based on the current evidence, and will require an update as new evidence and/or technologies becomes available.**

EXECUTIVE SUMMARY

Obstructive sleep apnea (OSA) is the most common medical disorder that causes excessive daytime sleepiness; it is a risk factor for both drowsy driving and car crashes due to falling asleep. The purpose of these Guidelines is to update the 1994 American Thoracic Society Statement that described the relationships among sleepiness, driving risk, and sleep-disordered breathing, the most common of which is OSA. The intended audience is the practitioner who encounters patients with sleep disorders.

Conclusions

- OSA versus non-OSA is associated with a two- to three-times increased overall risk for motor vehicle crashes, but prediction of risk in an individual is imprecise.
- A high-risk driver is defined as one who has moderate to severe daytime sleepiness and a recent unintended motor vehicle crash or a near-miss attributable to sleepiness, fatigue, or inattention.
- There is no compelling evidence to restrict driving privileges in patients with sleep apnea if there has not been a motor vehicle crash or an equivalent event.
- Treatment of OSA improves performance on driving simulators and might reduce the risk of drowsy driving and drowsy driving crashes.
- Timely diagnostic evaluation and treatment and education of the patient and family are likely to decrease the prevalence of sleepiness-related crashes in patients with OSA who are high-risk drivers.

Recommendations

- All patients being initially evaluated for suspected or confirmed OSA should be asked about daytime sleepiness, especially falling asleep unintentionally and inappropriately during daily activities, as well as recent unintended motor vehicle crashes or near-misses attributable to sleepiness, fatigue, or inattention. Patients with these characteristics are deemed high-risk drivers and should be immediately warned

The prior official statement of the American Thoracic Society was adopted by the ATS Board of Directors, June 1994. Sleep apnea, sleepiness, and driving risk. *Am J Respir Crit Care Med* 1994;150:1463–1473. http://www.atsjournals.org/doi/pdf/10.1164/ajrccm.150.5.7952578

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about the potential risk of driving until effective therapy is instituted.

- Additional information that should be elicited during an initial visit for suspected or confirmed OSA includes the clinical severity of the OSA and therapies that the patient has received, including behavioral interventions. Adherence and response to therapy should be assessed at subsequent visits. The drowsy driving risk should be reassessed at subsequent visits if it was initially increased.
- For patients in whom there is a **high clinical suspicion of OSA** and who have been deemed high-risk drivers:
  - We suggest that polysomnography be performed and, if indicated, treatment initiated as soon as possible, rather than delayed until convenient (*weak recommendation, very low–quality evidence*). We recognize that the duration that constitutes "as soon as possible" will vary according to the resources available, but we favor the goal of less than 1 month. For appropriately selected patients (e.g., no comorbidities, high clinical suspicion for OSA), at-home portable monitoring is a reasonable alternative to polysomnography.
  - We suggest NOT using empiric continuous positive airway pressure (CPAP) for the sole purpose of reducing driving risk (*weak recommendation, very low–quality evidence*).
- For patients with **confirmed OSA** who have been deemed high-risk drivers, we recommend CPAP therapy to reduce driving risk, rather than no treatment (*strong recommendation, moderate-quality evidence*). This suggestion is for CPAP because only its effects on driving performance have been well studied; other treatments that could accomplish the same goal have not been evaluated.
- For patients with **suspected or confirmed OSA** who have been deemed high-risk drivers, we suggest NOT using stimulant medications for the sole purpose of reducing driving risk (*weak recommendation, very low–quality evidence*).
- Opportunities to improve clinical practice include the following:
  - Clinicians should develop a practice-based plan to inform patients and their families about drowsy driving and other risks of excessive sleepiness as well as behavioral methods that may reduce those risks.
  - Clinicians should routinely inquire in patients suspected with OSA about non-OSA causes of excessive daytime sleepiness (e.g., sleep restriction, alcohol, and sedating medications), comorbid neurocognitive impairments (e.g., depression or neurological disorders), and diminished physical skills. Such factors may additively contribute to crash risk and affect the efficacy of sleep apnea treatment.
  - Clinicians should familiarize themselves with local and state statutes or regulations regarding the compulsory reporting of high-risk drivers with OSA.

INTRODUCTION

Automobile crashes are the fifth leading cause of death and injury in the United States (1). The number of crashes and severity of injury by distance driven are highest in young drivers (15–25 yr) and in those over the age of 65 years (2, 3). Fatality reduction currently targets increasing seat belt use and reducing speeding and alcohol (4, 5). However, inattentiveness, fatigue, and sleepiness are increasingly recognized as contributing, and possibly primary, factors (4, 6).

Sleepiness accounts for 15 to 20% of crashes on monotonous roads, especially highways. Crashes due to sleepiness typically involve running off the road or into the back of another vehicle (6). Sleepiness is most commonly caused by insufficient sleep, which is associated with prolonged wakefulness or chronic sleep restriction due to long hours of work or play (7, 8), shift work (comprising 7.4% of all those employed), or a variety of medical and neurological disorders (9–11). The most common medical disorder causing excessive daytime sleepiness is obstructive sleep apnea (OSA), a condition amenable to treatment (12–14).

