



**OTC SLEEP AIDS
AND SLEEP HEALTH
IN OLDER ADULTS**

Sleep Health and the Appropriate Use of OTC Sleep Aids in Older Adults

A White Paper Developed by The Gerontological
Society of America in Collaboration with Pfizer

NOVEMBER 2013



Introduction

One out of every 9 Americans is aged 65 years or older—a population that is greater than the number of inhabitants of New York, London, and Moscow combined.¹ The aging baby boomers are increasing the proportion of older adults in the United States with 10,000 people turning 65 years old every day.

Virtually all sleep disorders increase in prevalence with aging, resulting in a large number of adults who struggle with sleep problems.² Some of these individuals have chronic insomnia—unsatisfactory sleep on 3 or more nights per week that persists for 3 months or more.³ Others with difficulty sleeping experience only occasional sleeplessness that does not meet diagnostic criteria for insomnia.

Many older adults and their caregivers turn to over-the-counter (OTC) sleep aids to promote sleep. However, these products should be used only for occasional difficulty with sleep, and their safety and efficacy in older adults is unclear. Concerns exist regarding the impact of OTC sleep aids on the health of older adults especially

if these products are used chronically or in combination with other therapies.

Available data on OTC medication-taking behavior of older adults describe the extent of medication use and illustrate potential problems. For example, data from the 2008 National Social Health Survey found widespread use of both OTC and prescription medications among older adults. More than half of older adults (ages 57 to 85 years) reported using 5 or more prescription medications, OTC products, or dietary supplements. Furthermore, 1 in 25 older adults (approximately 2.2 million in the United States) were at risk for a major potential drug-drug interaction.⁴

Notably, the use of OTC products may be overlooked in discussions between patients and health care providers.⁵ Patients may assume that products available without a prescription are safe. Increased communication with members of the health care team to guide the selection and use of OTC products could potentially support more appropriate product use for sleep disturbances.

To engage national stakeholders in a discussion on OTC sleep aid use by older adults and explore strategies for improving safe use of these products, The Gerontological Society of America organized a multidisciplinary workgroup that convened with other national stakeholders on October 17, 2013, for the National Summit on OTC Sleep Aids and Sleep Health in Older Adults (see Box). This Summit was supported by an unrestricted grant from Pfizer Consumer Health.

The Summit began with participants discussing their perceptions regarding OTC sleep aids and sleep health in older adults. These discussions were followed by presentations from leading national experts to review available data on sleep health and use of OTC sleep aids in older adults. The Summit continued with a panel discussion with stakeholders' input to explore opportunities to improve safe use of OTC sleep aids as well as brainstorming sessions to recommend strategies to address these issues. Information from the Summit presentations and discussions is presented in this white paper.

Workgroup Members and Summit Participants

Workgroup Members

- **Steven Albert, Chair**
Professor of Behavioral and Community Health Sciences
University of Pittsburgh
- **Morris Lewis**
Senior Director of External Affairs
Pfizer Consumer Healthcare
- **Thomas Roth**
Director of Research and Division Head
Henry Ford Health Systems
- **Michael Toscani**
Adjunct Clinical Professor and Fellowship Administrator
Ernest Mario School of Pharmacy
- **Michael Vitiello**
Professor of Psychiatry and Behavioral Sciences
University of Washington
- **Phyllis Zee**
Professor of Neurology, Neurobiology, and Physiology
Northwestern University

Summit Participants

- **Joan Enstam Baird**
Director of Clinical Affairs
American Society of Consultant Pharmacists
- **Inne Barber**
Senior Director of Community Partnerships
National Sleep Foundation
- **Rosemary Blieszner**
President-elect
The Gerontological Society of America
- **Ray Bullman**
Executive Vice President
National Council on Patient Information and Education
- **Tom Clifford**
Director of Development
National Sleep Foundation
- **Deborah DiGilio**
Director of the Office on Aging
American Psychological Association
- **Sarah Dunicliff**
Program Manager
National Sleep Foundation
- **Christine Harding**
Director of Community Education
National Council on Aging
- **Marcia Howard**
Senior Director of Regulatory and Scientific Affairs
Consumer Healthcare Products Association
- **Dominique Kelly**
Clinical Research Physician
Pfizer Consumer Healthcare
- **Salma Lemtouni**
Medical Officer
Food and Drug Administration
- **James Owen**
Associate Vice President of Practice and Science Affairs
American Pharmacists Association
- **Jay Sirois**
Director of Regulatory and Scientific Affairs
Consumer Healthcare Products Association
- **Kaitlyn Whiton**
Program Manager
National Sleep Foundation
- **Mark Wingertzahn**
Head of Global Clinical Research
Pfizer Consumer Healthcare

This paper was sponsored by Pfizer as part of a collaboration with GSA to support GSA's campaign to address OTC sleep aids and sleep health in older adults. While Pfizer reviewed and provided input, GSA retained full editorial control over the final content of this paper.

