

Managed Care Considerations

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Abstract

Managed care issues arising from excessive daytime sleepiness (EDS), which impacts as many as 37% of adults, are widespread. In the United States, insomnia is among the 3 most common complaints. Often it is younger people who have difficulty falling asleep, whereas their elders report more difficulty remaining asleep. Currently, people in the United States sleep 25% fewer hours than they did 100 years ago. Chronic sleep deprivation may be a choice driven by economic or social factors. Industrialized countries engage about 20% of the work force in shifts, and people working night shifts are thought to average 8 fewer hours of sleep each week than day workers. Falling asleep behind the wheel is the single most imminent risk associated with excessive sleepiness.

Nonpharmacologic treatments for EDS include light variations, positive-airway pressure, dental and oral devices, and cognitive-behavioral therapy. When used, any pharmacologic treatment must carefully balance the amount of wakeful stimulation with bedtime drowsiness.

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Excessive daytime sleepiness (EDS) may not seem like a serious medical problem until you consider the fact that the states of sleepiness and alertness are mutually exclusive. Thus, a sensation of sleepiness is always reflective of an inability to perform expected waking functions. Sleepiness is not the same as fatigue, which is characterized by a reduced capacity (cognitive or muscular) and is often accompanied by weariness. Lack of sleep makes one sleepy; lack of rest makes one fatigued. There is overlap. Sleep lacking in quality—passing a restless night, for example—can cause one to feel fatigued as well as sleepy, whereas simply not getting enough sleep tends to leave one sleepy.

Causes of EDS can be medical, neurological, or psychiatric—or EDS can be a function of sleep habits, usually driven by economic pressures. Although everyone has had the experience of interrupted, sporadic, or nonrefreshing sleep, it is when this becomes chronic that problems begin to have clinical significance.

In the National Sleep Foundation's 2002 poll, *Sleep in America*, 37% of respondents reported that sleepiness interfered with daily activities a few days per month.¹ Such industrial disasters as Chernobyl, Three Mile Island, and Bhopal; the environmental disaster of the Exxon Valdez; and the national disaster of the Challenger have been narrowed down officially to lapses in judgment and/or attention arising from sleepiness.^{2,3} In the United States each year, car accidents blamed on drivers falling asleep exceed 100 000.⁴ Chronic EDS usually arises from a sleep disorder that, once identified, can be treated. Although for many narcolepsy comes to mind first, in reality the most common EDS-related sleep disorder is sleep-disordered breathing.⁵

EDS is not so much a condition but rather is a symptom attributable to 1 of 4 variables: (1) sleep loss and sleep fragmentation; (2) circadian rhythm disruption (as in jet lag, shift work, or phase delay), which usually manifests as wakefulness between the hours of 2 AM and 6 AM caused by primary sleep disorders (sleep-apnea syndrome, narcolepsy, insomnia); (3) central nervous system diseases or any disease or condition that involves the brain (narcolepsy, Parkinson's disease, restless legs syndrome [RLS], etc); and (4) drugs such as

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sleep-inducing dopamine agonists and benzodiazepines or the depressant alcohol.⁶

Frequency and Prevalence

In the United States, the 3 most common complaints in patients with sleep disorders are headache, symptoms of the common cold, and sleep dysfunction or insomnia, respectively.⁷ Insomnia affects more than 60 million people in the United States—approximately 20% of the population. Half of those afflicted with insomnia describe their insomnia as a health concern.⁸ Insomnia is more common in the elderly, in women, in individuals with medical or psychiatric disorders, or those working night or rotating shifts. One fifth of the US population occasionally takes some form of sleep aid, whereas 1.7% receive hypnotic prescriptions annually.⁷ Approximately 15% of adults in the United States have been sufficiently impacted by insomnia to seek medical attention for it.

In at least one study, among younger people the primary sleep complaint is difficulty falling asleep, whereas older people report more difficulty staying asleep.⁷ Age is associated with increases in at least 3 primary sleep disorders: sleep apnea, periodic limb movements during sleep, and RLS.⁷

Societal Implications

Sleep deprivation may be unpleasant, but is it always voluntary? Can it actually detract from enjoyment and quality of life (QOL)? If we take the World Health Organization (WHO) definition of health as *complete physical, mental, and social well-being*, and not merely the absence of disease or infirmity,⁹ then deprivation of sleep must qualify, if not as an illness, then certainly as a reducer of QOL.

