

## National Institutes of Health State of the Science Conference Statement

## Manifestations and Management of Chronic Insomnia in Adults June 13–15, 2005

*NIH consensus and state-of-the-science statements are prepared by independent panels of health professionals and public representatives on the basis of (1) the results of a systematic literature review prepared under contract with the Agency for Healthcare Research and Quality (AHRQ), (2) presentations by investigators working in areas relevant to the conference questions during a 2-day public session, (3) questions and statements from conference attendees during open discussion periods that are part of the public session, and (4) closed deliberations by the panel during the remainder of the second day and morning of the third. This statement is an independent report of the panel and is not a policy statement of the NIH or the Federal Government. The statement reflects the panel's assessment of medical knowledge available at the time the statement was written. Thus, it provides a "snapshot in time" of the state of knowledge on the conference topic. When reading the statement, keep in mind that new knowledge is inevitably accumulating through medical research.*

## INTRODUCTION

INSOMNIA IS THE MOST COMMON SLEEP COMPLAINT ACROSS ALL STAGES OF ADULTHOOD, AND FOR MILLIONS, THE PROBLEM IS CHRONIC. INSOMNIA can be a symptom of other disorders, like depression, or it can be a primary disorder in itself. Whether it is the primary disorder or secondary to some other condition, chronic insomnia is often associated with a wide range of adverse conditions, including mood disturbances; difficulties with concentration and memory; and some cardiovascular, pulmonary, and gastrointestinal disorders. Whether insomnia is the cause or result of associated problems is not always easily determined but is critical to treatment strategies for individual patients.

A variety of behavioral and pharmacological approaches show promise for managing chronic insomnia symptoms. However, there has been limited guidance for clinicians in choosing the best treatment for chronic insomnia, due to the paucity of randomized clinical trials for many widely used treatments. Available treatments include an array of behavioral or nonpharmacologic interventions; hypnotic medications; and antidepressant, antipsychotic, or antihistamine medications.

As pointed out in the recent *2003 National Sleep Disorders Research Plan*, published by the National Center on Sleep Disorders Research at the National Institutes of Health (NIH), there is great need for additional research to better define the nature of chronic insomnia and ways to characterize its detailed expression in diverse patients. Additional systematic research is also greatly needed to provide a more thorough database from which clinicians and patients can make more informed choices about treatment options.

To address these needs, the National Institute of Mental Health and the Office of Medical Applications of Research of the NIH sponsored a State-of-the-Science Conference on the Manifestations and Management of Chronic Insomnia in Adults on June 13–15, 2005, in Bethesda, MD. During the first 2 days of the conference, experts presented the latest scientific knowledge about chronic insomnia and available treatments. After weighing all of the scientific evidence, an independent panel prepared and presented the following state-of-the-science statement. The panel was charged with answering five specific questions:

- How is chronic insomnia defined, diagnosed, and classified, and what is known about its etiology?
- What are the prevalence, natural history, incidence, and risk factors for chronic insomnia?
- What are the consequences, morbidities, comorbidities, and

public health burden associated with chronic insomnia?

- What treatments are used for the management of chronic insomnia, and what is the evidence regarding their safety, efficacy, and effectiveness?
- What are important future directions for insomnia-related research?

The conference was intended for health care professionals, researchers, patients and their families, and members of the public interested in the nature of and available treatments for chronic insomnia. The conference included formal expert presentations focusing on the individual conference questions and oral and written input from professionals and members of the lay public. In addition, the independent panel benefited greatly from a comprehensive systematic literature review, prepared by the University of Alberta Evidence-based Practice Center.

### **1. How is chronic insomnia defined, diagnosed, and classified, and what is known about its etiology?**

#### **Definition**

Insomnia has historically been defined by complaints of disturbed sleep in the presence of adequate opportunity and circumstance for sleep. The disturbance may consist of one or more of three features: (1) difficulty in initiating sleep; (2) difficulty in maintaining sleep; or (3) waking up too early. A fourth characteristic, nonrestorative or poor-quality sleep, has frequently been included in the definition, although there is controversy as to whether individuals with this complaint share similar pathophysiologic mechanisms with the others.

The importance of sleep disruption often rests with its impact on the individual's daytime function. Guidelines incorporating impact on function along with the above features in the definition of insomnia have recently been published in an effort to standardize future insomnia research. In some populations, however, the impact of sleep disruption goes beyond the patient, such as the pediatric and the elderly (particularly nursing home residents), for whom the major impact may fall on the daytime function of parents and caregivers.