In 1994, the American Thoracic Society Assembly on Respiratory Neurobiology and Sleep reviewed the theoretical framework and evidence relating to sleep apnea as a potential risk factor for motor vehicle crashes (15). Since then, the visibility of sleep disorders and driving risk has increased in the legal and medical literature (16). A 2003 survey of the American Thoracic Society (ATS) membership suggested that approximately 30% of outpatient clinical practice is related to sleep. Fellowship programs in pulmonary and critical care medicine incorporate training on sleep disorders (17, 18). A web-based ATS survey conducted from 2008 to 2009 indicated that approximately 90% of practitioners regularly assess patients with sleepiness and approximately 98% for drowsy driving in the past year. Seventy-five percent reported that they used various methods to assess risk in patients, including the Epworth Sleepiness Scale (ESS), discussion with family members, and direct questions on drowsy driving. Seventy-seven percent stated they were aware of state requirements for reporting of patients to the Department of Motor Vehicles, and 53% had performed a medical assessment of a commercial driver. Seventy-three percent reported "yes" to the question, "Are you familiar with the ATS 1994 statement on driving risk?"

In 2007, a reassessment of the 1994 statement was authorized by the ATS Board of Directors with the following charges: (*1*) Provide practitioners with updated recommendations that describe how one would derive inferences about driving risks during a clinical visit, (*2*) Readdress and update the ethical (i.e., actions by the physician as a member of society) and legal (i.e., consequences of actions by a physician) ramifications that flow from these recommendations, and (*3*) Identify action or research that is required in this area. The following is a summary of the recommendations from these deliberations. An online supplement provides a more nuanced summary of group discussions, as well as tables that summarize the evidence supporting the recommendations.

METHODS

Guideline Panel

The Sleep and Respiratory Neurobiology Assembly of the ATS developed the project. Acting on recommendations from the proposers (Drs. Strohl and Schwab) after the collection and resolution of potential conflicts of interest, the panel was formed to represent broad interests, including the clinical management of sleep-disordered breathing (n = 6), driving risk (n = 2), behavioral sciences (n = 1), and legal implications for patients and medical systems (n = 1). In addition, the panel included international experience in medical issues of driving risk (n = 4). No formal arrangements for cosponsorship were arranged with other professional societies; however, committee members used contacts to disseminate questions and collect feedback. A methodologist (Dr. Wilson) assisted in applying guideline methodology, including pragmatic systematic reviews of the literature and the formulation and grading of recommendations

using the Grading of Recommendations, Assessment, Development, and Evaluation (GRADE) approach.

Scope, Questions, and Outcomes

Committee meetings were convened in 2008 and 2009 to identify the scope and framework of the guidelines. It was decided that the emphasis would be on noncommercial drivers, because this is the largest group of individuals likely to be seen by pulmonary specialists and others practicing sleep medicine (commercial licensing vehicle operators are regulated by specific medical requirements and assessed by certified medical examiners, processes that are now undergoing revision). A second decision was to focus on the evidence regarding physician decision-making, testing, and ideal behavior according to best medical practice.

During these initial deliberations, important clinical questions were posed with the intention of answering the questions with recommendations. Relevant clinical outcomes were also identified and prioritized; they included crash-related mortality and actual crashes as critical outcomes and near-miss crashes and driving performance as important outcomes.

Literature Search and Recommendations

A methods checklist is provided in Table 1. Some of the questions involved interventions for which there are no reasonable alternatives; recommendations answering such questions are considered best-practice recommendations (i.e., "motherhood statements"), which do not require a systematic review of the literature or the GRADE approach. In such cases, a comprehensive but nonsystematic literature review was conducted.

Key words for the literature search included "driving risk," "sleep apnea," "motor vehicle/automobile accidents/crashes," "legal issues," and "physician liability." Subsearches were performed to assess the nonsleep literature. The following sources were searched: Medline (1994–2009 and a second for 2009–2010); medical and law library searches (up to 2009); reviews of the bibliographic and abstract sections for the annual meetings of the American Thoracic Society and the Association of Professional Sleep Societies; and reference lists of selected papers, editorials, and chapters. We limited the review to peer-reviewed articles, reviews, and metaanalyses. Given the moral and ethical dimensions of the topic, editorials and book chapters were also included if the primary data, conclusions, and/or positions were provided in detail. When possible, the group used recent evidence-based reviews. Access was obtained for sponsored surveys of the medical literature on driving risk for the National Transportation and Safety Board Medical Board, some of which are now published (19). As noted in 1994, opinion and some studies are available regarding driving risk for individuals with acute and chronic illnesses other than sleep apnea. A search of the 2007 to 2010 literature on "driving risk" assessments in "aging," "psychiatric illness," "epilepsy," "cardiovascular disease," "diabetes," "Alzheimer's disease," "hypertension," "neurodegenerative disease," "stroke," "neurocognition," and "rehabilitation medicine" was performed and referenced to the degree applicable to driving risks in chronic disease.

Four questions required the selection of one course of action from among several reasonable options or approaches. Each was answered by a recommendation that was supported by a pragmatic systematic review of the literature and both formulated and graded using the GRADE approach.