Perceptions Regarding OTC Sleep Aids and Sleep Health in Older Adults

Participants engaged with four thought-provoking questions to explore their perceptions regarding OTC sleep aid use by older adults. Key themes from their discussions are presented here.

Question 1. What do you believe to be the key issues older adults face on OTC sleep aid use?

Knowledge gaps and communication gaps emerged as the theme when stakeholders explored this concern. They noted that these gaps exist among health care providers and patients as well as patients' caregivers. Key gap areas are summarized in the TABLE.

Patient and Caregiver Gaps

Participants believe that older adults, in general, lack knowledge about sleep health, including sleep hygiene, and when to discuss sleep issues with health care providers. They indicated that some older adults may accept insomnia as a normal part of aging. However, the group pointed out that there are many older adults who do experience restful sleep and poor sleep should not be accepted as normal.

They stated that unintentional misuse of OTC sleep aids is an important problem among older adults. Patients have gaps in knowledge regarding risks and benefits of OTC sleep aids. Participants thought that older adults may be more likely to use OTC products than prescription medications because OTCs are often less expensive and easier to obtain. Most patients and some providers do not recognize that OTC sleep products are neither indicated nor appropriate for chronic use.

Furthermore, many older adults may not read and follow OTC product labeling. As a result, they are not aware of the active ingredients in the products and do not realize the risks of drug interactions with other anticholinergic medications or the potential for therapeutic duplication with other products (a situation of particular concern for OTC sleep/pain aids that include acetaminophen). Many patients are unaware of how long it is appropriate to use an OTC sleep aid and unfamiliar with the risks of combining these products

Table. Gaps Identified by Summit Participants Regarding Sleep Issues in Older Adults

Knowledge Gaps About Sleep	Knowledge Gaps About OTC Sleep Aids	Communication Gaps
<ul style="list-style-type: none"> • Sleep hygiene • Normal vs. abnormal patterns • When to ask for help • Alternatives to OTC products 	<ul style="list-style-type: none"> • Safety • Drug-drug interactions • Active ingredients • Dose/duration • Risks of using with alcohol 	<ul style="list-style-type: none"> • Lack of discussion between patients and health care providers • Lack of health care provider education

with alcohol. Misuse may occur because patients do not consider OTC products to be risky and may assume, "If some is good, more is better."⁵

The group explored issues arising from heterogeneity among older adults. A 65-year-old adult may be physiologically very different from an 85-year-old adult, resulting in important differences in pharmacokinetics, including absorption, distribution, metabolism, and excretion. Many older adults have vision problems and/or cognitive impairment that can hinder OTC label comprehension. Additionally, when patients already have experience with a product, they are less likely to read the label. Older adults may lack knowledge about the importance of identifying the active ingredients in products and may simply identify a product by its brand name, which can be particularly problematic when using combination products. Older adults also do not access information the same way as younger adults—they are less likely to use smartphones or the Internet to gather information.

Health Care Provider Gaps

Participants noted a communication gap between patients and their health care providers as another key issue. Providers generally do not ask patients about their sleep habits. Additionally, patients may present with so many chronic medical conditions that providers do not have time to address sleep habits and disturbances. A third explanation offered by participants is that providers, like patients, accept sleep disturbances in older adults as a normal part of aging.

The group acknowledged that providers receive little training to identify and address sleep problems. Primary care

providers need better education to know when to refer patients to sleep specialists. Pharmacists need training to identify individuals who are overusing OTC sleep aids for insomnia or other sleep disorders. In addition, health care providers require education regarding the effect of various medications on sleep. Older adults tend to use numerous medications, many of which can cause sedation or insomnia. Providers need knowledge about these adverse effects and how to optimize therapy.

Question 2. What are 3 to 5 key reasons or benefits relevant to you or your organization for improving sleep health for older adults?

Participants reported many potential benefits of improving sleep health, including better patient quality of life, mood, daytime functioning, and productivity, as well as decreasing accidents, drowsy driving, falls, and medication errors. They said that better sleep health could improve management of comorbid conditions such as hypertension, obesity, and diabetes, and decrease the associated socioeconomic costs.

The group suggested that improved sleep health possibly could help in advancing medication adherence and reducing medication errors. They hypothesized that poor sleep could interfere with next-day cognitive function resulting in forgetfulness and mistakes in medication use. Researchers within the group noted that a fuller understanding of the impact of sleep health on cognitive ability would help researchers conducting other cognition studies, if the effects of poor sleep on cognitive performance could be a controlled factor in studies.

