

Sleep Apnea, Sleepiness, and Driving Risk

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Among patients with sleep apnea, risk for impaired driving is highest among those with both severe excessive daytime sleepiness and historic evidence of an unintended motor vehicle crash or, by history, an equivalent level of concern. The level of apneic activity by itself is not a factor that increases risk. The high-risk individual can be recognized by pulmonary physicians who, in turn, are in a position to inform and notify the patient of increased driving risk and to explore immediate measures to reduce risk. Effective therapy needs to be instituted promptly, and the effectiveness of therapy and compliance with therapy should be monitored on a routine basis. Historic information on sleepiness and driving impairment are at present the best information for medical follow-up. Among this group of high-risk patients, what is best for the patient's effective treatment is also best for society. In the opinion of the Committee, there is as yet no compelling evidence to restrict the driving privileges in apnea patients where there has not been a motor vehicle crash or an equivalent level of concern for increased driving risk. However, it is very appropriate for the physician to warn of potential dangers of driving while sleepy and inform the patient of this potential personal and social risk.

Whether and under what circumstances patients with sleep apnea should be reported to the licensing authority will depend

on the laws of the state in which the physician practices. In those jurisdictions in which conditions such as excessive daytime sleepiness caused by sleep apnea may be construed as reportable events, we recommend reporting to licensing bureaus if: (a) the patient has excessive daytime sleepiness and sleep apnea and a history of a motor vehicle accident or equivalent level of clinical concern; and (b) one of the following circumstances exists: (i) the patient's condition is untreatable or is not amenable to expeditious treatment (within two months of diagnosis); or (ii) the patient is not willing to accept treatment or is unwilling to restrict driving until effective treatment has been instituted.

Because of the imprecision of current markers of cognitive or biologic performance to prospectively identify patients at foreseeable driving risk, there can be no recommendations at this time for objective testing in patients diagnosed with or treated for sleep apnea or even for those patients presenting with either moderate or mild sleepiness.

Licensing agencies are challenged to develop guidelines and mechanisms to assist in the recognition and treatment of excessive sleepiness, of which untreated sleep apnea is but one cause. The public should be advised of the dangers of driving while sleepy or extremely fatigued and educational materials developed appropriate for all operators of motor vehicles.

Finally, pulmonary specialists along with other medical experts familiar with sleep apnea should help formulate public policy and support reasonable regulations and behavior that will identify and treat sleepy drivers.

INTRODUCTION

Automobile crashes are the third leading cause of death and injury in the United States with 40 to 50,000 people killed in approximately two million accidents per year (1). The number of crashes and severity of injury by distance driven are highest in young drivers (15 to 25 yr) and in those over the age of 65 yr (2, 3). The two most recognized factors are speeding and alcohol (4); however, inattentiveness, fatigue, and sleepiness are primary or contributing factors (5, 6, 7). Sleepiness, in particular, has been documented to occur as a consequence of human conditions, as well as of a variety of medical disorders (5, 8, 9). Sleepiness is linked to insufficient sleep, often resulting from shift work (10) or poor sleep hygiene (5); however, the most common medical disorder causing excessive daytime sleepiness appears to be sleep apnea (11, 8).

In 1992, the American Thoracic Society and its Assembly on Respiratory Neurobiology and Sleep formed an ad hoc Committee on Behavioral Morbidity and Sleep Apnea to review the potential impact of sleep apnea on driving impairment. This report reviews the evidence relating to sleep apnea as a potential risk factor for motor vehicle crashes and provides recommendations for the roles of physicians, licensing agencies, and drivers in identifying and reducing unintended injury or death. Although developed for the American Thoracic Society and its members, this report was recognized to have a potential audience that includes

the wider medical community, legislators, directors of licensing bureaus, and members of the legal profession.

METHODS

The Committee was formed to represent relatively broad interests in clinical management of sleep apnea, in driving risk, in behavioral sciences, and in medical liability. Liaison was sought from societies with an interest in sleep disorders and sleep research. Each Committee member was instructed to compile reference material germane to the assessment of driving risk in sleep apnea. In addition, a literature review was conducted, based primarily on MEDLINE (1966–1993), medical library catalog searches, and manual reviews of the bibliographic and abstract sections for the annual meetings of the American Thoracic Society, the Association of Professional Sleep Societies, and other professional societies, and of reference lists of selected papers and chapters. Key words included for literature search included driving risk, sleep apnea, motor vehicle/automobile accidents, legal issues, and physician liability. Concerning the medical literature, although abstracts and medical correspondence on the subject relevant to the assigned topic were found, it was decided to limit this review almost exclusively to peer-reviewed articles, reviews, and editorials, in which primary data, conclusions, and/or positions are available in greatest detail.

The general problem of medical assessment of driving risk was also addressed by searches of standard databases. Substantial material and opinion are available in regard to driving risk in individuals with illnesses other than sleep apnea. This literature, on such conditions as aging, psychiatric illness, epilepsy, cardiovascular disease, diabetes, etc., is referenced only to the degree that it is applicable to this report.

The legal literature was examined, including compilation of reported judicial decisions appearing in computerized databases and relevant articles in the *Index of Legal Periodicals*. Pertinent statutes and administrative regulations were also reviewed. Those referenced were considered germane to the present discussion.

Two committee conferences worked on developing the scope, framework, reviews, and recommendations, based upon this body of literature. Comments were solicited from the Assembly on Respiratory Neurobiology and Sleep at the 1992 and 1993 Annual Meetings of the American Thoracic Society and from the Standards of Practice Committee of the American Sleep Disorders Association. Early on, the emphasis was on noncommercial drivers, the largest group of individuals likely to be seen by pulmonary specialists. In the United States, such vehicle operators are licensed by state regulatory agencies. An Addendum to this document describes and comments upon recent federal initiatives by the United States government with respect to airline pilots and interstate motor vehicle drivers and discussion of Canadian regulatory initiatives regarding sleep apnea. In regard to commercial licensing, such vehicle operators are often regulated by separate medical examination requirements and rules. Such federal regulations may need review in light of what we know of sleep apnea; this report may help in that endeavor.

SLEEP APNEA AS A MEDICAL CONDITION

Apnea is defined as the cessation of airflow. In the adult, apnea during sleep is usually the result of closure of the upper airway at the level of the naso- and/or oropharynx. Closure is brief (10 to 20 s), but repetitive events, greater than 10 to 20/h of sleep, especially when accompanied by sleepiness, are of greater clinical concern than a lesser number (less than 5/h) of events unac-

companied by symptoms. Resumption of breathing is usually accompanied by a brief arousal from sleep. Apneas during sleep are commonly found in the general population (12); apneic activity > 15/h of sleep accompanied by some subjective report of sleepiness is estimated to occur in 2 to 4% of the American population (13). The presence of heavy snoring, male sex, obesity, and age over 40 are traits associated with increased odds for increased apneic activity (13).