We formulated a search strategy, and then one committee member (Dr. Wilson) searched Medline and the Cochrane Library (i.e., Cochrane Registry of Controlled Trials and Cochrane Database of Systematic Reviews) using these criteria (*see* Table E1 in the online supplement). Studies were selected according to prespecified selection criteria (Figures E1–E4). Additional studies were identified by reviewing bibliographies of selected studies and the personal files of the committee members.

Once the pertinent evidence was identified and appraised, the quality of evidence was rated as high, moderate, low, or very low using the GRADE approach. The quality of evidence indicates the committee's confidence in the direction and magnitude of the estimated effects of each course of action.

Recommendations were developed from the evidence. The strength of each recommendation was rated as "strong" or "weak" (19). A strong recommendation indicates that the committee is certain that the desirable consequences of the recommended course of action (i.e., the benefits) outweigh the potential undesirable consequences (i.e, risks, burdens, costs, resource use) in the vast majority of patients. In contrast, a weak recommendation indicates that the committee is uncertain about the balance of desirable and undesirable consequences, or that the

TABLE 1. METHODS CHECKLIST

	Yes	No
Panel assembly		
Included experts for relevant clinical and nonclinical disciplines	X	
Included individual who represents the views of patients and society at large	X	
Included a methodologist with appropriate expertise (documented expertise in conducting systematic reviews to identify the evidence base and the development of evidence-based recommendations)	X	
Literature review		
Performed in collaboration with librarian		X
Searched multiple electronic databases	X	
Reviewed reference lists of retrieved articles	X	
Evidence synthesis		
Applied prespecified inclusion and exclusion criteria	X	
Evaluated included studies for sources of bias	X	
Explicitly summarized benefits and harms	X	
Used PRISMA1 to report systematic review		X
Used GRADE to describe quality of evidence	X	
Generation of recommendations		
Used GRADE to rate the strength of recommendations	X	

Definition of abbreviation: GRADE = Grading of Recommendations, Assessment, Development, and Evaluation; PRISMA1 = Preferred Reporting Items for Systematic Reviews and Meta-Analyses, version 1.

TABLE 2. OPPORTUNITIES FOR GREATER INQUIRY AND RESEARCH

The high-risk driver with sleep apnea
How often do multiple risk factors for driving crash occur in patients with sleep apnea?
How feasible are these ATS recommendations across different pathways and platforms in the recognition and treatment of sleep apnea?
What is the magnitude of expected benefit of treating OSA relative to other driving risks?
Professional training and practice
How can competency of pulmonary practitioners in the assessment and prevention of drowsy driving be assessed?
Education on health effects of sleep
How can public perception of, and attitudes about, the assessment for drowsy driving risk be addressed, not only in regard to personal health but also in regard to the right to drive?
What educational tools are effective in reducing drowsy driving in populations of patients as well as for the public at large?
Challenges for licensing agencies
What performance-based testing is appropriate for those treated with problem sleepiness?

Definition of abbreviations: ATS = American Thoracic Society; OSA = obstructive sleep apnea.

desirable consequences and potential undesirable consequences are finely balanced. In this case, the recommended course of action is correct for most patients but may be incorrect for a substantial minority of patients.

Final recommendations were derived by consensus; voting was not necessary. Deliberations and recommendations were compiled into a document reviewed by the committee members in May 2010 and then sent by panel members to outside reviewers from July through August 2010. The document was referred for a final review to the ATS section on Sleep and Respiratory Neurobiology in October 2010. After revisions to conform to the ATS format and GRADE approaches, the guidelines were submitted to the ATS for external review in June 2011. Suggested revisions and commentary from the external reviewers were compiled and sent back to the committee in December 2011 and April 2012.

QUESTIONS, EVIDENCE, AND RECOMMENDATIONS

The statements summarized here are based on the prior document (15) and more recent deliberations and literature surveys. The online supplement discusses some of the topics in greater detail.

Question 1: Should driving risk be part of the initial assessment of patients who have suspected or confirmed OSA?

Evidence. Our literature search did not identify any studies that compared the effects of performing a driving risk assessment with the effects of not performing a driving risk assessment; thus, clinical experience was used to address the question. The Committee considers patients with OSA to be high-risk drivers if there is moderate to severe sleepiness (i.e., falling asleep unintentionally and inappropriately during daily activities) plus a previous motor vehicle crash (in the remainder of this report, the phrase "previous motor vehicle crash" includes near-miss events associated with driver behavior that raises clinical alarm to an equivalent level). In the opinion of the Committee, "recent times" is an appropriate time span, rather than lifetime exposure (12).

Both sleepiness and motor vehicle crashes are identified from the history provided by the patient or an informed observer. Although it is advocated that family members or others provide additional insight about sleep and sleepiness at the time of the initial evaluation, it is not required that the physician wait until such information is available to make an assessment about the degree of sleepiness and its risks. Obtaining an official driving record is not practical, because it is unlikely to arrive in a timely manner, given the need for a signed release of information form and other procedural inertia.