Participants emphasized the importance of corporate responsibility for promoting

“Available data indicate that 50 million to 70 million Americans have a chronic sleep disorder. Furthermore, 28% of adults report frequent insufficient sleep.”

appropriate sleep aid use. They agreed that manufacturers of medications available on the OTC marketplace have a responsibility to support appropriate use in partnership with retailers and health care providers.

Question 3. What are the greatest barriers you face in your organization to support improved OTC sleep aid use in older adults?

Lack of funding to disseminate knowledge was a key barrier cited by Summit participants. In addition, insufficient information about OTC sleep aid use by older adults was reported as a barrier to development of program tools and initiatives. Other barriers include a lack of understanding of various issues such as the underlying reasons that older adults decide to use OTC sleep medications. For example, sometimes patients use sleep aids when there is a comorbid problem of pain that also needs to be treated. Other research knowledge gaps include scant information on the process that older adults use to select particular OTC sleep aids, as well as the impact of these medications on patient health and well-being. Additionally, there are surprisingly few comparisons between pharmacotherapy and behavioral approaches in the literature.

Participants noted that OTC and dietary supplement use is not commonly recorded in patient medical and pharmacy records. They acknowledge that some pharmacists' services, such as medication therapy management (MTM), do allow for collection of data on OTC and dietary supplement use, but it is not often shared in electronic health records.

Best strategies for communicating sleep health and OTC sleep aid information to older adults is another area where participants acknowledged that research is needed, particularly since many older adults do not access information from the Internet. Participants cited a shortage of research on both consumer behavior and the behaviors of health care providers and pharmacists who may educate older adults about OTC sleep aid use.

Lack of communication and collaboration among stakeholders including national organizations, health care providers, retailers, and manufacturers also was recognized as a barrier.

Question 4. What are 3 to 5 key ways you or your organization could contribute to achieve safe use of OTC sleep aids in older adults?

Participants had many ideas about strategies to promote safe use of OTC sleep aids in older adults. They clearly recognized a need to better educate the older adult population and caregivers about proper use of OTC sleep aids, and suggested educational initiatives targeted to both of these groups. One proposed strategy is the development and distribution of patient-friendly brochures that provide information about sleep aid use that could be disseminated at the point-of-sale for sleep aids, particularly within community pharmacies. Participants also suggested that their organizations pursue more partnerships to advocate for consumer education. They recommended developing educational initiatives that discuss good sleep hygiene practices and support appropriate use of cognitive behavioral therapy.

Development of a screening tool for consumers and providers to use would help identify sleep-related issues that should be discussed with providers. Participants recommended incorporating questions about sleep health as part of routine health care reviews and mental health care interactions. They stated that it would be important to educate pharmacists, mental health care professionals, and specialists about insomnia and the need for outreach to patients.

The group expressed concern that it would be difficult to assess the impact of whether initiatives were having a benefit and thus proper surveillance networks would need to be identified or established. They voiced a need for national data sources of information regarding OTC product use and a place to help coordinate research activities.

Review of Available Data Sleep Health in Older Adults

Phyllis Zee, MD, PhD, Professor of Neurology, Neurobiology, and Physiology at Northwestern University and Past President of the Sleep Research Society, presented data on sleep health in older adults. Sleep is a biological imperative. Most people spend approximately one third of their lives sleeping. However, a good night's sleep is elusive for many. Available data indicate that 50 million to 70 million Americans have a chronic sleep disorder.⁶ Furthermore, 28% of adults report frequent insufficient sleep.⁷

Sleep disorders and deprivation are associated with many deleterious health consequences. Annual direct (e.g., medical) and indirect (e.g., accidents, lost productivity) costs total hundreds of billions of dollars.⁶ Alarmingly, in one survey 4.7% of adults reported falling asleep while driving in the past 30 days.⁷

The prevalence of disturbed sleep has been shown to increase as individuals age. Aging interacts with genetic susceptibility to sleep problems to increase the risk of sleep deficiency. Other contributing factors include declining health, institutionalization, stress, and normal changes in circadian rhythms associated with aging.^{8,9} For example, Mellinger et al. found a steady rise in the prevalence of trouble falling asleep or staying asleep (FIGURE).⁹ Approximately 44% of older individuals experience disturbed sleep at least a few nights each week.¹⁰ Rates of disturbed sleep are even higher among individuals with dementia and their family caregivers.¹¹ The impact of poor sleep in individuals with dementia is a major contributing factor to family caregivers' decisions to institutionalize older adults.