To distinguish chronic from acute insomnia, which may occur in anyone at one time or another, varied definitions for chronic insomnia have been utilized from study to study, with minimum durations ranging from 30 days to as long as 6 months.

Most cases of insomnia are comorbid with other conditions. Historically, this has been termed "secondary insomnia." However, the limited understanding of mechanistic pathways in chronic

insomnia precludes drawing firm conclusions about the nature of these associations or direction of causality. Furthermore, there is concern that the term secondary insomnia may promote undertreatment. Therefore, we propose that the term “comorbid insomnia” may be more appropriate. Common comorbidities include psychiatric disorders, particularly depression and substance use disorders; cardiopulmonary disorders; and conditions resulting in chronic somatic complaints that may result in sleep disruption. Other associated sleep disorders can also contribute to insomnia, such as obstructive sleep apnea, restless legs syndrome, or periodic limb movement disorder. “Primary insomnia” implies that no other cause of sleep disturbance has been identified.

## Diagnosis

Diagnosis is based primarily on patient-derived and family or caregiver complaints, as determined by the clinical interview. Medical history and physical examination are useful in establishing the presence of comorbid syndromes. Other tools have been used as an aid to diagnosis, with varying utility. Sleep diaries may help document sleep/wake cycles. Various questionnaires have been formulated but are limited by the lack of standardization. Actigraphy, in which a wrist-worn device measures movement to infer sleep and wake cycles, has not been fully validated in chronic insomnia. Finally, multichannel polysomnography, both in-lab and at home, is most often used in cases in which other sleep disorders, such as sleep apnea, are suspected.

## Classification and Etiology

Insomnia may be classified based on specific symptoms (i.e., sleep onset or sleep maintenance) or the duration of symptoms. Etiology-based classification schemes have also been advocated. Evidence supports both psychological and physiological models in the etiology of insomnia. Models include the concepts of conditioning, hyperarousal, stress response, predisposing personality traits, and attitudes and beliefs about sleep. Animal models are used to identify neural systems that regulate arousal and sleep. The precise relationship between physical illness and changes in brain function that result in insomnia remains to be further elucidated.

## **2. What are the prevalence, natural history, incidence, and risk factors for chronic insomnia?**

### Prevalence

Although chronic insomnia is considered to be common, studies on its actual prevalence have yielded variable estimates (i.e., the proportion of persons who have the disorder at a given point in time). Conclusive evidence from epidemiologic studies has been limited by their different definitions of chronic insomnia and by the lack of standardized diagnostic and screening methods. Population-based studies suggest that about 30 percent of the general population has complaints of sleep disruption, while approximately 10 percent has associated symptoms of daytime functional impairment consistent with the diagnosis of insomnia. Not surprisingly, prevalence appears to be greater in clinical practices, where about one-half of respondents report symptoms of sleep disruption.

## Natural History

Few studies specifically describe the course and duration of insomnia. Unpublished data from a middle-aged population followed over 10 years describe a persistence of symptoms. A prospective study of outpatients of hospital-based populations with sleep complaints of at least a month's duration showed that in the majority of insomniacs the symptoms are of long duration. The paucity of literature describing the natural course of insomnia underscores the need for large-scale longitudinal studies.

## Incidence

Very little is known about chronic insomnia's incidence, which is the frequency with which new cases of the disorder arise as time passes. Because incidence is affected only by the factors that cause and prevent a health outcome, it is the preferable frequency measure for etiologic research. Unfortunately, only a few studies of chronic insomnia occurrence have examined its incidence. Increasing the number of studies of the incidence of chronic insomnia is a clear research priority.

In conjunction with studies of incidence, research on the duration of chronic insomnia is also needed. The disorder can last for relatively short periods of time in some patients and for decades in others. Insomnia can also recur after a period of remission. When studies of chronic insomnia incidence are conducted, the newly ascertained cases can be followed longitudinally to describe the disorder's natural history. In these studies, it will be possible to investigate factors that are suspected of affecting chronic insomnia's incidence, duration, or both. It will be particularly important to determine which therapies the treated patients receive and to distinguish patients whose chronic insomnia is produced by specific, preexisting medical or psychological conditions.

## Risk Factors

Several problems limit the ability to compare and integrate available information from existing observational studies on correlates of insomnia: (1) validated diagnostic instruments have not been applied in large, population-based studies; (2) the many comorbid physical and psychiatric conditions that precede or follow a diagnosis of insomnia challenge the ability to identify the independent relationships of related factors with insomnia; and (3) most observational research has used a cross-sectional design, so causal relationships cannot be inferred and only correlates of insomnia can be identified.