The clinician must directly question the patient to identify high-risk drivers. The alternatives—self-reported sleepiness, family-initiated reports of drowsy driving, and a high (i.e., >17 out of 24) ESS score—are insufficient to identify high-risk drivers. Self-reported sleepiness is subject to interpretation and bias, and the ESS can neither confirm nor exclude sleepiness (20). Such findings are, however, useful prompts for the clinician to initiate direct questioning. Use of a single simplified question has been compared with the ESS and other objective tests and found to have some internal validity (21). The question, "Please measure your sleepiness on a typical day," was rated by patients from 0 (i.e., no sleepiness) to 10 (i.e., the highest amount of sleepiness possible). Scores less than or equal to 2 and greater than or equal to 9 reliably predicted normal and abnormal ESS scores, respectively. This might be a simpler screening tool, with follow-up questions in those with a sleepiness rating greater than or equal to 9.

The combination of moderate to severe daytime sleepiness and a previous motor vehicle crash in a patient with OSA is so compelling that physicians are obligated to intervene. The physician should immediately warn the patient of the potential risk of driving until effective therapy is instituted. Many patients with OSA present with milder sleepiness and only a slightly increased driving risk, just as many people with other chronic medical conditions associated with increased driving risk present with only a slightly increased risk (11). It is appropriate to educate those with lesser degrees of sleepiness about the hazards of sleepiness, but such patients do not warrant expedited management.

Objective tests and measurements are also insufficient to identify high-risk drivers. As an example, consider the body mass index. An elevated body mass index implies that there is an increased driving risk, according to many reports (22); however, this feature is common among individuals without OSA and, therefore, predicts motor vehicle crashes with poor specificity. Test results without clinical assessment are not accurate enough to make a decision about the risk for drowsy driving.

The definition of a high-risk driver is the same for patients whose initial assessment follows a sleep study. The apnea-hypopnea index is not part of the determination of driving risk, because using it puts the patient into double jeopardy; if the patient was not deemed to be an increased risk before the sleep study, then he or she should not be at higher risk after the study if there is no intervening event or clinical change.

Recommendation 1: All patients being initially evaluated for suspected or confirmed OSA should be asked about daytime sleepiness (i.e., falling asleep unintentionally and inappropriately during daily activities) as well as recent unintended motor vehicle crashes or near-misses attributable to sleepiness, fatigue, or inattention. Patients with these characteristics are deemed high-risk drivers and should be immediately warned about the potential risk of driving until effective therapy is instituted.

This recommendation is similar to the 1994 ATS statement (15) and is reaffirmed.

Question 2: In addition to the queries about sleepiness and driving events described above, are there clinical inquiries that should be routine when assessing driving risk in a patient who has suspected or confirmed OSA?

Evidence. Our literature search identified no studies that compared the effects of various clinical inquiries with the effects of not making those inquiries, so clinical experience was used to answer the question. The Committee believes that assessment of the driving risk of a patient with OSA should include consideration of potential coexisting factors that may precipitate, perpetuate, or predispose patients to a higher driving risk (17, 23). Examples include other sleep problems or disorders (e.g., sleep restriction), medical comorbidities, substances (e.g., alcohol) and some medications (e.g., sedatives), all of which probably escalate the driving risk by increasing sleepiness (24). Other conditions that may coexist with OSA and contribute to driving risk without causing sleepiness include neurocognitive impairments (e.g., depression, neurological disorders) and diminished physical skills. Addressing such risks may reduce driving risk, even without treatment of the OSA.

Recommendation 2: For all patients who have suspected or confirmed OSA, clinicians should routinely inquire about additional causes of sleepiness (e.g., sleep restriction, alcohol, or sedating medications), comorbid neurocognitive impairments (e.g., depression or neurologic disorders), and diminished physical skills as part of the assessment of driving risk. Such factors may additively contribute to crashes due to falling asleep and affect the efficacy of sleep apnea treatment.

Question 3: What information unrelated to driving risk assessment should be routinely elicited during the initial evaluation of a patient who has suspected or confirmed OSA? And, what information should be obtained during routine follow-up?

Evidence. Our literature search identified no studies that compared the effects of various clinical inquiries with the effects of not making those inquiries, so clinical experience was again used to answer the question. The precise role of the primary care practitioner in the assessment of OSA is still being established, in part because the degree to which sleepiness and OSA pose hazards to the health and safety of the country was not appreciated when our previous statement was written in 1994 (15). In the opinion of the Committee, it is unreasonable to hold primary care practitioners to a standard for recognition of sleepiness and its consequences. In contrast, specialists who have medical training and skills in the recognition and management of OSA should be held to a higher standard. The clinical management of OSA has been included in American Board of Internal Medicine Pulmonary Board certification testing for the past 25 years, indicating that pulmonary specialists in particular are expected to be aware of the presentations and complications of OSA, including excessive sleepiness (17).

Common elements of the initial evaluation of a patient with OSA include assessment of the severity of the OSA in clinical terms; assessment of sleepiness and drowsy driving (described above); estimation of the time until diagnosis or the initiation of therapy; determination of the types of therapy that the patient has already tried, including behavioral interventions; documentation of the plan or initiation of therapy; and documentation of adherence to positive airway pressure therapy or another therapy.