A subset of the population presents to physicians for clinical evaluation most often on the basis of excessive daytime sleepiness, loud snoring, and disrupted sleep (14). In this group, repetitive apneas and arousals result in disrupted and fragmented sleep; in some cases, moderate to severe nocturnal hypoxemia (oxygen deprivation) occurs. This presentation is called sleep apnea syndrome (15, 16). Physiologic research suggests that fragmentation of sleep, nocturnal hypoxemia, and suppression of stage 3 to 4 of sleep interact and affect the patient's ability to stay alert and awake and to effectively perform complex tasks, such as functioning in a driving simulator (17–19). Patients frequently report morning grogginess and headaches, and daytime fatigue. Other major symptoms of this disorder include observed apneas and restlessness during sleep. Sleep apnea syndrome may occur in all ages and among both sexes; however, a group most often affected is hypertensive, middle-aged, and older males who are obese.

Other factors interact with apneas to increase their incidence during sleep and/or to amplify daytime sleepiness (18–21). Sedative drugs and alcohol increase apneic activity and reduce a patient's ability to arouse from sleep and/or end the apneic event; chronic sleep deprivation, such as that of shift workers or those unable to obtain sufficient sleep time, aggravates the condition; and other medical disorders, particularly those of cardiopulmonary origin with abnormalities in gas exchange, increase the severity of apneas or their consequences during sleep. Hence, clinical assessment of patients with sleepiness will require a full medical history and physical examination (21, 22).

Clinical Evaluation

Often the presence of sleep apnea is suspected on the basis of the risk factors and clinical history described above. The documentation of sleep apneas and the quantification of sleep disruption confirm the diagnosis. The most common diagnostic evaluation for suspected apnea is nocturnal polysomnography, a test that simultaneously monitors a number of physiologic signals including EEG, respiration, EKG, and oxygenation (23). In selected patients when other diagnoses are entertained, or where the history is unclear, daytime electrophysiologic tests are used to document and quantify daytime sleepiness or ability to remain awake (15, 18, 24–26).

Treatment of sleep apnea is available and effective (14). Options include behavioral modification (sleep hygiene, weight loss, alcohol abstinence, etc.) and surgical procedures on the nose and upper airway (15). The most commonly prescribed treatment is nasal continuous positive airway pressure (CPAP), delivered by a device consisting of a small air blower attached via a flexible tube to a snug-fitting nasal mask. Air pressure delivered via this device serves as a "pneumatic" splint and keeps the airway open. Sleep is no longer interrupted by closure of the upper airway. Although symptomatic response, including a reduction in sleepiness, can be immediate, data indicate that approximately 6 wk of successful treatment are usually required for maximum improvement (27). Although compliance with this therapy ranges from 75 to 85%, even those who "routinely" use CPAP may have it on dur-

ing only a portion of the night or for only a fraction of nights (28, 29). The rate of return of behavioral morbidity when CPAP is discontinued has been reported in one study, which suggested that one night off therapy can result in reappearance of pretreatment levels of daytime sleepiness as objectively measured (30). The functional consequences of this intermittent use or discontinuation, particularly in regard to driving risk, are not known. Surgery to the nose and pharynx and behavioral modifications are less well studied (15), and, likewise, are not uniformly successful.

For those patients whose pathologic sleepiness is not corrected by treatment, further evaluations for additional sleep disorders, lifestyle changes, or therapy are indicated.

Degrees of Subjective Sleepiness

Of immediate relevance to driving risk with sleep apnea is the assessment of reduced daytime alertness and sleepiness. Sleepiness is a common experience related to lack of sleep and time of day (18, 5). Excessive daytime sleepiness, the term used to refer to dysfunctional or distressing sleepiness, can present in varying degrees. The severity of sleepiness as a symptom is defined in the *International Classification of Sleep Disorders* (31), and can be summarized as follows:

Mild sleepiness describes infrequent sleep episodes present during times of rest or when little attention is required. Situations in which mild sleepiness can become evident include but are not limited to lying down in a quiet room, watching television or reading, or traveling as a passenger. Mild sleepiness may not be present every day. The symptoms of mild sleepiness produce minor impairment of social or occupational function. This degree of sleepiness is often found in otherwise healthy population and can be related to restricted sleep time, shift work, time zone change, or other activities which impede time for needed sleep, i.e., enough sleep to sufficiently inhibit daytime sleepiness.

Moderate sleepiness describes sleep episodes that occur on a regular basis during activities requiring some degree of attention. Examples of such situations include attending concerts, movies, the theater, or similar group meetings; operating machinery or motor vehicles; and watching children. Often the individual alters his/her behavior or takes other steps (increased caffeine intake, afternoon naps, self-imposed driving restriction, avoidance of theater events, etc.) to limit the impact of such sleepiness on social or occupational function. Both activities of daily living, such as shift work, and medical conditions or their therapy can contribute to produce moderate degrees of sleepiness.

Severe sleepiness describes sleep episodes that are present daily and during activities that require sustained attention. Examples of such situations include eating, direct personal conversation, walking, and physical activities, as well as operating motor vehicles. Severe sleepiness produces a marked impairment of social or occupational function. Often, the subject and his/her family are aware of such "sleep attacks;" yet, not infrequently, the subject does not or cannot recognize impending sleep. Hence, excessive sleepiness significantly and consistently impairs behavior or produce social dysfunction. Such individuals are regarded as having pathologic sleepiness.

The tendency toward sleepiness is affected by age, circadian factors, medications and drugs, and sleep hygiene, including insufficient nocturnal sleep (19, 32). Alcohol and some medications can exacerbate the tendency toward sleepiness, particularly in the elderly or in the presence of insufficient sleep. The *International Classification of Sleep Disorders* (31) lists 33 medical and psychiatric disorders that produce excessive sleepiness. Of those,

sleep apnea syndrome and narcolepsy are the two most common medical causes of moderate and severe sleepiness.

Evaluation of Sleepiness

Sleepiness may need to be quantified because subjective reports of sleepiness are imprecise compared with observer reports or tests of sleepiness (18, 33). Typically, the severity of sleepiness is unappreciated by the patient; reports by patients and their spouses regarding the former falling asleep when reading or watching television have a 72% agreement owing to an underestimation by the patient of the presence of sleepiness (33). Our social attitude towards sleepiness underestimates its impact on behavior and risk (8) and, as such, would lessen individual and family awareness.

Sleepiness may be denied by a patient because of lack of awareness of risk, embarrassment, or concern regarding punitive actions, such as loss of occupation (34). Occasionally, symptoms of fatigue and tiredness may be misconstrued by the medical profession as being due to excessive sleepiness, particularly in patients suffering from psychiatric disorders such as depression. Finally, excessive sleepiness may be falsely reported in an effort to obtain restricted stimulant medications.