Many studies have found greater prevalence of insomnia among older people, perhaps as a consequence of declining health and/or institutionalization. Whether rates of insomnia increase with age in healthy older people remains unclear. Most observational studies of insomnia have found greater prevalence among women, especially in the postmenopausal years.

Current evidence on differences among racial or ethnic groups in prevalence of insomnia within the United States is limited and inconclusive. Several studies have found higher prevalence of insomnia in divorced, separated, and widowed adults relative to married adults. Lower education and income have sometimes been associated with higher prevalence of insomnia.

Several psychiatric and physical illnesses have strong and theoretically expected relationships with insomnia. Insomnia is a symptom of depression. Other medical conditions, including

arthritis, heart failure, pulmonary and gastrointestinal disorders, Parkinson's disease, stroke, and incontinence, also affect sleep and increase the prevalence of insomnia. The extent to which treatment for these conditions ameliorates insomnia remains unclear.

Cigarette smoking, alcohol and coffee consumption, and numerous prescription drugs also affect sleep and are associated with increased prevalence of insomnia. Although modification of these behaviors has the potential to reduce the prevalence of insomnia, evidence of this is limited.

## Future Studies

Validated instruments with known psychometric properties are needed, with attention paid to ease of administration, cross-cultural applicability, and comparability to objective measures of sleep performance, both overall and within important subgroups. Attention is also needed concerning the reliable measurement of the degree of sleep disturbance and the severity of symptoms of insomnia.

Another hypothesis relates to the possible genetic etiology of insomnia. Work is needed to quantify the importance of family history, along with a systematic search for specific genes.

Correlates of insomnia should be explored for their relationships with the development of subsequent insomnia. For example, studies are needed of the impact on incidence of insomnia of divorce, separation and bereavement, polypharmacy, and major chronic diseases.

Longitudinal observational studies are needed to identify factors affecting incidence of and remission from insomnia. An efficient approach would be to add validated questions on chronic insomnia to ongoing observational studies that assess the many potential determinants of insomnia incidence, persistence, and remission.

## **3. What are the consequences, morbidities, comorbidities, and public health burden associated with chronic insomnia?**

### **Consequences, Morbidities, and Comorbidities**

Some evidence suggests that insomnia may be associated with high health care utilization. The direct and indirect costs of chronic insomnia have been estimated as tens of billions of dollars annually. However, these estimates are highly variable and depend on many assumptions. In estimating the economic consequences of insomnia, it is difficult to separate the effects of insomnia from the effects of comorbid conditions. For example, a person with arthritis may have problems sleeping but may seek health care for the arthritis rather than for sleep problems.

Only a few studies have examined the effects of insomnia on functioning in everyday life. These studies suggest that insomnia reduces quality of life and hinders social functioning. Two studies have identified a relationship between chronic insomnia and work days missed. Furthermore, insomnia is related to impaired work performance. There is at least some evidence of a relationship between chronic insomnia and impaired memory, cognitive functioning, and depressed mood.

Laboratory studies indicate that sleep loss results in impaired psychomotor and cognitive functioning. There is evidence that chronic insomnia or its treatment contributes to the increased number of falls in older adults.

Insomnia usually appears in the presence of at least one other disorder. Particularly common comorbidities are major depression, generalized anxiety, substance abuse, attention deficit/hyperactivity in children, dementia, and a variety of physical problems. The research diagnostic criteria for insomnia recently developed by the American Academy of Sleep Medicine indeed share many of the criteria of major depressive disorder. Explaining this overlap requires a study that determines how often insomnia precedes the disorders with which it is associated and continues to exist after the other disorders are cured or go into temporary remission.

A greater range of outcome measures is needed for future research. It may be valuable to validate patient self-reports of sleep latency, awakenings, and morning wakings.

Both insomnia and its treatment may affect quality of life. Overall summary measures that simultaneously consider side effects and benefits of treatments should be used. These measures can assess the outcomes of interventions using quality-adjusted life years. Costs of illness should also be assessed to allow for an analysis of the cost-effectiveness of treatments. The U.S. Department of Health and Human Services has developed guidelines for these assessments, and these should be consulted in the development of evaluation protocols. In addition to generic measures, insomnia-specific quality of life measures should also be used.