While occasional sleeplessness lasting a few weeks is common, many people have sleep problems that persist for much longer. Chronic insomnia can last for months or years.¹²

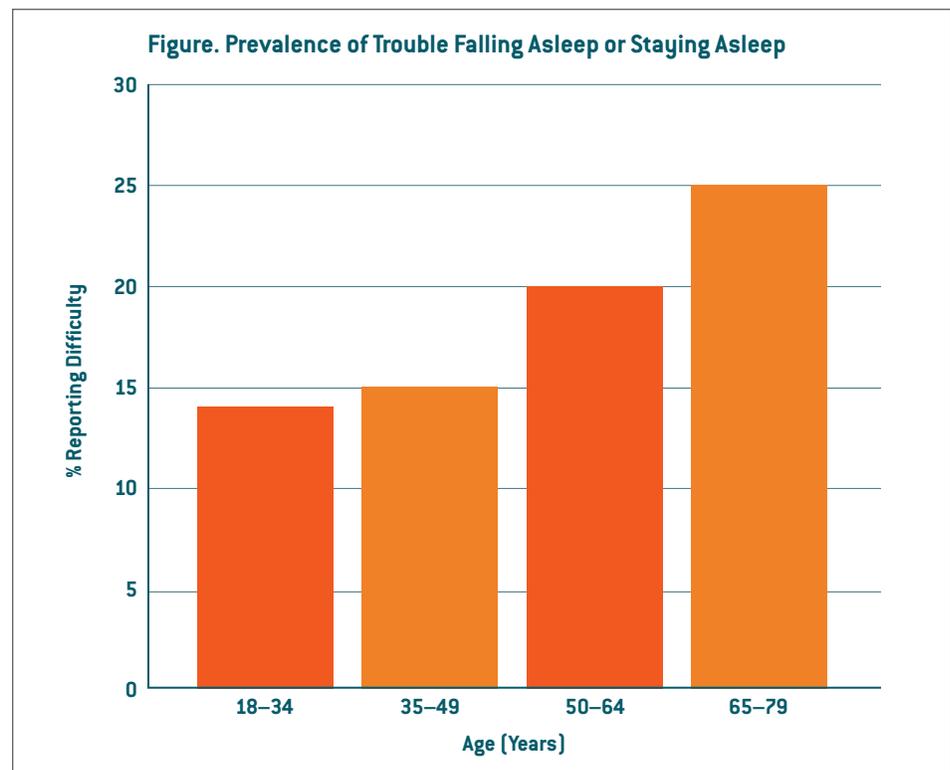
Ohayon et al. performed a meta-analysis of 65 sleep studies, which revealed that most individuals who develop sleep disturbances as they age do so in midlife. In healthy older adults, sleep habits remain roughly the same, except for decreases in sleep efficiency and slow wave sleep, and increases in wake after sleep onset.¹³ Aging does change some sleep parameters but it is not primarily responsible for the increased prevalence of insomnia and other sleep disorders in older adults.

Although fatigue and drowsiness are common effects of disturbed sleep, ill effects are much more pervasive. Sleep disorders have a bidirectional relationship with a wide range of medical and psychiatric conditions—sleep disorders increase the likelihood and severity of these disorders and these disorders often cause poor sleep. Diseases associated with poor sleep include obesity, diabetes, cardiovascular disease, respiratory conditions, mood disorders, cognitive decline, and neurologic disorders.¹⁴

The healthiest of older adults experience much less sleep disturbance than those who are not as healthy.^{13,15} Comorbid medical and psychiatric conditions likely contribute to the development of sleep disturbances more than healthy aging. Clearly, the more chronic medical diseases individuals have, the worse their sleep will be.¹⁶

In elderly adults, the effects of poor sleep extend even further. Documented impacts of poor sleep in elderly adults include:¹⁷⁻²¹

- Difficulty sustaining attention and slowed response time.
- Decreased ability to accomplish daily tasks.
- Increased likelihood of cognitive decline.
- Impairments in memory and concentration.
- Increased risk of falls.
- Shorter survival; (both difficulty falling asleep and sleep efficiency are associated with increased all-cause mortality).



Source: Mellinger GD, Balter MB, Uhlenhuth EH. Insomnia and its treatment. Prevalence and correlates. *Arch Gen Psychiatry*. 1985;42:225-232.

- Inability to enjoy social relationships.
- Increased incidence of pain.
- Reduced quality of life (all domains).
- Increased days out of work (for those still employed).
- Increased consumption of health care resources.

Despite the widespread effect of poor sleep on health and well-being, sleep difficulties in older adults are under-recognized in medical practice. Reid et al. performed a series of direct patient interviews with more than 1,500 patients, followed by comparisons with patients' medical records. In the direct interviews, 69% of patients reported at least one sleep-related problem and 45% reported having insomnia. However, only 19% of patients had any mention of sleep in their medical charts.²²

Nonprescription Sleep Aid Use by Older Adults

Thomas Roth, MD, Director of Research and Division Head of the Henry Ford Health Systems Sleep Disorders and Research Center, presented available

data on OTC sleep aid use. A number of nonprescription strategies are used in the treatment of insomnia and occasional sleeplessness, including both nonpharmacologic and pharmacologic approaches. Nonpharmacologic approaches include cognitive behavioral therapy, relaxation training, and exercise.^{23,24} In addition to these treatment approaches, many patients opt to use pharmacologic treatments.