Body language indicators such as yawning, reduced activity, ptosis, lapses in attention, and head-dropping may be seen in patients who are sleepy, but these signs are variably present and influenced by motivation and activity (34). Subjective rating scales, such as the Epworth Sleepiness Scale (35), have been developed. These questionnaires have demonstrated internal validity in small numbers of subjects enrolled in clinical research programs (18). Also, their usefulness is limited, due to individual differences in descriptions of subjective sleepiness. For instance, subjects have been observed falling asleep while rating themselves fully alert (34).

The Multiple Sleep Latency Test is an electrophysiologic test for detecting and measuring the functional consequences of sleepiness, namely falling asleep in the daytime or across the time span of customary wakefulness (26). Detailed standard guidelines for the performance of the Multiple Sleep Latency Test are available (24, 26). For correct interpretation, the Multiple Sleep Latency Test must be performed under appropriate conditions and requires accurate technique. A related test, the Maintenance of Wakefulness Test, is currently being examined for its clinical usefulness. This test measures the patient's ability to remain awake (25, 36, 37). Other proposed but unvalidated tests for measuring reduced alertness and/or sleepiness include pupillometry, evoked potential studies, performance tests such as the Wilkinson Vigilance Test, continuous ambulatory electroencephalographic monitoring techniques, actigraphy, and computer performance testing (18).

The Multiple Sleep Latency Test is more attractive than other measures because it is currently the only electrophysiologic test that has been validated to be correlated with different degrees of sleepiness (24, 26). In addition, it measures functional consequences of sleep disruption at 2-h intervals across the waking portion of the day. However, the Multiple Sleep Latency Test does not simulate the environment for operating a motor vehicle and thus has uncertain predictability for driving risk or morbidity from sleepiness. The only study to investigate sleep latency (measured by the Multiple Sleep Latency Test) and automobile crashes in patients with sleep disorders showed no relationship between sleep latency and reported accidents (38). Other measures of wakefulness and/or alertness would be more attractive if and when they are validated and examined by outcome assessment.

In summary, despite the attractions of objective tests and questionnaires, no current studies have directly linked test outcome

with foreseeable driving risk in the general population. Further research in this area is necessary.

Other Cognitive Impairments Associated with Sleep Apnea

There is emerging a literature on cognitive impairment associated with sleep apnea (18). These studies are not yet immediately relevant to clinical practice, but are important in understanding potential driving risk. Studies have addressed areas of general intellectual ability, memory, attention and concentration, complex problem solving, visual and psychomotor performance. Generally, the performance of patients with large numbers of apneas is compared with established norms for a given test derived from the performance of age-matched, healthy subjects with lower indices (AHI < 5). Neuropsychologic measures of overall performance are found to be moderately impaired in approximately half of all subjects with more than 30 events/h of sleep (39). Cognitive abilities inversely correlated with respiratory measures (lowest oxygen saturation and total apnea time) include perceptual organizational ability and bilateral motor speed (40). Studies show that some, but not all, patients can have markedly delayed reaction times, verbal and nonverbal memory, and difficulty maintaining vigilance and concentration (41-43). There is also evidence in the nondemented elderly population that increasing numbers of abnormal respiratory events during sleep are correlated with poor performance in cognitive function after correction for effects of education, age, depression, self-rated sleepiness, or fatigue (44). Abnormalities in neuropsychologic performance in heavy snoring with minimal respiratory disturbances during sleep, 1 to 10 events/h, have been reported in a small number of patients (45-47). However, in all these reports, small numbers of subjects were studied and the effects of comorbidity and socioeconomic status were not controlled. At the present time, a role for identification of the cognitive deficits in clinical practice has not been established.

Driving Performance and Sleep Apnea

Recent reviews of automobile accident rates among patients with sleep apnea syndrome concluded that such patients have higher automobile accident rates than other drivers (7, 17, 43, 48, 49, 50, 51, 52, 53). In attempts to define mechanisms, one recent study showed that the patients with more accidents were those with severe sleep apnea and who performed poorly on a driving simulator (54). In separate experiments, Findley (55) and Haraldsson (56) compared apneic patients, snorers, and normal subjects and found that patients did worse on driving simulator tests compared with normal subjects. However, the number of reports in this area is limited and involves relatively small numbers of patients. Furthermore, the generalizability of these findings may be limited by the fact that patients are selected from clinic populations rather than from the general population. Hence, a potential bias will be toward the more symptomatic or affected individual with concomitant medical illness (57). A recent review suggested that a relationship existed between impaired vigilance and performance on a driving simulator in elderly subjects with sleep apnea compared with a comparable group without apnea (44). Although one could propose a causal linkage to apnea, an alternative explanation is that driving risk is related to poor performance on a driving simulator rather than to sleep apnea *per se*. Furthermore, although reductions in sleep apnea may produce dramatic improvement in the Multiple Sleep Latency Test (17) and in driving simulator performance (55), the relationship of these studies to driving performance is unknown. No study has prospectively addressed the stratification of sleepiness or driving simulator performance by age, comorbidity, and apneic activity, allowing for better definition of the issue for the driving public and for public agencies.

Although sleep apnea may be associated with impaired driving performance, most patients with sleep apnea can drive safely. In one study, more than two-thirds of patients with sleep apnea had no reported crashes during a 5-yr period (50). Research has also shown that some patients with apnea can maintain wakefulness under motivating conditions (36, 37). Finally, patients or their families may take steps to limit driving exposure or risk, a behavior known to occur with the elderly driver (21, 58).

In sum, knowledge regarding the relation between sleep apnea and driving performance is currently inadequate. The condition is undoubtedly a risk factor, but is not invariably linked with impaired driving. A subset of patients with sleep apnea appear to present an elevated risk, so efforts to reduce excessive driving risk should most sensibly be directed at selected patients with excessive daytime sleepiness, rather than categorically applied to anyone with apnea or with a certain number of sleep apneic events. Using sleep apnea or its associated traits (snoring, gender, obesity, and/or age) as reportable conditions would be impractical. In this regard, 9% of women and 24% of men in the middle-aged population have > 5 abnormal breathing events/h of sleep and some degree of sleepiness (13), so statutes or codes based solely on apneic activity would be over-inclusive and probably unpopular.