## **Public Health Burden**

The focus of public health is on populations rather than solely on individuals. The public health consequences of insomnia are difficult to evaluate because the literature is not well developed at this time. Sleep research has focused on basic mechanisms and clinical studies. Relatively little attention has been paid to the public health burden of insomnia. To better understand the public health consequences of insomnia, several lines of research should be considered.

The effects of insomnia upon premature death are not known. Separating the effects of insomnia from the effects of its comorbidities will be a methodological challenge. Measures of sleep have been added to the National Health and Nutrition Examination Survey and should be added to other major epidemiological studies, including the Behavioral Risk Factor Surveillance Survey.

The effect of insomnia on quality of life has been reported in few studies. Secondary analysis of data from major population studies that include both measures of sleep and measures of functioning and quality of life should be supported. New studies are needed to determine whether insomnia causes job-related disability. Furthermore, we need to support additional studies to determine whether treatment for insomnia affects job performance and academic performance.

The economic consequences of insomnia are not clearly understood. New studies are needed to estimate the direct and indirect costs of chronic insomnia and the potential societal benefits that might accrue from successful intervention programs. Finally, insomnia has effects beyond individual patients. Families, caregivers, and friends are also affected by the condition. More evidence is needed to document these effects.

## **4. What treatments are used for the management of chronic insomnia, and what is the evidence regarding their safety, efficacy, and effectiveness?**

Epidemiological surveys have shown that the most common treatments used by people with chronic insomnia are over-the-counter (OTC) antihistamines, self-medication with alcohol, and prescription medications. The major forms of psychological treatments that have been systematically evaluated are the cognitive and behavioral therapies. Alternative and complementary treatments include melatonin and herbal remedies, such as valerian.

Assessment of the efficacy of treatments for chronic insomnia is complicated by a number of factors. These include a lack of consistency in the criteria used to diagnose chronic insomnia, gaps in understanding the natural history of insomnia, and lack of clarity or consensus about the crucial outcomes of treatment. Further complicating the ability to assess treatments for chronic insomnia is its overlap with many medical and psychiatric conditions, most notably depression. Although there have been randomized clinical trials (RCTs) for several treatments, there is inconsistency in applying rigorous methodology to the assessment of a number of currently used treatments. Additionally, most clinical trials are relatively short term. There is a paucity of information about the long-term effects on sleep, daytime functioning, and quality of life.

### Behavioral and Cognitive Therapies

Behavioral and cognitive-behavioral therapies (CBTs) have demonstrated efficacy in RCTs. However, because few clinicians are experts in the use of CBT for the treatment of chronic insomnia, these techniques are not in widespread use. The degree to which this treatment can be successfully disseminated to more diverse populations is unknown. Behavioral methods, which include relaxation training, stimulus control, and sleep restriction, were developed and first tested in the 1970s. More recently, cognitive therapy methods have been added to behavioral methods. Cognitive therapy methods include cognitive restructuring, in which anxiety-producing beliefs and erroneous beliefs about sleep and sleep loss are specifically targeted. When these cognitive methods have been added to the behavioral methods to compose a cognitive-behavioral treatment package, it has been found to be as effective as prescription medications are for brief treatment of chronic insomnia. Moreover, there are indications that the beneficial effects of CBT, in contrast to those produced by medications, may last well beyond the termination of treatment. There is no evidence that such treatment produces adverse effects, but thus far, there has been little, if any, study of this possibility.

### Prescription Medications

This section describes the use of two categories of medications, those that are approved by the U.S. Food and Drug Administration (FDA) for the treatment of insomnia and those that are FDA-approved for the treatment of other disorders but are prescribed to treat insomnia. (The latter category is considered “off-label” usage.) There are currently eight medications approved by the FDA for treatment of insomnia. Despite the fact that insomnia is often a chronic condition, only one of these medications (eszopiclone) has been approved for use without a specified time limit. The other medications have approved use limited to 35 days or less.

### Benzodiazepine Receptor Agonists

There are two broad groups of agents in this class of prescrip-

tion hypnotics: benzodiazepines (e.g., estazolam, flurazepam, quazepam, temazepam, and triazolam) and the more recently introduced agents that act as benzodiazepine receptors but have a nonbenzodiazepine structure (e.g., zaleplon, zolpidem, and eszopiclone). Results from clinical trials indicate that these agents are efficacious in the short-term management of insomnia. With the exception of eszopiclone, the benefits of these agents for long-term use have not been studied using RCTs. A recent clinical trial of eszopiclone provided evidence of sustained efficacy for 6 months. Adverse effects associated with these medications include residual daytime sedation, cognitive impairment, motor incoordination, dependence, and rebound insomnia. The frequency and severity of these adverse effects are much lower in the newer benzodiazepine receptor agonists, most likely because these agents have shorter half-lives. Although the available literature suggests that, in the short term, tolerance and abuse of the benzodiazepine receptor agonists are not major problems in the general population with chronic insomnia, long-term use needs further study.