Reassessment of driving risk after the initiation of any OSA therapy should be performed routinely in those deemed high-risk drivers before the initiation of therapy. Retrospection by the patient or family after treatment may suggest that the driving risk was higher before treatment than previously appreciated. This is an opportunity to reinforce to the patient the importance of adherence to therapy and to reiterate that treatment of sleep apnea may reduce the risk of drowsy driving–related crashes. Documentation of risk reassessment over time is prudent for patients initially deemed high-risk drivers. There are no reliable objective tests that indicate that treatment has reduced the driving risk to an acceptable or community baseline level, and test results without clinical assessment are not accurate enough to make a decision about the risk for drowsy driving.

Recommendation 3: Information that should be routinely elicited during an initial visit for patients with suspected or confirmed OSA includes the clinical severity of the OSA, driving risk, and therapies that the patient has received, including behavioral interventions. At subsequent visits, adherence and response to therapy should be assessed, and the drowsy driving risk should be reassessed if it was initially increased.

Question 4: Should information on drowsy driving be provided at the initial assessment of a patient who has suspected or confirmed OSA?

Evidence. Only drivers are responsible for safe operation of a motor vehicle. However, the public and family members of a patient with sleepiness and sleep apnea can play an important role in mitigating risk, even though most are largely uninformed about sleepiness and driving risk. Counseling about the risks of drowsy driving may identify patients who have already reduced their driving exposure or who will voluntarily stop driving (25, 26). Additional counseling may be appropriate, and alternatives to driving may need to be explored for those who are unconvinced or unwilling to acknowledge their increased crash risk. Although such educational efforts may be most important for high-risk drivers, they are also appropriate for those with lesser degrees of sleepiness, even though such patients do not warrant expedited management. There is concern that institution of punitive measures for noncommercial drivers might result in a misinformed, fearful individual and family who believe that a doctor's interview can compromise their ability to drive an automobile.

Recommendation 4: For patients who have suspected or confirmed OSA, we suggest educating patients and their families about drowsy driving and other risks of excessive sleepiness as well as behavioral methods that reduce those risks.

Question 5: How soon should diagnostic testing occur and, if indicated, should treatment be initiated in patients with suspected OSA who have been determined to be high-risk drivers?

Evidence. We performed a pragmatic systematic review of the literature, which sought studies that evaluated the effects of the duration until diagnostic evaluation and initiation of therapy on crash-related mortality, real crash rate, near crash rate, or driving performance in patients with suspected OSA (Table E1). Our search identified no studies that met our prespecified selection criteria (Figure E1).

Despite the paucity of supporting evidence, the Committee believes that the desirable effects of early diagnosis and treatment outweigh the undesirable consequences in most high-risk drivers with suspected OSA. Desirable consequences include earlier prevention of motor vehicle crashes and, possibly, related mortality. Undesirable consequences include inconvenience to both patients and staff related to rearranging the sleep laboratory schedule to accommodate high-risk drivers. The Committee's impression is based on nonsystematic clinical observations, similar to our previous document (15). Nonsystematic observations provide very low confidence in the estimated effects (i.e., very low quality of evidence). The related recommendation is weak because the very low quality of evidence creates uncertainty about the balance of the desirable and undesirable consequences.

Polysomnography is the most definitive and, therefore, the preferred diagnostic test. However, for appropriately selected patients (e.g., no comorbidities, high clinical suspicion for OSA), at-home portable monitoring is a reasonable alternative to polysomnography.

Recommendation 5: For patients in whom there is a high clinical suspicion of OSA and who have been deemed high-risk drivers, we suggest that polysomnography be performed and, if indicated, treatment initiated as soon as possible, rather than delayed until convenient* (weak recommendation, very low–quality evidence).** ***We recognize that the duration that constitutes "as soon as possible" will vary according to the resources available, but we favor the goal of less than 1 month. For appropriately selected patients (e.g., no comorbidities, high clinical suspicion for OSA), at-home portable monitoring is a reasonable alternative to polysomnography.

Question 6: Is there any value in initiating empiric continuous positive airway pressure (CPAP) in high-risk drivers with suspected OSA while awaiting the diagnostic evaluation?

Evidence. We performed another pragmatic systematic review of the literature to look for studies that evaluated the effects of empiric CPAP on crash-related mortality, real crash rate, near crash rate, or driving performance in patients with suspected OSA (Table E1). Again, our search identified no studies that met our prespecified selection criteria (Figure E2).

Despite the lack of supporting evidence, the Committee believes that the undesirable effects of empiric CPAP outweigh the desirable effects in most high-risk drivers with suspected OSA. Undesirable consequences include the burden, cost, possibility that some patients will be unnecessarily treated, and possibility that the empiric CPAP will affect the accuracy of the diagnostic test leading to errors with long-term impact. Desirable consequences include the possibility of lowering the driving risk sooner. The Committee's impression is based on nonsystematic clinical observations. Nonsystematic clinical observations provide very low confidence in the estimated effects (i.e., very low–quality evidence). The recommendation is weak because the very low quality of evidence causes uncertainty about the balance of desirable and undesirable consequences.

Recommendation 6: For patients in whom there is a high clinical suspicion of OSA and who have been deemed high-risk drivers, we suggest NOT using empiric CPAP for the sole purpose of reducing driving risk **(weak recommendation, very low–quality evidence).**

Question 7: Should patients with confirmed OSA who have been deemed high-risk drivers have their OSA treated for the purpose of reducing the driving risk?