People in the United States currently sleep 25% less than 100 years ago.⁵ As biological sleep requirements are unlikely to have changed in that interval, our chronic state of sleep deprivation must in many cases be chosen, likely driven by economic and social factors. Examples include the perceived necessity of the long commute or of constant travel, or the real necessity of rotating or extended shifts. Industrialized countries engage about 20% of the work force in shifts. Increasingly, telephone banks in outsourced companies require staffing at locally odd hours. People working night shifts are said to average 8 fewer hours of sleep each week

than day workers, thus losing an entire night's sleep every week. The sleepless have many things to keep them occupied, such as all-night television, 24-hour convenience stores, and the Internet.

How much sleep does a body need? The amount varies: the average nightly amount for healthy adults normally is about 8 hours, with little variability in sleep need but large variability in how much sleep is obtained.⁵ The determinant of a sufficient night's sleep is not the hourly total, but rather the state of awakening refreshed and restored. A person who needs 10 hours of sleep but gets only 8 hours will be excessively sleepy during the day and will be neither physiologically adapted to an 8-hour schedule nor become accustomed to chronic sleep deprivation.

The state of sleep deprivation is not only unpleasant to the individual; it impairs alertness, memory, and performance. Sleep deprivation increases on-the-job or scholarly errors and increases the likelihood of vehicular accidents. But what should be most important to the physician is that lack of adequate sleep carries medical consequences. Chronically sleep-deprived people are at higher risk of developing obesity, type 2 diabetes, hypertension, and major depression.¹⁰

Public Health Effects

Sleep specialists are represented by various disciplines, such as psychiatrists, pulmonologists, and neurologists, many who claim board certification. William Dement, MD, PhD, one of the world's recognized authorities in sleep medicine at the Sleep Disorders 2006 symposium, ascribed more than 50 000 deaths per year and more than \$100 billion per year to preventable accidents related to sleep deprivation and sleep disorders.¹¹

When sleep is frequently insufficient or interrupted and not made up, the condition of sleep debt begins to accrue. As the debt expands, the trend is for patients not to adapt, but instead they become more impaired, fatigued, and increasingly capable of falling asleep at the wrong time. Awareness of the impairment may not be apparent to the patient. Excessive sleep debt has been attributed to accidents involving long-haul truckers and bus drivers, mistakes in medical practice, diminished workplace performance, and exacerbation of already existing medical conditions.

Falling asleep behind the wheel is the single most imminent danger associated with excessive sleepiness. Using data from the National Safety Council for the year 2000, Sassani et al¹² calculated the annual number of collisions, costs, and fatalities in the United States related to obstructive sleep apnea (OSA) to be 800 000, resulting in 1400 deaths and \$15.9 billion in costs. In 2004, the US National Highway Traffic Safety Association (NHTSA) estimated that principal casual factors behind approximately 100 000 motor vehicle crashes comprised drowsiness and fatigue.¹³ In a 1999 NHTSA poll, 62% of the adults surveyed reported driving a car while feeling “drowsy,” and 27% reported dosing off at some time while driving. Given the personal and public safety aspects of driving while sleepy, clinicians expose themselves to liability if they do not advise patients with OSA or other sleep disorders not to drive until they are adequately treated.

EDS often indicates that the affected person is nursing a large sleep debt.¹³ A person in severe sleep debt can go from a wakeful state to one of being asleep in about 15 seconds. The National Transportation Safety Board attributes fatigue as a direct or contributing cause in every accident involving human error unless fatigue has been specifically ruled out. Caffeine can sometimes give a temporary boost, but in the end it is no substitute for sleep.

Primary Evaluation

Given the prevalence of EDS, primary care physicians (PCPs) are crucial for detecting the problem. Diagnosis of EDS is important because, in addition to its obvious negative effects on the patient’s QOL, productivity, and safety, it can impact health as well. Unfortunately, most PCPs’ time is limited, and the time they have with patients is often severely truncated. Yet, patients impacted by a chronic state of sleepiness often do not present with sleep complaints, but instead present with comorbid factors arising from or exacerbated by a sleep disorder. The PCP can easily detect the presence of an underlying sleep disturbance by asking the following 2 questions:

- In general, are you sleeping well?
- Are you able to maintain alertness throughout the day?

Negative responses to these questions usually mean the person likely suffers from a sleep disorder and evaluation is warranted. If the cause or treatment of the patient’s EDS is beyond the scope of the PCP’s expertise, that patient can be referred to a specialist for consultation and/or testing.

It is imperative that the PCP take the symptoms of EDS seriously whenever they’re suspected. This is a problem that could pose harm to the patient or to others should he or she fall asleep while driving or engaging in anything potentially dangerous.