Available OTC sleep aids include the first-generation antihistamines diphenhydramine and doxylamine, which are approved by the Food and Drug Administration (FDA). Diphenhydramine is found in the majority of products under a variety of brand names including Nytol, Sominex, Tylenol PM, Excedrin PM, Advil PM, Unisom SleepGels, and Zzzquil. Doxylamine can be found in products with brand names such as Unisom SleepTabs, Equaline Sleep Aid, and Good Sense Sleep Aid. Although these agents are indicated for treatment of occasional sleeplessness (and are not indicated for chronic insomnia), many patients use them on a regular basis.

Beyond FDA-approved therapies, several dietary supplements, including valerian and melatonin, are used as sleep aids. In general, strong evidence to support their use is lacking and questions remain about their safety, especially when used chronically.²⁴ Notably, dietary supplements do not receive the same level of scrutiny from the FDA that OTC and prescription products are required to undergo.

Many adults use alcohol to promote sleep, a behavior that may further worsen sleep and complicate the use of OTC sleep aids. One survey found that 13% of adults 18 to 45 years of age reported using alcohol as a sleep aid in the past year; 5% reported using a combination of alcohol and medications intended to treat insomnia.²⁵ In other surveys, up to 28% of patients have reported using alcohol to promote sleep. Although alcohol may reduce sleep-onset latency, it is not recommended as a sleep aid because alcohol fragments sleep in the second part of the night and can increase daytime sleepiness and promote future sleep disturbances.²⁵

Patients with chronic insomnia may be appropriate candidates for hypnotic prescription therapies, such as benzodiazepines, sedative-hypnotics, and melatonin receptor agonists.

Data on Older Adults' Use of OTC Sleep Aids

Few data describe the use of OTC sleep aids. Among adults 18 to 45 years of age, Johnson et al. found that 10% of the population used OTC sleep aids. The majority (70%) of individuals used the products for less than 1 week at a time, and the overwhelming majority (84%) used the products less than a total of 30 times. However, 9% of individuals used these products for 4 weeks or more, and 3% had used them 180 times or more.²⁵

OTC sleep aid use appears to be even more extensive in the older adult population. Recent data from the Kantar Health March 2013 National Health and Wellness Survey found extensive OTC sleep aid use among adults older than 65 years of age with sleep problems. Among these individuals:²⁶

- 17% to 18% reported using OTC sleep aids alone, approximately 3%

used OTCs combined with herbals, and 15% to 18% of those older adults taking OTCs used them in combination with prescription sleep aids.

- More than 73% reported taking OTC pain and sleep combination products, with single-molecule product use at nearly 30%. Only about 1% reported using cold and sleep products.
- Of the respondents ages 65 years and older taking OTC sleep agents, approximately 40% also currently take one or more anticholinergic medications. (All currently available OTC sleep aids have anticholinergic properties and are associated with cognitive impairments, especially in older adults.)

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Pharmacokinetic Data

Data describing the pharmacokinetics of OTC sleep aids are scarce; available data are limited to diphenhydramine. Because older adults have slower metabolisms than younger adults, medication half-lives tend to be prolonged in older adults and data suggest this is the case for diphenhydramine. Simons et al. reported that diphenhydramine has a half-life of 9.2 hours in adults (mean age 31.5 years), rising to 13.5 hours in elderly adults (mean age 69.4 years). The half-life was reported to be 5.4 hours in children (mean age 8.9 years).²⁷ However, another study found the half-life to range from 4.1 hours in young adults to 7.4 hours in older adults.²⁸ A review article published in 1986 found a

reported half-life range from 3.3 hours to 9.3 hours for diphenhydramine.²⁹

It is important to note that these studies were published in the 1980s and 1990s and did not employ the same techniques to establish pharmacokinetic parameters that are accepted today. Therefore, the actual half-life of these products remains unclear. However, it appears that for some individuals, there still may be a substantial amount of circulating diphenhydramine when they awaken in the morning which could cause dizziness or falls, and this appears to be more likely for older adults.

Data on the Efficacy and Safety of OTC Sleep Aid Use

Decades of use of first-generation antihistamines for the treatment of allergic disorders demonstrate that these agents are sedating. In fact, these agents are often referred to as “sedating antihistamines.” However, whether this effect translates into efficacy for treating occasional sleeplessness or chronic insomnia remains unclear. Because diphenhydramine and doxylamine were marketed before the FDA began the OTC drug monograph process in 1972, these drugs were grandfathered in and not subject to the same requirements for randomized controlled trials that exist today for drugs going through a New Drug Application approval process.³⁰

The risks and benefits of OTC sleep aids for the treatment of disturbed sleep in elderly adults have not been carefully examined in randomized controlled trials. The few available data on doxylamine may not be fully relevant for assessing efficacy or safety for use by older adults to manage sleep disturbances.