THE PHYSICIAN'S LEGAL OBLIGATIONS

Overview of Current Legal Process

Under general principles of malpractice liability, physicians are obligated to adhere to the prevailing standard of care (59). In regard to the recognition and treatment of sleep apnea, the report from the congressionally mandated National Commission for Sleep Disorders Research concluded that health care practitioners were generally unaware of the hazards that sleepiness and sleep apnea posed to the health and safety of the country (8). Hence, in the opinion of this Committee, it is unreasonable *at the present time* to hold general or primary care practitioners to a routine standard for recognition of sleep apnea and its consequences. Also, current therapy for severe sleepiness is not in the domain of the generalist or primary care practitioner. On the other hand, specialists who have, or hold themselves to have, medical training and skills in the recognition and management of sleep apnea are held to a higher standard because clinical management of this condition has been in their domain for at least the past 10 years. Pulmonary specialists, in particular, are expected to be aware of the presentations and complications of excessive sleepiness, of which sleep apnea is a common cause.

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 (2, 4, 60). These steps would ordinarily include describing the risks of a medical impairment and warning the patient to take appropriate precautions (7, 61). Similar obligations arise if the physician prescribes medications that could impair driving performance (62, 63). 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 (64) and has been extended to recent years to cases involving psychiatric patients who present a foreseeable risk of violence to others (61, 62, 65, 66). Liability to third parties has also clearly been established in connection with potential impairments in driving performance, such as those associated with the side effects of medication (67). Thus, a physician who fails to adhere to the prevailing standard of care in managing a patient with severe sleep-

ness is 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 (7, 68).

These background duties under tort law are supplemented in all states by a statutory obligation to report the names of certain classes of patients to the state. In some jurisdictions, physicians report patients directly to the agency responsible for licensing drivers; and in others, physicians report to the state or local health officer, who will forward the information. These statutes vary widely (61, 69) as will be discussed below, but two general points should be noted here. First, if a physician is obligated to file a report under the statute or under any implementing Department of Motor Vehicles' regulations, a failure to do so will establish a *per se* basis for tort liability—to the patient or to a third party who is injured—if the patient does have a crash. Second, even if the statutory reporting obligation does not specifically cover sleep apnea, the physician is still potentially liable in a tort suit. That is, a reporting statute does not displace or preempt tort liability.

State statutes regulating noncommercial licensing vary widely in detail and scope; in addition, statutes change over time. A physician should consult the statute and Department of Motor Vehicles' regulations in his or her own state. Overall, current state laws are of two general types: permissive or mandatory. Under a *permissive* reporting statute, reporting is permitted, but not required, in the physician's discretion. Such a statute has the legal purpose and effect of authorizing what otherwise would be a breach of confidentiality and is usually coupled with immunity for the physician who chooses to report. States taking this approach include Rhode Island and Florida.

Under a *mandatory* reporting statute, the physician is obligated to report patients under specific conditions. Mandatory statutes take two general forms. Some may take a *categorical* approach, under which the physician is obligated to report patients who have specified medical conditions such as epilepsy. In these states, the reporting obligation is based on diagnosis alone. Reportable conditions may appear either in the statute or, more likely, in regulations adopted by the Department of Motor Vehicles, often on the basis of suggestions by a medical advisory group. This list should be available upon request. Other states take a *functional* approach, requiring a physician to report patients with certain medical conditions if, and only if, he or she believes that a condition impairs the patient's driving ability. In effect, the decision to report in these states must be predicated on a functional risk assessment rather than on diagnosis alone. The level of risk or impairment which triggers the reporting obligation can be defined with a low threshold, i.e., whenever the physician believes that the patient's ability to drive *could be* impaired, or a higher one, i.e., whenever the physician believes that there is substantial evidence that the patient *will* injure himself or someone else.

Differences between states in regard to statutes reflect locally shared intuitions regarding the competing interests of drivers and the public. In some regions of the country, the "privilege" of driving is regarded as a personal necessity for activities of daily living and/or employment. In these regions, principles of fairness and/or political necessity might lead one state more than another to require a more clear and well-documented impairment of driving ability before denying or revoking a license to drive a personal motor vehicle. State statutes establish more restrictive criteria for commercial or occupational licenses (such as bus drivers) than for personal licenses, based upon the premise that a crash of a commercial vehicle is more destructive to life and property than a crash involving only passenger cars. When the person is seek-

ing a commercial license, a lower threshold of risk may be used because the frequency of driving or presence of passengers would increase the chance of unintentional injury; in this case, the individual's necessity to drive would be given reduced weight in regard to public and private interests (70). Current Federal Aviation Administration and Federal Highway Administration regulations, described in the ADDENDUM, regarding licensing of interstate truckers and pilots, reflect the risk-averse stance of occupational licensing. Fatigue-induced accidents are beginning to be recognized as a factor in occupational safety and preventive medicine (8, 10, 32, 34, 70, 71). Thus, besides evidence-based medical opinion, societal values, political trends, and local regulatory agencies influence the establishment and modification of specific statutes.

Uncertainties Regarding Current Law

Our investigation has indicated that physicians are confused and uncertain about their reporting obligations in relation to patients with sleep apnea. What is the prevailing standard of care for recognition and treatment of sleep apnea? Do reporting statutes impose the same obligations on primary care physicians and specialists? In addition, physicians are increasingly doubtful that driving licensing authorities have realistic policies which address driving skills rather than diagnostic labels.

Besides these general concerns, several specific questions arise. First, is sleep apnea itself a reportable condition? Currently, no state law or regulation appears to include sleep apnea as a listed disorder, but some state laws refer to conditions that may cause "unconsciousness." Does this include conditions, such as sleep apnea, that result in unexpected sleep attacks?

Second, when the reporting obligation is not categorical and requires a functional assessment, what is the physician expected to do in order to make the necessary assessment? On the one hand, physicians are not experts in assessing driving ability and must reach their judgments on the basis of records and information obtained in the course of a normal medical evaluation (21, 63). On the other hand, physicians are often expected to address not only personal health but public health as well (69).

Third, how risk-averse should a physician be in determining whether the patient's driving ability is impaired? Assume, for example, that a doctor is extremely risk-averse, and chooses to report any patient who has sleep apnea, regardless of the severity of the patient's condition, the patient's driving history, or his willingness to comply with treatment. Does this doctor expose him or herself to liability to the patient for breaching confidentiality? On the other hand, if the doctor adopts a very demanding criterion—and reports only patients who have had actual mishaps on the road due to falling asleep—is such a high threshold consistent with the doctor's obligations under the reporting statute or under tort law? What continuing obligation does the doctor have once a report has been made to the state's agency? Does the doctor have a continuing obligation to monitor the patient's condition, or has this obligation passed to the state? None of these issues has been directly addressed by statute or precedent in regard to sleep apnea and sleepiness.

To add to uncertainties, each state (through the mandated state agency or its advisory committee) has a responsibility to continually review its current law in order to clarify the nature and scope of the physician's reporting obligation in relation to specific medical conditions. This process often is precipitated by public debate, of which this report is one example. Hence, any state-by-state listing of legal statutes this Committee compiled today would or could be obsolete by the time of publication of this report. Also, such

a listing does not serve to protect the physician if regulations or statutes change.

