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# Preface

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Over the past decade, research on insomnia and its management has significantly changed the accepted clinical view of this disorder. This revised view has been outlined most clearly in the National Institutes of Health (NIH) State-of-the-Science panel report on insomnia [1], which reflects the changes in the previous views of insomnia as described in the NIH consensus conference of 1983 [2].

In 1983, the NIH conference concluded that insomnia is a symptom of an underlying disorder or condition and therefore treatment should be aimed at the underlying condition rather than the symptoms of insomnia. It was also concluded that the greatest risk associated with insomnia was diminished daytime performance. The report concludes that when treatment for an insomnia symptom is necessary, benzodiazepines are the treatment of choice, but they should be used for periods of no more than 2 to 3 weeks.

Although there have been fundamental changes in our view of insomnia, there are constants in insomnia definition and treatment. Insomnia continues to be defined by a report of difficulty falling asleep, staying asleep, or nonrefreshing sleep in association with some daytime impairment or distress. These symptoms must occur in the context of an adequate opportunity to sleep. In addition, the risk factors for insomnia are age, sex, and medical and psychiatric disorders. Whereas historically the major focus has been on the elderly, recent work has focused on the importance of insomnia in pediatric populations.

The other major constant is that currently, as has been the case for the past 4 decades, the medications of choice for the treatment of insomnia are the benzodiazepine receptor agonists. The selection of a medication within this class should be based primarily on the half life and dose (and possibly the biding characteristics), because they define the safety and the efficacy of these compounds.

However, there are fundamental changes in our view of insomnia and its etiology, evolution, and treatment. Most importantly, it has been pointed out that in the vast majority of cases insomnia is present in the context of a medical or psychiatric disorder. However, it was stressed in the 2005 NIH report that insomnia is a disorder in and of itself independent of any other disease. Conference participants recommended that insomnia presenting with other medical or psychiatric conditions

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should be thought of as a comorbid disorder rather than as a symptom of an underlying disease, and that treatment targeting the insomnia should be considered in addition to treatment of the comorbidity. In this context it was emphasized that clinical trials in insomnia need to focus on patients with comorbid insomnias, rather than only primary insomnia.

By 2005, researchers had documented the association of insomnia with significant impairment in cognitive functions, including memory and attention. Daytime fatigue and sleepiness and associated increased accident risk have also been demonstrated. Finally, decreased quality of life, including difficulties in interpersonal relationships, has been a common finding in patients with insomnia. Recent work has shown that many of these consequences are related not to insomnia per se but to various comorbidities. Specific medical conditions associated with insomnia include coronary artery disease, hypertension, and disorders associated with pain and dyspnea. In these conditions, there is an interrelation between the insomnia and the comorbidity. For example, pain can cause sleep loss and sleep fragmentation, which in turn increase pain sensitivity. Furthermore, numerous studies have established a remarkably high association between insomnia and psychiatric disorders, especially depression and other affective disorders. Eight distinct studies have shown that insomnia is a risk factor of depression and that treatment of the insomnia augments the antidepressant response.

Finally, a much broader range of treatment options were discussed at the meeting, with substantial evidence indicating the use of cognitive behavioral therapies and benzodiazepine receptor agonists. In the area of pharmacotherapy, there was concern about the lack of data with regard to the efficacy and safety of the various medications commonly used "off label" to treat insomnia. With regard to benzodiazepine receptor agonists, it was pointed out that there is an abundance of data on the safety and efficacy of these medications when used over the short term. However, because insomnia is a chronic disorder, more long-term efficacy data are needed. In fact, there is only one published double-blind placebo-controlled study to date demonstrating the efficacy of these medications when used nightly over an extended period of time (6 months).

Cognitive and behavioral therapies cover a broad spectrum of treatments, including stimulus control, sleep restriction, relaxation training, cognitive therapy, paradoxical intention and biofeedback. The literature indicates that these types of therapies, in isolation or more typically in combination are effective in improving sleep in insomniacs and that these improvements were sustained over time as evidenced by follow-up visits. Despite not being commonly used in most clinical practices, sleep restriction offers significant potential for improvements in sleep by increasing the homeostatic sleep drive through partial sleep deprivation. However, there are many challenges in applying these treatments in clinical practice: clinicians must be trained in the techniques, they must have enough time available to deliver adequate services to the patient, and they must be compensated appropriately.

Finally, a major limitation of the present research on therapeutics is the relative lack of data on nonsleep end points. In virtually all clinical trials, the primary focus is the efficacy of treatment on measures of sleep initiation, sleep maintenance, and sleep duration. However, because the diagnostic criteria also require a report of impaired daytime function or daytime distress, there is a need to evaluate daytime outcome measures as an important end point in defining efficacy of insomnia therapies. Furthermore, because insomnia is typically associated with a comorbid condition, it is important to determine how improved sleep affects comorbid conditions. Does improved sleep affect depression in patients with comorbid depression? Does improved sleep lead to better pain management?

Our understanding of insomnia and insomnia therapeutics has changed dramatically over the last decade. This issue of the *Sleep Medicine Clinics* attempts to synthesize these new advances and to define their relevance to the practicing clinician.

## References

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[2] National Institutes of Health. NIH State-of-the-Science Conference on Drugs and Insomnia: the use of medications to promote sleep. Available at: http://consensus.nih.gov/1983/1983InsomniaDrugs039html.htm. Accessed in 2005.