Evidence. We performed a pragmatic systematic review of the literature, which sought studies that evaluated the effect of treatment on crash-related mortality, real crash rate, near crash rate, or driving performance in patients with confirmed OSA (Table E1). Our search identified three systematic reviews that included studies that met our prespecified selection criteria (Figure E3) (22, 27, 28). There was considerable overlap among the studies included, and the findings were similar. All of the systematic reviews evaluated CPAP therapy and not oral appliances or surgery.

We chose the most recent systematic review to inform our judgments (27). This review included 15 before-versus-after studies and observational studies (1,293 patients) (27). Metaanalyses found a marked reduction in the incidence of real crashes (odds ratio, 0.21; 95% confidence interval [CI], 0.12–0.35), near-misses (odds ratio, 0.09; 95% CI, 0.04–0.21), and crash-related events in a driving simulator (standard mean difference [SMD], −1.20 events; 95% CI, −1.75 to −0.064 events) after the initiation of OSA treatment. The committee's confidence in the estimated effects was increased by the magnitude of effect, although this was partially offset by inconsistency of estimates across studies (Table E2).

Our pragmatic systematic review also identified two before-versus-after trials that were published after the systematic reviews. These studies could not be pooled with the previous metaanalyses because different outcomes were measured and the crude data were not reported. However, it is exceedingly unlikely that these studies would have changed the estimates of effect, because the studies are small and their findings are consistent with the meta-analyses. Specifically, one study (n = 11 patients with OSA) found that CPAP was associated with decreased steering deviation (29), and the other study (n = 11 patients being treated for OSA) found more driving-related incidents in a driving simulator after one-night cessation of CPAP (30).

Taken together, these observational studies with a large magnitude of effect provide moderate confidence (i.e., moderate-quality evidence) in the estimated effects of CPAP on driving risk. The related recommendation for CPAP therapy is strong, because the Committee is certain that the desirable consequences of CPAP therapy (i.e., fewer real and near-miss crashes) substantially outweigh the undesirable consequences (i.e., cost, burden, minor side effects).

Recommendation 7: For patients with confirmed OSA who have been deemed high-risk drivers, we recommend CPAP therapy to reduce driving risk, rather than no treatment **(strong recommendation, moderate-quality evidence).** ***This suggestion is for CPAP because only its effects on driving performance have been well studied; other treatments that could accomplish the same goal have not been evaluated.***

Question 8: Can stimulant medications be used to reduce the driving risk among patients with suspected or confirmed OSA who have been deemed high-risk drivers?

Evidence. There is interest in using alerting medications to improve or restore vigilance in the presence of sleep apnea (31, 32). We performed a pragmatic systematic review of the literature, which sought studies that evaluated the effect of alerting medications (e.g., modafinil, methylphenidate) on crash-related mortality, real crash rate, near crash rate, or driving performance in patients with suspected or confirmed OSA (Table E1). Our search identified no relevant studies (Figure E4)

In light of this, we broadened our search and sought indirect evidence. This revised search identified a trial in which 16 healthy individuals were sleep deprived by remaining awake overnight and then randomly assigned in a crossover manner to received modafinil or placebo, with driving performance then assessed in a driving simulator. The study found that modafinil was associated with less lane deviation, but there was no effect on speed deviation, off-road incidents, or reaction time. However, modafinil was associated with improved subjective appraisals of driving performance, suggesting that modafinil therapy may lead to overconfidence in one's driving abilities during sleep deprivation (33).

The committee's confidence in these results is very low, despite its randomized design, because the study's small size creates imprecise estimates of effect, and there is indirectness of both the population and outcome. The related recommendation against alerting medication is weak, because the very low quality of evidence creates uncertainty about the balance of undesirable effects (i.e., cost, burden, side effects, and false reassurance) and desirable effects (i.e., better driving performance).

Recommendation 8: For patients with suspected or confirmed OSA who have been deemed high-risk drivers, we suggest NOT using a stimulant medication for the sole purpose of reducing driving risk **(weak recommendation, very low–quality evidence).**

Question 9: Is there a legal standard for assessment of sleepiness and sleep apnea for pulmonary specialists and for other health professionals with expertise in sleep apnea?

Evidence. Under general principles of malpractice liability, physicians are obligated to adhere to the prevailing standard of care (16, 34, 35). The pulmonary physician has the knowledge and skills to perform a history and physical examination, being aware that many conditions, including sleep apnea, confer high functional risk for drowsy driving and need identification as "red flags." Steps to mitigate risk can be instituted immediately while awaiting diagnosis and treatment. Once sleep apnea is detected, there needs to be a plan to explain the goal of therapy and to assess the patient's response, with a goal of reducing risk (22).