An Illustrative Statute: California

For many years, section 410 of the State of California Health and Safety Codes has required physicians to report patients with certain medical conditions characterized by "lapses of consciousness." Thus, this statute imposes a mandatory reporting requirement for a condition that may be associated with sleep apnea. In addition, the statute also includes a "permissive" provision which authorizes a physician to report a patient to the public health officer, if the physician "reasonably and in good faith believes" that doing so "will serve the public interest," even if the patient's condition is not encompassed by the class of disorders subject to mandatory reporting.

The mandatory provision is the one of interest here. Under applicable regulations issued in California, the physician must determine "a) if the patient is 14 years or older, b) within the last three years has the patient experienced lapses of consciousness or episodes of confusion and c) if there is a probability (not a possibility) that symptoms may reoccur in the future." The descriptive language does not specifically identify sleep disorders, but it does refer to "abrupt loss of consciousness or marked acute reduction of alertness or responsiveness to external stimuli" and therefore could be construed to apply to sleep attacks.

Any physician knowledgeable about the patient's diagnosis or condition is obligated to file the prescribed report (or a so-called "Confidential Morbidity Report Card") with the local health department for eventual submission to the appropriate agency. Physicians are to retain a copy of the card. The statute confers immunity on physicians for reports that patients claim to be erroneous. A patient need be reported only once; however, a physician who concludes that a patient should be reported has the responsibility to verify that a report has previously been filed. No language in the statute addresses physician responsibility for monitoring previously reported patients when licenses have been restored.

No guidelines were subsequently developed to help physicians comply with statutes or with driving restrictions imposed by the Department of Motor Vehicles. In 1990, concerns about the over-inclusiveness of the mandatory reporting provisions led the legislature to amend the statute to enable the Department of Health to narrow the conditions under which reporting is mandatory. In effect, the legislature instructed the Department to move from a categorical approach to a more functional approach. Unfortunately, however, this change has only served to increase physicians' uncertainty. The relevant provision of the statute now provides:

The [Health] Department, in cooperation with the Department of Motor Vehicles, shall define disorders characterized by lapses of consciousness based upon existing clinical standards . . . and shall include Alzheimer's disease and those related disorders which are severe enough to be likely to impair a person's ability to operate a motor vehicle in the definition. The [Health] Department, in cooperation with the Department of Motor Vehicles, shall list those circumstances which shall not require reporting because the patient is unable to ever operate a motor vehicle or is otherwise unlikely to represent a danger which requires reporting. The Department shall consult with professional medical organizations whose members have specific expertise in the diagnosis and treatment of those disorders in the development of the definition of what constitutes a disorder characterized by lapses of consciousness as well as definitions of functional severity to guide reporting so that diagnosed cases reported pursuant to this section are only those where there is a reason to believe that the patients' conditions are likely to impair their ability to operate a motor vehicle.

Although the Department was directed to issue these guide-

lines by January 1, 1992, we have been advised that, as of this date, neither guidelines nor mechanisms have been promulgated. In this ambiguous regulatory setting, a consortium of California specialists in sleep disorders convened a meeting of the Southern California Sleep Centers on April 16, 1992, to develop a consensus statement regarding the medical/legal handling of patients with very severe daytime excessive sleepiness. These guidelines are still in the formulation stage.

The Relation Between Reporting and Licensing

One of the Committee's chief aims in this report is to provide guidance regarding the scope of the physician's reporting obligation for patients with sleep apnea. In the course of our deliberations, it became clear that the physician's role in protecting public safety must be seen in relation to the roles of the patient and the licensing authority. Of particular importance is the allocation of responsibility for risk assessment between physicians and the licensing agency. This section sets forth the framework for the recommendations made later in this report.

Under existing driver licensing reporting laws, the medical profession serves a screening role on behalf of society by identifying individuals whose medical conditions could adversely affect their driving. As with all screening responsibilities, the question is what level of risk should trigger an intervention. How should these laws be framed? Should physicians be expected to establish a low threshold for reporting, e.g., any condition that poses any possible risk, or should the law prescribe a higher threshold? One answer to this question depends on what policies the licensing agencies will apply after cases have been identified (by physicians or by applicants themselves).

In choosing its policies, the licensing agency (or the legislature) must address sometimes delicate balances. For example, if the licensing agency were to adopt a *per se* rule denying driver licenses to all persons with a specific condition, then a rule requiring physicians to report all patients with the specified condition would be essential. However, such a categorical exclusion would be grossly over-inclusive for sleep apnea (and for most other conditions) because it would unfairly disadvantage many individuals who have the medical condition but who experience no significant impairment of driving ability (7, 58, 72, 73). Categorical exclusions also would potentially violate Title II of the Americans with Disabilities Act which requires individualized, functional decision making by state and local governments.

Ideally, the licensing agency would make its own functional assessment of driving impairment among patients with, or suspected of having, specified conditions. If such a procedure were available, it would be reassuring and appropriate to expect physicians to report all patients with the specified condition to the licensing authority, which would then be responsible for making the individualized functional assessments of driving ability, including the authority to remove driving licenses and, in extreme cases, to disable the vehicle or otherwise limit opportunity to drive.

However, in the absence of any method of accurately differentiating between persons with sleep apnea who do and do not pose a significant risk, policy choices become much more difficult. On the one side, a risk-averse strategy (in which the existence of a potentially risky condition is the sole criterion) would unfairly disadvantage many persons whose driving performance would not have been impaired. On the other side, insistence on documented "proof" of a past driving impairment due to sleep apnea as a predicate for reporting or disqualification will expose the patient and the public to an unreasonable level of harm.

Under these circumstances, the only satisfactory solution is

to rely on "clinical" risk assessments in each case. In light of current knowledge, these decisions are bound to be imperfect and must ultimately be influenced by subtle value judgments. This is why physicians are reluctant (and, in the opinion of the Committee, appropriately so) to be assigned the responsibility for making them. Yet, the only way for physicians to escape this responsibility altogether would be for them to notify the state, or its appointed authority, about all patients with a potentially dangerous condition so that state could make the necessary individualized risk assessment in all cases. The problem with this strategy is that it would affect many patients who do not pose a risk and be potentially harmful to medical care. It can be expected that risk assessments by the licensing authority would tend to err heavily on the side of public safety and that many patients would be unnecessarily disadvantaged. Moreover, the fear of being reported might lead patients to withhold medical information, thereby compromising recognition and treatment, eroding the physician-patient relationship, and frustrating the regulatory goal as well.

In light of these concerns, the Committee prefers a flexible reporting requirement which would allow some room for clinical discretion—i.e., one that gives a physician the prerogative to decline to report patients with sleep apnea who do *not* seem to pose a significant risk. This seems to have been the purpose to the 1990 amendment to the California reporting statute quoted earlier. It is also our impression that most current reporting laws are construed to take this approach. It must be emphasized, however, that this approach necessarily requires the physician to shoulder some responsibility for making the initial risk assessments.