A Concept of Assessment

Particularly with a symptom as vague as sleep disruption, which may not be a disease in and of itself, it is useful to think of a model of assessment that incorporates not only objective signs but also patient-evaluated symptoms and QOL issues. To give a more complete picture of individual health as intended by the WHO, it may be helpful for the clinician to use the framework entitled *Assessing the Impact of Disease (AID)*. This can be helpful in establishing dimensions of assessment.⁹ The AID concept incorporates symptoms, disease severity, and QOL (**Figure**).

Symptoms. Symptoms are a patient’s experience of departure from a previous desired norm.⁹ They need not indicate illness as such. A symptom might vary in severity, character, or persistence, and it may vary in its level of importance to the patient. A symptom may also be diminished or ignored, whether consciously or subconsciously, for fear of embarrassment or ridicule. A person whose schedule allows only 6 nightly hours of sleep, for example, may not admit or even recognize being in a state of sleepiness and may self-medicate with caffeine and struggle to contain annoyance at things that should not bother him or her. Many people in the United States think they can get by with 6 hours of sleep, and that is seldom, if ever, sufficient for truly adequate daytime functioning.

Disease Severity. Disease severity is the objective assessment of disease through the established standard means of a complete history and physical examination and diagnostic testing.⁹ Applied to the general concept of EDS, the emphasis will often be on testing measures, as patients may present with

vague or comorbid complaints. Various means of measurement, subjective and objective, are available, but, as to sensitivity, they are not the same. Over the course of a night in the laboratory, polysomnography measures airflow through the nose and mouth and respiratory flow and effort. Other measures include body position, heart rate, pulse oximetry, electroencephalogram, electrooculogram, and electromyogram. The Epworth Sleepiness Scale (ESS) is the standard measure of patient estimate of EDS.^{14,15} The multiple sleep-latency test (MSLT) is a laboratory test and is the gold standard for quantifying sleepiness.¹⁶

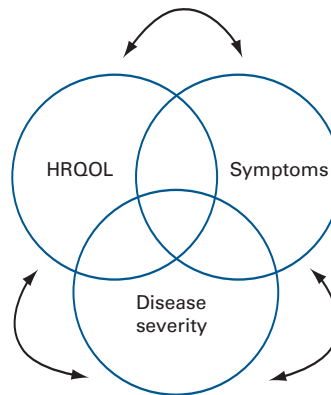
QOL. The meaning of QOL varies. Recall the WHO definition of health as complete well-being and not merely the absence of disease. Physicians might not include psychological, social, and spiritual aspects into a health-related QOL (HRQOL) concept.⁹ If this is the case, the patient becomes the assessor. In clinical medicine, HRQOL integrates the psychological and social effect of illness and its treatment as the patient perceives it.

Screening

Once EDS is confirmed and after ruling out insufficient sleep as its cause, it is appropriate to evaluate the severity of the EDS. Questionnaires, such as the Functional Outcomes of Sleep, have been devised to help patients impart their views about their sleep dysfunction on HRQOL issues.⁹ The ESS, a standard for EDS assessment, does not ask the patient if he or she is sleepy, because patients often are unaware of their sleepiness. Essentially, they have been sleepy for a long time. Instead, it asks if he or she falls asleep, or has a propensity to, in a variety of situations, all of which are at inopportune times. Sleep diaries are helpful when insomnia, circadian rhythm disorders, or insufficient sleep are being considered.

Easily obtained and administered, the ESS is also a sensitive assessor of EDS. On the ESS, patients assess their likelihood of drowsiness in 8 common daily situations on a 4-point scale, from 0 for never to 3 for high chance.¹⁷ Sums of all scores below 10 are usually considered normal; those that exceed 11 are reportedly predictive of excessive sleepiness. Some studies report an association between higher scores on the ESS and accident risk. Patients who

■ **Figure.** Assessing the Impact of Disease Framework



HRQOL indicates health-related quality of life.
Adapted with permission from Reference 8.

score themselves higher than 10 on the ESS scale need to understand the consequences of the disorder and should be asked not to drive until treatment has been evaluated.