A study published by Rickels et al. in 1983 provides some data that support the efficacy of diphenhydramine. In this 2-week cross-over study, patients received both diphenhydramine 50 mg at bedtime and placebo for 1 week each. Diphenhydramine was found to significantly improve various sleep parameters, including sleep latency and reports of feeling more rested the following morning. Patients reported that they preferred the diphenhydramine to the placebo despite experiencing more side effects.³¹

The Rickels study is the most positive study to support the use of diphenhydr-

amine as a sleep aid; other published data are less encouraging. Morin et al. conducted a randomized, parallel-group study in 9 sleep disorders centers throughout the United States to compare the dietary supplement valerian with diphenhydramine and placebo.³² In this study, both valerian and diphenhydramine produced some improvements in subjective sleep parameters, but few group comparisons with placebo reached statistical significance. Sleep efficiency was significantly improved with diphenhydramine compared with placebo, but there was no significant difference in sleep latency or overall sleep time. Diphenhydramine did not differ significantly from valerian.³²

Diphenhydramine has been found to have negative residual effects in older adults. Meuleman et al. studied diphenhydramine in a nursing home population. Diphenhydramine improved sleep latency, but there were no other significant benefits compared with placebo. Tests of psychomotor and cognitive function found significant impairments compared with placebo for several measures of neurologic function.³³ In addition, Zhang et al. used positron emission tomography to assess the residual sedating effects of diphenhydramine and found a significant next-day “hangover” effect.³⁴

Additional concerns regarding the use of diphenhydramine relate to its anticholinergic activity. Anticholinergic effects include blurred vision, constipation, dry mouth, urinary retention, and risk of increased intraocular pressure in patients with narrow-angle glaucoma. According to the Beers Criteria for potentially inappropriate medication use in older adults, first-generation antihistamines should generally be avoided in older adults due to their anticholinergic activity. Regarding these agents, the criteria state: “Highly anticholinergic; clearance reduced with advanced age, and tolerance develops when used as hypnotic; greater risk of confusion, dry mouth, constipation, and other anticholinergic effects and toxicity.” (The criteria do note that use of diphenhydramine in special situations, such as acute treatment of severe allergic reaction, may be appropriate.)³⁵

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Panel Discussion With Stakeholder Input

Following these presentations, panelists participated in a lively moderated discussion. The panel members were James Owen, PharmD, BCPS; Deborah DiGilio, MPH; and Joan Enstam Baird, PharmD, CGP, FASCP. Steven Albert, PhD, served as the moderator.

Opportunities to Utilize Pharmacists

Dr. Owen, Associate Vice President of Practice and Science Affairs at the American Pharmacists Association, described opportunities to engage community pharmacists to improve OTC sleep aid use. He reported that because pharmacists are accessible health care providers in the community, they frequently interact with patients who purchase OTC products and have questions about their health conditions. Pharmacists can help patients identify whether their conditions are self-treatable, assist patients with product selection, and educate them to use products appropriately. Pharmacists also can collaborate with interdisciplinary teams that include both primary care providers and sleep specialists.

Dr. Owen recommended that stakeholders could leverage community pharmacists to provide education and information as well as coordinate OTC sleep aid use with prescription medication lists. Additionally, pharmacists could refer patients to other health care providers when appropriate.

Many pharmacists are involved in the provision of MTM services. Designed to optimize therapeutic outcomes for individual patients, MTM services include medication therapy reviews, medication reconciliation services during transitions of care, pharmacotherapy consultations,

health and wellness programs, and many other clinical services. Many older adults receive coverage for these services, including a yearly medication review, through their Medicare Part D plans. Dr. Owen recommended greater utilization of MTM services by older adults, and supported collection of data regarding OTC sleep aid use during these visits. Making questions about use of OTC products a standard part of MTM visits and integrating this information in electronic health records that are shared with other health care providers could enhance collaboration among health care team members and elevate awareness of patients’ complete medication intake.

Educational campaigns are needed to encourage pharmacists to assume this role. Additionally, pharmacists could be involved with educating patients to avoid potentially risky behaviors related to OTC sleep aid use. Pharmacist training on patient interviewing and communication techniques focused on OTC sleep aid use would support appropriate messaging and help reach the target population.