Under present circumstances—based on current scientific knowledge and in the absence of an objective procedure for risk assessment—the Committee believes that a categorical reporting requirement obligating physicians to report all patients with sleep apnea (or with a specified number of apneic events) would be undesirable. This would be unfair to patients and is not now scientifically justified. At the same time, the Committee rejects the positions that lie at the opposite pole—that patients with sleep apnea should never be reported or that reporting should be entirely permissive. These approaches would not provide adequate protection for the public and are not compatible with the prevailing ethical standards of the medical profession.

Instead, a specialist should be expected—and in some states is now legally obligated—to report a patient whenever the physician believes that the patient's ability to drive safely is significantly impaired. The Committee's view rests on two assumptions. First, the responsibility for risk assessment—at least at the level of screening for significant risk—is inescapable for the physician in cases where the condition of excessive sleepiness and reasonable evidence for a high driving risk coexist. Second, the physician can fairly expect the licensing agency and the legal system to interpret, develop, or modify statutory guidelines based on current scientific knowledge. In the remainder of this report, the Committee will outline factors and perspectives which should be taken into account in developing these guidelines.

AN INTERACTIVE MODEL OF RESPONSIBILITIES

The Committee came to the conclusion that an ideal evaluative system should be designed to recognize cases of excessive sleepiness as a potential source of impaired driving risk and to facilitate a quantitative assessment of the risk posed by a person who is experiencing excessive sleepiness, including persons with sleep apnea. In addition, methods of case-finding for excessive driving risk by sleepiness and of assessing the impact of intervention must be developed. A comprehensive system should also encourage

medical evaluation and licensure screening in appropriate cases. Increased public awareness would contribute to the achievement of those objectives.

The Committee examined a number of potential models for the duties and roles of physicians, patients, and licensing bureaus in reducing driving risk in patients with sleep apnea and severe excessive daytime sleepiness. The ideal model is one of mutual understanding and respect that has as its basis the recognition of sleepiness as a risk factor for safe driving, and the encouragement of medical intervention to reduce that risk. Linear models of cause and effect relationships are not appropriate. The appropriate model is an interactive one involving the driver, the physician, and the licensing authority.

Driver Responsibility

Licensed drivers are expected to act responsibly. In regard to medical illness, they are expected to take note of and report symptoms and signs of disease and to comply with medical therapy in a reasonable fashion. Patients with dementia and their families, once educated to the high risk and cost of driving, often responsibly take measures to reduce that risk (58). It is reasonable to expect that patients with moderate and severe sleepiness and their families will respond similarly. Once informed of the risk by a physician, failure to take measures to reduce driving risk can carry consequences beyond the obvious threat to health and can include insurance risk and civil and criminal liabilities (68, 74, 75). The ability of persons who experience excessive sleepiness to act responsibly can be enhanced by improved public awareness of the nature of the risk. The public is now largely uninformed about sleepiness and of the factors that induce sleepiness, including the interactive effects of alcohol, sedatives, insufficient sleep, and disease on vigilance, awareness, and state of arousal (8). Primary prevention rests with a more informed public.

Physician Responsibility

Pulmonary physicians are expected to diagnose, treat, and assess respiratory illnesses, in general, and in the case of excessive daytime sleepiness and sleep apnea, to recognize the potential impact this disorder has on health and behavior. Once the disorder has been diagnosed, the physician is expected to assess the patient's response by eliciting appropriate historical information, including those activities in which significant sleepiness could constitute a significant risk.

The pulmonary specialist clearly has a responsibility to inform the patient of the nature of sleep apnea, including the potential risks inherent in operating a motor vehicle while sleepy or inattentive. In the opinion of the Committee, a particular element that would obligate the physician to intervene would be the presence of severe daytime sleepiness and a history of a previous motor vehicle accident. (In the remainder of this report, the phrase "previous motor vehicle accident" is meant to include near-miss events that raise the level of clinical alarm to an equivalent level.) In our opinion, that information alone is of such compelling clinical importance that the physician should immediately warn the patient of the potential risk of driving until effective therapy is instituted. Additional counseling to the family members may be appropriate and alternatives to driving may need to be explored for those who are unaware of their sleepiness or unwilling to acknowledge their increased risk.

When the physician informs the patient of the diagnosis and makes cautionary recommendations, the legal status of the patient as a motor vehicle operator is irrevocably changed. In the event that the patient thereafter has a traffic accident, the patient

no longer can avoid civil and criminal liability by claiming that his falling asleep was sudden or unexpected (68). For this reason alone, it is advisable for the physician to document his warning in writing, documenting concerns, or any recommendations specific to the individual patient. Such an approach will reinforce the seriousness of the warning in the patient's mind (17).

Once treatment has begun, the physician should have a plan for follow-up to determine that the treatment is effective in reducing or eliminating severe daytime sleepiness, and evaluations should be continued at regular intervals until such therapy has controlled the condition. The physician should help the patient with sleep apnea to restore his/her driving privileges if removed by any authority whenever there is reasonable indication that the excessive daytime sleepiness has improved, or when effective treatment has been instituted. A restriction based on sleep apnea should never be regarded as permanent.

It is not possible to provide definitive advice concerning the circumstances under which the physician should report a patient to the Department of Motor Vehicles because this depends on the applicable provisions of state law. However, 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 accident, insists on driving before the condition has been successfully treated or fails to comply with treatment requirements. Other indications for reporting might be increased occupational exposure to driving, or increased occupational risk for an accident of significant import to the public, e.g., truck drivers with hazardous waste or school bus drivers.

Whether reports should be filed under other circumstances will depend on the law of the particular state. Many state laws appear to allow room for clinical discretion so that the physician is obligated to report a patient only if the physician believes the patient presents a current risk; but other state laws may obligate the physician to report based on diagnosis or symptoms alone. It must be reemphasized that each physician is obligated to adhere to the requirements of the law in the specific state in which he or she practices, even if those laws do not reflect sound public policy or medical evidence.

State societies for professionals who diagnose and treat sleep apnea should coordinate their efforts to periodically review and disseminate updated information on applicable statutes and regulations. In the opinion of the Committee, professional organizations should also make collective efforts to address the problems posed by impaired drivers with excessive daytime sleepiness and promote the obligation of physicians to preserve confidentiality for patients with sleep apnea unless a demonstrable risk exists in a particular case. If statutes of any state appear to require categorical reporting of patients with sleep apnea or are unclear, physicians and their professional societies should seek to modify these provisions to reflect more closely the desired objectives, i.e., reduction in excess driving risk.