In general, any physician owes a duty to the patient to take steps to reduce the foreseeable risk that the patient will harm him or herself, including the task of operating a motor vehicle (16). This obligation would ordinarily include describing the risks of a medical impairment and warning the patient to take appropriate precautions. If a patient's disorder also poses a danger to other people, the physician has a duty to these potential victims to take appropriate precautions to reduce the risks of harm to them. This duty has long been established in connection with infectious diseases and has been extended in recent years to cases involving psychiatric patients who present a foreseeable risk of violence to others (16). Liability to third parties has been established in connection with potential

impairments in driving performance, such as those associated with the side effects of medication (36). It should be noted that there are countries, such as Belgium, where reporting is simply unlawful, so that physicians who do report patients face possible prosecution (37). Thus, a physician who assesses patients with sleepiness should conform to the prevailing standard of care and legal requirements in managing a patient with severe sleepiness. To do otherwise makes the physician liable to any person injured as a result of the patient's impaired driving. To what degree the doctor is obligated to monitor the patient's compliance with the prescribed warnings is less clear, especially in light of the legally acknowledged responsibility of the patient to adhere to the doctor's instructions (38).

There is the expectation of meeting prevailing legal requirements, which could vary by state or country. In states with permissive reporting mechanisms, the Committee believes that, at a minimum, the physician should notify the Department of Motor Vehicles if a highest-risk patient (e.g., severe daytime sleepiness and a previous motor vehicle crash or near miss) insists on driving before the condition has been successfully treated or fails to comply with treatment requirements.

Recommendation 9: Clinicians should familiarize themselves with the presentations and complications of excessive sleepiness as well as local and state statutes or regulations regarding the compulsory reporting of high-risk drivers with OSA.

FINAL COMMENTS

Physicians, patients, and regulatory/legal systems ideally would have a mutual understanding of the importance of recognition of sleepiness as a risk factor for safe driving and encourage interventions to reduce risk involved in drowsy driving. Society is responsible for deciding thresholds for tolerance and implementation of policy and regulations. Physicians are responsible for clinical management but are also citizens and opinion leaders. Patients are drivers, workers, family members, and voters. However, the elements in assessments and prevention form a social triangle. At any one time, the players can change roles as victim, savior, or persecutor. Communication as to the manner and purpose of assessments is essential, as is the physician's character as an advocate for the patient's rehabilitation and health in regard to the management of sleep apnea. Many interesting questions that might be useful for discussion or research at a medical undergraduate or graduate level were identified during the course of the discussions (Table 2).

These guidelines were prepared by an *ad hoc* Committee of the Assembly for Sleep and Respiratory Neurobiology.

Members of the Committee are as follows:

Kingman P. Strohl, M.D. (*Chair*)
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References

1. Miniño AM, Arias E, Kochanek KD, Sherry L, Murphy SL, Smith BL. Deaths: final data for 2000. National Vital Statistics Reports; Vol. 50, No. 15. Hyattsville, MD: National Center for Health Statistics; 2002.
2. McConnell CF, Bretz KM, Dwyer WO. Falling asleep at the wheel: a close look at 1,269 fatal and serious injury-producing crashes. *Behav Sleep Med* 2003;1:171–183.
3. National Transportation Statistics 2009. Washington, DC: Research and Innovative Technology Administration, Bureau of Transportation Statistics; 2009. Available from: http://www.rita.dot.gov/bts/sites/rita.dot.gov.bts/files/publications/national_transportation_statistics/2009/pdf/entire.pdf
4. Fatality analysis reporting system encyclopedia. Washington, DC: National Highway Traffic Safety Administration [accessed 2008]. Available from: http://www-fars.nhtsa.dot.gov/Main/index.aspx
5. Siskind V, Steinhardt D, Sheehan M, O'Connor T, Hanks H. Risk factors for fatal crashes in rural Australia. *Accid Anal Prev* 2011;43:1082–1088.
6. Driver sleepiness no. 21. London: Department for Transport, UK; 2008.
7. Dinges DF, Kribbs NB. Performing while sleepy: effects of experimentally induced sleepiness In: Monk T, editor. Sleep, sleepiness and performance. Winchester, UK: John Wiley; 1991. pp. 97–128.
8. Kribbs NB, Getsy JE, Dinges DF. Investigation and management of daytime sleepiness in sleep apnea. In: Saunders N, Sullivan, CE, editors. Sleeping and breathing. Vol 2. New York: Marcel Dekker; 1993. pp. 575–604.
9. Horne JA, Reyner LA. Sleep related vehicle accidents. *BMJ* 1995;310:565–567.
10. Horne J, Reyner L. Vehicle accidents related to sleep: a review. *Occup Environ Med* 1999;56:289–294.
11. Marshall SC. The role of reduced fitness to drive due to medical impairments in explaining crashes involving older drivers. *Traffic Inj Prev* 2008;9:291–298.
12. George CF. Sleep apnea, alertness, and motor vehicle crashes. *Am J Respir Crit Care Med* 2007;176:954–956.
13. Landrigan CP. Driving drowsy. *J Clin Sleep Med* 2008;4:536–537.
14. Lyznicki JM, Doege TC, Davis RM, Williams MA. Sleepiness, driving, and motor vehicle crashes. Council on Scientific Affairs, American Medical Association. *JAMA* 1998;279:1908–1913.
15. American Thoracic Society. Sleep apnea, sleepiness, and driving risk. *Am J Respir Crit Care Med* 1994;150:1463–1473.
16. Brown DB. Legal implications of obstructive sleep apnea. In: Kushida CA, editor. Obstructive sleep apnea: diagnosis and treatment. New York, NY: Informa Healthcare USA; 2007.
17. Strohl KP, Ingbar DH, Berry R, Copolla M, Harding S, Matthay R, Papp K, Sateia M, Skatrud J, White DP, *et al.*; American Thoracic Society (ATS). Curriculum and competency assessment tools for sleep disorders in pulmonary fellowship training programs. *Am J Respir Crit Care Med* 2005;172:391–397.
18. Buckley JD, Addrizzo-Harris DJ, Clay AS, Curtis JR, Kotloff RM, Lorin SM, Murin S, Sessler CN, Rogers PL, Rosen MJ, *et al.* Multisociety task