Dr. Baird, Director of Clinical Affairs for the American Society of Consultant Pharmacists, described opportunities for consultant pharmacists working in long-term care (LTC) facilities to improve OTC sleep aid use when performing medication reviews for patients. Dr. Baird recommended that all consultant pharmacists scrutinize the medical records of LTC patients for OTC sleep aid use. She suggested that if diphenhydramine use is identified in LTC facility residents, then consultant pharmacists should work with the staff to implement other approaches to promote sleep health.

Dr. Baird underscored the risks of falls in LTC patients receiving diphenhydramine as one of the reasons why OTC sleep aids

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should be used with great caution in this population. Furthermore, she noted that LTC residents have a high use of several anticholinergic medications including tricyclic antidepressants and medications for the treatment of overactive bladder. The combined anticholinergic burden of these agents along with diphenhydramine increases the risk of adverse events in these patients.

Finally, Dr. Baird noted that many LTC residents can benefit from nonpharmacologic interventions, particularly sleep hygiene.

Ms. DiGilio, Director of the American Psychological Association Office on Aging, called for more attention to psychological interventions for sleep problems. Such interventions have minimal likelihood for producing undesirable side effects and they avoid the risks of drug interactions and other issues related to changing pharmacokinetics in older adults. She reported that cognitive behavioral therapy for insomnia in older adults consistently shows positive results. For example, she cited a review of psychological interventions published by McCurry et al. in 2007. This study found that two treatments—multicomponent cognitive behavioral therapy and sleep restriction/sleep compression therapy—were beneficial for treating insomnia in older adults.²

Due to the high rates of comorbidity of sleep disorders with psychological disorders, and the bidirectional interaction among the disorders, Ms. DiGilio highlighted the importance of sleep health for the well-being of older adults. She emphasized the need for interdisciplinary teams to collaborate to address patients' sleep issues holistically, including referrals to sleep specialists when appropriate.

Group Discussion

Following the expert presentations and panel discussions, Summit participants discussed the issues. Many of the Summit participants asserted that diphenhydramine should not be used routinely for sleep in elderly patients. They noted that in some carefully selected cases it may be appropriate, but believe that chronic use should be avoided. They also acknowledged that available data indicate there is a sizeable population of older adults who are taking diphenhydramine inappropriately. However, the participants conceded that if such a large group is using diphenhydramine in this manner, these older adults must feel that they are obtaining a benefit from it. The Summit participants noted that more research was needed to explore these issues and learn why patients are taking the medication (e.g., Are they taking combination products to manage pain at night? Do they have anxiety and take medication to help them relax?).

The group thought that sleep health is not regarded with enough concern by patients, health care providers, or the public and policy makers. Participants also challenged the notion that poor sleep should be regarded as an acceptable consequence of aging. If half of the older population experiences poor sleep, it indicates that the other half does not. Exploring reasons for these differences would be an interesting research topic.

The lack of data to inform evidence-based decision making was cited as an important area for improvement. Participants were surprised that there are not good data to support the efficacy of diphenhydramine or clearly establish its half-life. The fact that diphenhydramine's association with sedation did not directly translate to robust efficacy for sleeplessness was an important point for many of the participants.

Summit participants also discussed information related to diphenhydramine's anticholinergic burden. They noted that health care providers may not be familiar with the magnitude of the anticholinergic effect of diphenhydramine. They agreed that it would be important

to educate patients about this issue, but acknowledged that total anticholinergic burden is a complicated concept for patients, especially those who have mild cognitive impairment. Development of a strategy is needed to communicate this concept to nonprofessionals so they can know when to change their behavior to reduce adverse effects. Participants suggested development of a mechanism for pharmacies to track patients purchases and resulting anticholinergic burden.

Information gaps were another key focus. The group agreed that patients are generally not aware of the risks of OTC sleep aids, and regard the agents as safe because of their availability without a prescription. Other knowledge gaps pertaining to diphenhydramine that were areas of concern included appropriate dosing and duration, insomnia versus sleep disturbance, and risks for falls, delirium, and drug interactions.

Strategies to Improve Safe Use of OTC Sleep Aids—Now and in the Future

To improve OTC sleep aid use, Summit participants called for the creation of a multidisciplinary and multi-organizational “safe sleep coalition” to develop and implement research, education, and policy initiatives. In addition to The Gerontological Society of America, other organizations that could be involved in the coalition include the American Pharmacists Association, the American Society of Consultant Pharmacists, the Consumer Healthcare Products Association, and the National Sleep Foundation.

Summit participants recommended that the coalition aim to partner with other organizations such as AARP and patient advocacy groups that have the capacity to communicate with target populations. (Additionally, AARP's broad constituency may enable them to have more of an effect than sleep researchers on influencing policy.) Other possible partners for the coalition include organizations that have an interest in outcomes associated with improved sleep health (e.g., National Highway Traffic Safety Administration,

American Automobile Association, Area Agencies on Aging) as well as local institutions and professional societies that could be integral for implementing events and initiatives. Involving the media in coalition initiatives was seen as an important strategy for communicating messages.