### Antidepressants

Over the past 20 years, there has been a significant change in the use of prescription medications to treat chronic insomnia, with a decrease in the use of benzodiazepine-like agents and a substantial increase in the off-label use of antidepressants. Based on recent surveys, the antidepressant trazodone is now the most commonly prescribed medication for the treatment of insomnia in the United States. In short-term use, trazodone is sedating and improves several sleep parameters. These initial effects may not last beyond 2 weeks. However, there are no studies of long-term use of trazodone for treatment of insomnia. Another antidepressant, doxepin, has been found to have beneficial effects on sleep for up to 4 weeks for individuals with insomnia. Data on other antidepressants (e.g., amitriptyline and mirtazepine) in individuals with chronic insomnia are lacking. All antidepressants have potentially significant adverse effects, raising concerns about the risk-benefit ratio. Moreover, there is a need to establish and communicate to prescribers dose-response relationships for all of these agents.

### Other Prescription Medications

A number of other sedating medications have been used in the treatment of insomnia. These include barbiturates (e.g., phenobarbital) and antipsychotics (e.g., quetiapine and olanzapine). Studies demonstrating the usefulness of these medications for either short- or long-term management of insomnia are lacking. Furthermore, all of these agents have significant risks, and thus their use in the treatment of chronic insomnia cannot be recommended.

### OTC Medications

Antihistamines (H1 receptor antagonists, such as diphenhydramine) are the most commonly used OTC treatments for chronic insomnia, but there is no systematic evidence for efficacy and there are significant concerns about risks of these medications. Adverse effects include residual daytime sedation, diminished cognitive function, and delirium, the latter being of particular concern in the elderly. Other adverse effects include dry mouth, blurred vision, urinary retention, constipation, and risk of increased intraocular

pressure in individuals with narrow angle glaucoma.

## Alcohol

There is no systematic evidence of benefit from alcohol as self-medication for chronic insomnia, despite its common usage. The numerous risks of excess alcohol consumption greatly outweigh any benefits for therapeutic use in insomnia. The adverse effects of alcohol on sleep quality are well documented.

## Alternative and Complementary Therapies

### Melatonin

Melatonin is a natural hormone produced by the pineal gland that plays a role in the control of circadian rhythms. Melatonin is not regulated by the FDA, and preparations vary in their melatonin content, making comparisons across studies difficult. Although melatonin appears to be effective for the treatment of circadian rhythm disorders, little evidence exists for efficacy in the treatment of insomnia. Problems with melatonin include lack of a well-defined, effective dose. In short-term use, melatonin is thought to be safe, but there is no information about the safety of long-term use.

### Herbal Therapies

Valerian is derived from the root of plants of the species *valeriana* and is thought to promote sleep. Limited evidence shows no benefit beyond that provided by placebo. The FDA does not regulate valerian, and thus different preparations vary in valerian content. Safety data are minimal, but there have been case reports of hepatotoxicity in persons taking herbal products containing valerian. Many other herbal remedies have been promoted, but some are known to have toxicity and efficacy evidence is lacking.

### L-tryptophan

L-tryptophan is an endogenous amino acid that has been used as a hypnotic. Systematic evidence supporting its use in the treatment of insomnia is extremely limited and based on studies with a small number of subjects. Concerns are also raised about possible toxic effects of L-tryptophan, particularly when used in combination with certain psychiatric medications.

### Other Treatments

There are a number of other alternative treatments, including tai chi, yoga, acupuncture, and light therapy, that have potential utility in the treatment of insomnia. These treatments have not been adequately evaluated at this time.

## Research Recommendations

CBT and benzodiazepine receptor agonists have been shown to be beneficial in the acute management of chronic insomnia. Other therapies have also demonstrated some promise. However, little is known about the comparative benefits of these treatments, their generalizability, and their effects on understudied features of chronic insomnia.

In order to address this lack of knowledge, RCTs will be required that:

- Are large-scale and multisite.