force recommendations of competencies in Pulmonary and Critical Care Medicine. *Am J Respir Crit Care Med* 2009;180:290–295.
19. Schünemann HJ, Jaeschke R, Cook DJ, Bria WF, El-Solh AA, Ernst A, Fahy BF, Gould MK, Horan KL, Krishnan JA, *et al.*; ATS Documents Development and Implementation Committee. An official ATS statement: grading the quality of evidence and strength of recommendations in ATS guidelines and recommendations. *Am J Respir Crit Care Med* 2006;174: 605–614.
20. Olson LG, Cole MF, Ambrogetti A. Correlations among Epworth Sleepiness Scale scores, multiple sleep latency tests and psychological symptoms. *J Sleep Res* 1998;7:248–253.
21. Zallek SN, Redenius R, Fisk H, Murphy C, O'Neill E. A single question as a sleepiness screening tool. *J Clin Sleep Med* 2008;4:143–148.
22. Ellen RL, Marshall SC, Palayew M, Molnar FJ, Wilson KG, Man-Son-Hing M. Systematic review of motor vehicle crash risk in persons with sleep apnea. *J Clin Sleep Med* 2006;2:193–200.
23. Rizzo M. Impaired driving from medical conditions: a 70-year-old man trying to decide if he should continue driving. *JAMA* 2011;305:1018–1026.
24. National Commission on Sleep Disorders Research; United States Department of Health and Human Services. Wake up America: a national sleep alert: report of the National Commission on Sleep Disorders Research. Washington, DC: The Commission; 1993–1995.
25. Marshall SC, Man-Son-Hing M. Multiple chronic medical conditions and associated driving risk: a systematic review. *Traffic Inj Prev* 2011;12:142–148.
26. Naumann RB, Dellinger AM, Kresnow MJ. Driving self-restriction in high-risk conditions: how do older drivers compare to others? *J Safety Res* 2011;42:67–71.
27. Antonopoulos CN, Sergentanis TN, Daskalopoulou SS, Petridou ET. Nasal continuous positive airway pressure (nCPAP) treatment for obstructive sleep apnea, road traffic accidents and driving simulator performance: a meta-analysis. *Sleep Med Rev* 2011;15:301–310.
28. Tregear S, Reston J, Schoelles K, Phillips B. Continuous positive airway pressure reduces risk of motor vehicle crash among drivers with obstructive sleep apnea: systematic review and meta-analysis. *Sleep* 2010;33:1373–1380.
29. Vakulin A, Baulk SD, Catcheside PG, Antic NA, van den Heuvel CJ, Dorrian J, McEvoy RD. Driving simulator performance remains impaired in patients with severe OSA after CPAP treatment. *J Clin Sleep Med* 2011;7:246–253.
30. Filtness AJ, Reyner LA, Horne JA. One night's CPAP withdrawal in otherwise compliant OSA patients: marked driving impairment but good awareness of increased sleepiness. *Sleep Breath* 2012;16:865–871.
31. Williams SC, Marshall NS, Kennerson M, Rogers NL, Liu PY, Grunstein RR. Modafinil effects during acute continuous positive airway pressure withdrawal: a randomized crossover double-blind placebo-controlled trial. *Am J Respir Crit Care Med* 2010;181:825–831.
32. Williams SC, Rogers NL, Marshall NS, Leung S, Starmer GA, Grunstein RR. The effect of modafinil following acute CPAP withdrawal: a preliminary study. *Sleep Breath* 2008;12:359–364.
33. Gurtman CG, Broadbear JH, Redman JR. Effects of modafinil on simulator driving and self-assessment of driving following sleep deprivation. *Hum Psychopharmacol* 2008;23:681–692.
34. Desai AV, Ellis E, Wheatley JR, Grunstein RR. Fatal distraction: a case series of fatal fall-asleep road accidents and their medicolegal outcomes. *Med J Aust* 2003;178:396–399.
35. Beran RG, Devereux JA. Road not taken: lessons to be learned from Queen v. Gillett. *Intern Med J* 2007;37:336–339.
36. Kryworuk PW, Nickle SE. Mandatory physician reporting of drivers with medical conditions: legal considerations. *Can J Cardiol* 2004;20:1324–1328.
37. Rodenstein D. Sleep apnea: traffic and occupational accidents—individual risks, socioeconomic and legal implications. *Respiration* 2009;78:241–248.
38. Pandi-Perumal SR, Verster JC, Kayumov L, Lowe AD, Santana MG, Pires ML, Tufik S, Mello MT. Sleep disorders, sleepiness and traffic safety: a public health menace. *Braz J Med Biol Res* 2006;39:863–871.