Actigraphy measures activity and sleep by means of the patient wearing a small actigraph unit for some time. This portable device looks like a watch and records movement over extended periods to study sleep and circadian rhythms.¹⁸ However, actigraphy is more often used for research rather than clinically, because it may not detect impaired alertness and does not assist in diagnosis.⁶

A formal sleep study in a laboratory may be necessary and is always necessary for sleep apnea and periodic limb movement disorder. Sleep studies measure certain parameters such as the time to sleep onset under sleep-appropriate, or inappropriate, conditions. Overnight polysomnography produces summaries of apneic episodes per hour, valuable for evaluating OSA.⁹ However, in one small study at least, polysomnograms detected no strong correlation between EDS and night-sleep disruptions.¹⁹ In suspected cases of narcolepsy, the MSLT should be administered following all-night polysomnography to determine severity of sleepiness and frequency of rapid eye movement (REM) onsets.⁵ The MSLT consists of up to 5 opportunities, at intervals of 2 hours during an entire day, to take a nap. Patients with narcolepsy, who often fall asleep in less than 5 minutes, also usually have REM sleep during 2 or more of the naps, which sel-

dom happens in people without narcolepsy. When further objective evaluation is appropriate, a patient in street clothing might be positioned on a semireclined bed in a dim, quiet, sleep-inducing room 2 hours after waking and remain undisturbed there for 30 minutes to assess his or her ability to stay awake. Applying the AID concept (symptoms, disease severity, and QOL) to this evaluation, symptom severity essentially determines disease severity.

Treatment

Nonpharmacologic. Good sleep practices are behaviors one might establish to ensure getting a good night's sleep. Such habits include not eating, drinking, or exercising in large amounts immediately before going to bed. Patients should establish regular times for retiring and rising and also allocate enough time for sleep and exercise during the day. Some behavioral treatments for insomnia include limiting the time spent in bed trying to obtain sleep, progressive muscle relaxation, and stimulus control (strengthening the mental connection between time spent in bed and sleep). Combined with behavioral approaches, stimulus control is an effective sleep strategy.

For those who can't arrange their schedule to allow enough sleep in 1 interval or for those with narcolepsy, napping at well-chosen times can be helpful. However, being unable to get through a day without a nap suggests the need for further investigation into the reason. For those with OSA, a continuous positive-airway pressure (CPAP) may be prescribed.²⁰ Despite its daunting appearance, usually after some adjustments for proper fit to an individual's needs, the CPAP can be highly effective. For those with shift-work sleep disorder (SWSD), the use of light during the night shift and preserving darkness during the day is very important.

Pharmacologic. For treating insomnia, some people find such nonprescription sleep aids as valerian, melatonin, kava-kava, tryptophan, or chamomile helpful for sleeping.¹ However, there are no data to establish the efficacy or safety of such agents. For EDS, the number of people who self-medicate with caffeine are legion. Medications used to stimulate alertness work through dopaminergic

channels and are associated with significant abuse potential. Also of concern are their effects on cardiovascular function. A more recently developed drug, modafinil, minimizes these concerns. Any treatment for insomnia or EDS must be chosen judiciously to balance nighttime sleep with daytime wakefulness. The choice of medications to use are highly contingent on the patient's diagnosis and age, with dosages as low as possible. Any drug has side effects and people may respond idiosyncratically; sometimes drug or dosage must change. In addition, duration of action of the medication must be carefully considered; if a stimulant taken at noon disrupts a patient's sleep, that patient will be sleepy the next day. Similarly, sleep-promoting agents with half-lives longer than 6 hours, while improving sleep, will impair next-day function.

Despite the abuse potential of some sleep aids in individuals prone to substance abuse, people with insomnia rarely abuse these medications. Nevertheless, hypnotics, when withdrawn, should be gradually tapered.¹ For narcolepsy, a number of medications have been approved and are available.²¹ Either stimulants or wake-promoting agents may be used to control daytime hypersomnia. Ancillary symptoms of narcolepsy outside of cataplexy may be treated with tricyclic antidepressants, selective serotonin-reuptake inhibitors, serotonin- and norepinephrine-reuptake inhibitors, or, more recently, GABA_B-receptor agonists. Other wake-promoting agents have also been approved for treatment of narcolepsy and can be used for treating such other causes of EDS as SWSD and apnea, according to sleep researcher Michael J. Thorpy, MD. Monoamine oxidase inhibitors have been used to treat cataplexy, but have not been formally studied. Other medications used to treat narcolepsy may be associated with cardiovascular issues or potential for abuse, all of which accentuate the need for accurate diagnosis and prudent prescribing.

Benefits of Treatment

While some disorders may be diagnosed primarily from clinical and laboratory parameters, it is important to include the patient's subjective perspective when considering a diagnosis for EDS. Symptoms that are real to the patient yet vague or invisible to the clinician can disrupt the lives of the

patient and their loved ones and extend to society as a whole. Conversely, it is possible that abnormal sleep patterns may or may not affect the QOL of any particular individual case. This is why a general grasp of overlap and interaction of the AID concepts—symptoms, disease severity, and HRQOL—can be valuable.⁹ Despite its varied causes and complexities, EDS is usually caused by a sleep disorder that can be identified and treated.

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