- Compare at least two effective or promising treatments so that the comparative benefits of effective treatments can be evaluated. This should include comparisons among pharmacological agents, CBT, and combined treatment.
- Evaluate the positive and adverse effects of treatments over longer timeframes, including the period after discontinuation of treatment.
- Incorporate objective and subjective measures of daytime function and quality of life in addition to traditional sleep parameters, such as sleep onset latency and total sleep time.
- Systematically evaluate a variety of commonly used OTC and alternative remedies for insomnia that have not been formally evaluated.
- Measure the costs and cost-effectiveness of treatments.

The pharmaceutical industry is called upon to support comparisons of its medications not only with placebo but also with other effective treatments, including CBT.

Studies should be directed to important population subgroups, including children, nursing home residents, postmenopausal women, those with primary chronic insomnia, and those with insomnia comorbid with other conditions.

To overcome potential problems with reporting bias in clinical trials, the development of a central registry for all insomnia trials is recommended. This registry would allow a systematic synthesis of the available clinical trial data.

As comparative efficacy data become available, it will be critical to conduct effectiveness studies to determine generalizability to broader clinical populations in community settings.

Surveys of physician prescribing behavior and decisionmaking are recommended to permit the anticipation and understanding of developments, such as the recent, dramatic increase in prescriptions for the antidepressant trazodone in the management of chronic insomnia.

## 5. What are important future directions for insomnia-related research?

Validated instruments are needed to assess chronic insomnia, with attention paid to the ease of administration and cross-cultural applicability. A greater range of outcome measures related to chronic insomnia and its consequences is also needed. Measures of sleep should be added to major epidemiologic studies.

Studies are needed of the possible genetic etiology of chronic insomnia. The neural mechanisms underlying chronic insomnia are poorly understood. Studies aiming to identify neural mechanisms should use animal models and in vivo neural imaging approaches in people with insomnia and in individuals with normal sleep. Work is needed to quantify the importance of family history, along with a systematic search for specific genes.

Longitudinal observational studies are needed to identify factors affecting incidence of, natural history of, and remission from chronic insomnia. An efficient approach would be to add questions on chronic insomnia to ongoing observational studies that assess the many potential determinants of insomnia incidence, persistence, and remission.

The effects of insomnia on quality of life have been reported in few studies. Analyses of data from major population studies that include measures of sleep, measures of functioning, and quality of life should be supported. Studies are needed to determine whether insomnia causes job-related disability and whether treatment for

insomnia enhances job performance and academic performance.

Studies are needed to estimate the direct and indirect societal costs of insomnia and the potential societal benefits that might accrue from successful intervention programs. Moreover, because chronic insomnia has effects that go beyond individual patients, more research is needed to quantify effects on families, friends, and caregivers.

Cognitive-behavioral therapy (CBT) and benzodiazepine receptor agonists have been shown to be beneficial in the acute management of chronic insomnia. Other therapies have also demonstrated some promise. However, little is known about the comparative benefits of these treatments, their combination, and their effects on understudied features of chronic insomnia. To address this lack of knowledge, randomized controlled trials will be required that are large scale and multisite and compare at least two effective or promising treatments. This should include comparisons between pharmacological agents as well as between those agents and CBT. The pharmaceutical industry is called upon to compare its medications not only with placebo but also with other effective treatments, including CBT. Trials should include measures of cost and cost-effectiveness.

To overcome potential problems with reporting bias in clinical trials, the development of a central registry for all clinical trials is recommended. This registry would allow a systematic synthesis of the available clinical trial data.

As comparative efficacy data become available, it will be critical to conduct effectiveness studies to determine generalizability to broader clinical populations in community settings.

Studies should be directed to important population subgroups, including children, nursing home residents, postmenopausal women, those with primary chronic insomnia, and those with insomnia comorbid with other conditions.

## CONCLUSIONS

Chronic insomnia is a major public health problem affecting millions of individuals, along with their families and communities. Little is known about the mechanisms, causes, clinical course, comorbidities, and consequences of chronic insomnia. Evidence supports the efficacy of cognitive-behavioral therapy and benzodiazepine receptor agonists in the treatment of this disorder. Very little evidence supports the efficacy of other treatments, despite their widespread use. Moreover, even for those treatments that have been systematically evaluated, the panel is concerned about the mismatch between the potential lifelong nature of this illness and the longest clinical trials, which have lasted 1 year or less. A substantial public and private research effort is warranted, including the development of research tools and the conduct of longitudinal studies and randomized clinical trials. Finally, there is a major need for educational programs directed at physicians, health care providers, and the public.

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