In those instances in which the licensing agency has been notified about a patient's condition (by the patient, physician, or anyone else), it is appropriate for the agency to consult a specialist with respect to the patient's ability to operate a motor vehicle. However, a physician can only comment on the nature of the diagnosis, the facts concerning treatment, and the extent of treatment effectiveness as reported to him by the patient. Given the lack of mandate and training for licensure, the physician is in no position to certify the patient's ability to operate any motorized vehicle.

Responsibility of the Licensing Agencies

The state licensing agency or "Department of Motor Vehicles" has a legal responsibility to identify risk, to reduce risk, and to en-

hance public safety by issuing permits to operate private motor vehicles based on established norms, tests, and information provided by an applicant. The details and extent of such legislation vary from state to state and are directed at socially as well as medically acceptable levels of risk. At the present time, information requested is only indirectly related to sleep apnea. As discussed above, the common category of "lapse of consciousness" is not ordinarily understood to encompass sleep attacks or excessive daytime sleepiness; sleep apnea may be one of several causes for these symptoms.

The adjudicative role of a Department of Motor Vehicles in regard to medical conditions varies from state to state and information is not available as to how the medical boards of those licensing agencies view sleepiness or sleep apnea. Anecdotal evidence suggests that there is a tendency to consider sleep apnea only in categorical terms. It is the opinion of this Committee that such an attitude should be discouraged. Likewise, threshold levels for apneic activity are not consistent with current medical knowledge or epidemiologic data and can cause unnecessary harm to patients and to the physician-patient relationship. Given that a Department of Motor Vehicles has statutory powers to license driving activity, it is inappropriate for them to delegate that responsibility to physicians or other groups.

The licensing body is also legislated to explore and develop new means to ascertain an individual's ability to operate a motor vehicle. This mandate covers the potential threat of excessive sleepiness. In the absence of any predictive data that is applicable to the condition of sleepiness, a prolonged in-car evaluation may be a practical but expensive approach. However, it may be that any testing procedure results in hyperarousal and, therefore, may artificially inflate the number of people passing the test. Alternatively, if a license applicant does lose alertness during a test, then this would probably identify an individual as inattentive or sleepy and, therefore, at higher risk. How often this might occur in patients with sleep apnea is unknown. Reevaluation of driving record could be an option for patients with sleep apnea or other causes of sleepiness, but criteria would need to be nonprejudicial, defined, and reevaluated as more information emerges. At present, a Department of Motor Vehicles can expect only qualitative information with respect to a given medical diagnosis or symptom.

If a licensing authority were to request objective documentation of response to treatment (either repeat sleep study and/or other measures of sleepiness or performance), the additional cost, as well as the appropriateness, for this testing will become an issue (see EVALUATION OF SLEEPINESS above). Because such testing is not clinically justified by existing data, it may not be covered by existing health insurance. This may lead to problems because an agency may require a test that the patient cannot afford. On the other hand, if the applicant then "fails" a driving exam because of loss of alertness and/or falling asleep, in essence there is now an indication for medical reevaluation.

A performance-based, nonmedical evaluation is needed to assess sleepiness and driving risk in general and sleep apnea and driving risk in particular. Funding and conducting research in this area is an appropriate activity for state and federal agencies mandated to address transportation safety. This approach may be appropriately modified by other licensing authorities that grant specialized privileges, e.g., operation of aircraft, ships, heavy equipment, and in some cases, firearms and/or weapons in the civilian, police and military sectors.

RECOMMENDATIONS

Public Education on Health Effects of Sleep

An informed medical and general public is of highest priority for

prevention of motor vehicle crashes, unintended injury, and/or unintended death. Education of primary physicians, patients, licensing agencies, and the public, including employers, on the impact of insufficient sleep and of sleepiness on driving will be necessary to implement any measures designed to reduce risk. The interactions of insufficient sleep, alcohol, working hours, and medications are potentially more important than the identification of sleep apnea in the general effort to reduce crashes from fatigue and sleepiness. The importance of sleep and of recognition of sleepiness should be incorporated into educational and evaluation materials for licensing and operation of noncommercial vehicles. Even more education regarding sleep hygiene and preventive measures regarding sleepiness may be needed for commercial licensure, especially of persons with potentially higher exposure to the public, e.g., bus drivers, truckers, etc. Funding for educational projects to increase driver awareness should be linked with defined outcomes and interventions to reduce risk of accidents, of which crashes are but one example.

The High-Risk Driver With Sleep Apnea

The Committee recognizes the profile of a high-risk driver as being that person with severe daytime sleepiness accompanied by historic evidence of an unintended motor vehicle crash. This kind of information should be routinely obtained as part of a medical assessment of sleep apnea by a pulmonary specialist or other health professional with special expertise in sleep apnea.

It is not known what proportion of patients currently have this condition. Nor is it known what proportion of crashes are attributable to this extreme condition. However, there are advantages to assisting this group of patients, both to improve their medical condition as well as reduce excess risk for unintended injury or death. There is sufficient medical evidence to warrant immediate attention by the specialist to educating and warning such individuals on driving risks associated with sleepiness. There is need for prompt further assessment for diagnosis of excessive sleepiness and treatment of the underlying condition. In the absence of any data, the Committee believes that treatment can generally be instituted and effectiveness judged within 2 mo after initial assessment. This time frame may not be a time frame that society should reasonably expect.

Physicians who take care of patients with sleep apnea must be aware of state statutes or regulations regarding reporting of high-risk drivers. We suggest that in states with applicable requirements, reporting should occur when the high-risk patient's condition is untreatable or not amenable to expeditious treatment within 2 mo when the patient is not willing to accept treatment or is unwilling to restrict driving until effective treatment has been instituted.

There is insufficient evidence to suggest this level of caution for drivers with lesser forms of sleepiness, for any given level of apneic activity *per se*, or for persons without a history of a motor vehicle accident. More study is needed to define the attributable risk in these less extreme cases. Education, research, and an informed public will be crucial elements in defining how to respond to this larger group of individuals.

Medical Assessment of Risk

At the present time, driving risk is considered elevated by the presence of moderate and severe sleepiness, as based upon historic information from the patient or an informed observer, of which the strongest evidence is a history of a previous motor vehicle crash. Response to therapy is also judged similarly. There is no reliable objective test that is predictive of increased driving risk or that would indicate that, after treatment, driving risk has been reduced to an acceptable level.

There is a need to define biologic markers or cognitive tasks with sufficient precision, predictability, and causality to address driving risk before or after treatment of sleep apnea. The licensing agencies are challenged to develop and test performance-based, nonmedical evaluations that could be utilized as a basis for making decisions regarding granting, restoring, or revoking licenses.

Challenges for Licensing Agencies

The licensing agency should institute measures that would track and potentially identify those individuals with motor vehicle accidents that are or potentially were produced by conditions of sleepiness, of which one cause could be sleep apnea. Public agencies that investigate or maintain records of motor vehicle accidents should include questions regarding the role of quality and quantity of preaccident sleep in standard postaccident questionnaires. The intent is to help these individuals and to reduce risk. In addition, the medical boards of licensing bureaus should be aware of the potential impact of sleepiness and sleep apnea on driving risks and of the effective therapy that is available for these conditions. Performance-based nonmedical evaluations to screen and/or detect the sleepy driver should be developed and tested. Public information on the risks of driving while sleepy should be written and widely distributed. Each state agency should accept and exercise its responsibility to define reporting requirements and mechanisms for physicians. Communication can be accomplished in cooperation with medical boards and medical societies.

This Statement was prepared by an ad hoc Committee of the Assembly on Respiratory Neurobiology and Sleep. Members of the Committee were:

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ADDENDUM: COMMENTS ON RECENT FEDERAL REGULATORY DEVELOPMENTS

The relation between sleep apnea and licensing for motor vehicles has recently been of regulatory interest to a number of federal safety agencies in Canada and the United States. In this Section, the Committee describes and comments on three regulatory initiatives involving commercial or occupational drivers.

The Canadian Motor Vehicle Safety Code (76)

The Association of Medical Directors of Licensing Boards in Canada develops safety codes for motor vehicle operators. The section of the current published code specifically relates to Narcolepsy and Other Sleep Disorders and states unequivocally that "... an individual subject to sleep disorders cannot drive any type of motor vehicle safely." As a result, physicians are required, categorically, to report patients with those conditions. However, if the patients "respond favorably to treatment and have no periods of uncontrollable sleepiness for a period of three months and are experiencing no side effects from medication, then they can drive pri-

vate motor vehicles safely," and their licenses can be restored. No such exceptions for persons under successful treatment is provided for passenger transport or heavy commercial vehicles—although it is not clear whether the permanent ban applies only to patients with narcolepsy rather than to patients with sleep apnea.

In 1992, the Association of Medical Directors of Licensing Boards in Canada discussed modifying the recommendations for both sleep apnea and narcolepsy. The group recommended continuation of the requirement for physicians to report patients they believe to be impaired from these disorders; however, the language was not specific as to whether this proposal suggested removing the obligation for categorical reporting and replacing it with functional reporting. The previous regulations requiring treatment for three months were recommended to be dropped, and there would be no time limit or vehicle-type restrictions on patients with treated sleep disorders. Apparently this modification was recommended with the recognition that there was no evidence to mandate either a fixed time period or a specific motor vehicle restriction given the available evidence on driving risk.

This Canadian regulation is the first to have evolved over time. However, the categorical reporting requirement for sleep apnea is unwarranted in the absence of specific criteria or acknowledgment that excessive daytime sleepiness appears to constitute the probable excess risk rather than the mere presence of sleep apneic activity.

U.S. Federal Highway Administration

As yet there is no definitive language for sleep disorders in the United States Federal code for licensing commercial drivers for interstate travel. In 1987, the Federal Highway Commission Task Force was instructed to update and revise the current regulations for medical certification, which were first published in 1971, before sleep disorders were more widely recognized. The guidelines for evaluating pulmonary or general respiratory disorders have not been formally modified since then. In September 1990, the Department of Transportation convened a group of respiratory experts at a Conference on Pulmonary/Respiratory Disorders in Commercial Drivers. The report from this group (9) concluded that disorders of breathing during sleep could have a significant impact on driving, based upon the hypersomnolence and sleepiness during waking hours. The report recommended that operators with suspected sleep apnea—e.g., symptoms of snoring and hypersomnolence—or with proven but untreated sleep apnea should not be medically qualified for commercial vehicle operation "until the diagnosis has been eliminated or accurately treated." The diagnosis was stated to occur "when an individual has greater than 30 episodes of apnea during each hour of sleep or has hypersomnolence during waking hours associated with any apneic activity (greater than 5 per hour)." The document anticipates that successful therapy would be assessed objectively by a Multiple Sleep Latency Test and with the goal to restore values to within the normal range. Furthermore, continuous successful therapy should be in place for 1 mo. Observing that untreated sleep apnea appears to be a major preventable cause of vehicular accidents, the Department of Transportation Task Force also recommended a major effort aimed at evaluating the prevalence of sleep apnea among commercial drivers in North America.

We have already expressed our view that categorical reporting of patients with sleep apnea is not acceptable in the context of personal driving licenses. Whether categorical reporting is more appropriate in the context of occupational licenses can be argued more successfully. At a minimum, the threshold for suspicion of increased driving risk from sleepiness should be lower, given the increased hazard. It may be that symptoms of moderate and severe sleepiness should be routinely elicited from applicants for these licenses.

The Department of Transportation report also seems to be unduly optimistic regarding the ability of physicians to assess objectively the success of treatment with the Multiple Sleep Latency Test. The difficulty of assessing sleepiness and compliance with therapy in regard to driving activity has been previously reviewed in this paper. The degree and interval of assessments for adequate therapy and the locus for responsibility for ongoing risk assessment are not addressed in this report.

U.S. Federal Aviation Administration

According to the Federal Aviation Administration general guidelines, a

commercial pilot is required to report if, at any time, he/she has a new medical diagnosis or condition, experiences a relapse of symptoms, requires a change in therapy, or routinely takes a medication required for management of any medical condition. To monitor health status, each commercial pilot is assigned a physician who takes the responsibility to manage medical conditions, if present, and who works with the pilot to assess risk. Hence, responsibility for evaluation and education of the pilot are mandated as a physician responsibility, allowing significant leeway for functional and permissive reporting of many more conditions than those identified by federal or state law. Medical opinions serve to alert this network of physicians to new conditions or problems.

A Federal Aviation Administration specification letter (77), entitled "Sleep Apnea Evaluation Specifications," states that the complications of obstructive sleep apnea, e.g., "daytime hypersomnolence, also referred to as excessive daytime sleepiness, cardiac dysrhythmia, and significant hypertension," present a risk to flying safety and recommends an initial work-up (conditions not stated) that would include sleep studies and a Maintenance of Wakefulness Test. Acceptable treatments are stated to be surgery or CPAP; unacceptable treatments include weight loss and positional therapy. There is recommended follow-up protocol involving the Maintenance of Wakefulness Test for assessing sleepiness.

This letter wisely aims to define the scope of complications associated with sleep apnea that are relevant to pilot assessment, rather than categorically excluding pilots with apneas. The Committee also applauds the attempt to define a functional end-point for therapy and license reinstatement, namely the ability to sustain wakefulness. Whether a test like the Maintenance of Wakefulness Test fulfills that requirement is problematic, as has been discussed earlier in this document (see EVALUATION OF SLEEPINESS).

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