The group suggested a wide range of multifaceted interventions to support overall program goals in each area.

Research Initiatives

A number of research initiatives were proposed to address knowledge gaps related to sleep health and sleep aid use in older adults. Potential topics for research that were discussed include:

- Characteristics of patients with intermittent sleeplessness compared with insomnia.
- Definitions for sleep disturbances that do not meet diagnostic criteria for insomnia.
- Patients' beliefs regarding occasional sleeplessness and insomnia.
- Utility of behavioral treatments.
- Utility of alternative treatment strategies.
- Comparisons among behavioral and pharmacological interventions.
- Epidemiologic data regarding OTC product use to:
 - Better characterize who uses the products, how they are used, and why they are used.
 - Determine anticholinergic burden in patients using these products.
 - Assess prevalence of therapeutic duplication and other drug-drug interactions.
- Impact of sleep aids on next-day behavior and function.
- Impact of sleep aids on accidents, falls, etc.
- Effect of aging on response to OTC sleep aids, including pharmacokinetic parameters during short-term and chronic use.
- Identification of educational messages regarding appropriate sleep aid use.
- Effect of diphenhydramine on the ability of older adults to drive.
- Identification of best practice models.

Summit participants also called for the development of tools to support appropriate sleep aid use. Such tools could be based on research and developed with the guidance and consensus of expert panels. Suggested tools include:

- Educational materials for patients to identify their risk for sleep issues.
- Screening questionnaires to assist patients in evaluating their sleep issues and determine when to seek medical care.
- Materials for health care providers to use to identify and explore sleep health issues.
- Print materials, software programs, or Internet-based tools for assessing anticholinergic burden from sleep aids and other anticholinergic drugs.

“To improve OTC sleep aid use, Summit participants called for the creation of a multidisciplinary and multi-organizational ‘safe sleep coalition’ to develop and implement research, education, and policy initiatives.”

To conduct research, participants suggested the use of existing databases when possible. For example, the National Health and Nutrition Examination Survey from the National Center for Health Statistics and Kantar Health's National Health and Wellness Survey may be useful sources of data for retrospective analyses. Surveys of patients, caregivers, and health care providers also could provide valuable information. To support future research, the group recommended development of sleep health-related questions and having them incorporated in appropriate surveys.

Participants suggested using pharmacies as a surveillance point for post-marketing

data collection. Information could be gathered for analysis from counseling and MTM encounters. Additionally, participants proposed using community pharmacy loyalty cards to track purchases. They recommended exploring the feasibility of linking data from loyalty cards to prescription dispensing data to assess anticholinergic burden. They also suggested use of point-of-purchase longitudinal studies, whereby individuals are offered study enrollment when they purchase an OTC sleep aid and agree to provide information on various issues and outcomes in the future.

The need to develop new OTC sleep aids that are safe and effective for older adults was emphasized by participants and they called upon manufacturers to conduct more research in this area.

Education Initiatives

Although there are many important gaps in knowledge, participants noted that available data have not been widely disseminated and there is a need for a multipronged educational strategy targeted to health care providers as well as patients and caregivers. Furthermore, there is a need for general education on the value of sleep and the use of OTC sleep aids.

Education to Patients and Caregivers

Participants recommended educational initiatives that could reach the target population in a number of ways. They suggested creation of clear and concise patient-friendly educational materials on a variety of topics such as:

- How to speak with your health care provider about sleep.
- How to read an OTC product label.
- Risks of combining multiple OTC products or using OTCs together with prescription medications.
- Minimizing anticholinergic burden.
- List of do's and don'ts for OTC sleep aid use.
- Good sleep hygiene practices and cognitive behavioral therapy.
- Differences between prescription, OTC, and dietary supplement products.

Tools for communicating this information to patients include brochures, 1-page information sheets, checklists, diaries, and

“Through a series of presentations and discussions, participants identified opportunities for improving education about this important topic among health care providers, patients, and caregivers, and identified many potential research opportunities and policy initiatives to promote sleep health.”

posters. In addition to making materials available for distribution by health care providers and local partner institutions, participants recommended placing selected materials in pharmacy aisles next to OTC sleep aids. Other direct-to-consumer strategies could include printing messages on register receipts when patients purchase OTC sleep aids.

While recognizing that older adults are not as adept at using the Internet as younger adults, participants recommended that coalition partners could create a website that would serve as a repository for information on OTC sleep aid use in older adults. The information could be targeted to both older adults and their caregivers and could include education on various interventions including prescription medications, OTC products, dietary supplements, cognitive behavioral therapy, and sleep hygiene. Brochures, checklists, and other tools could be posted to the website as pdfs. In addition to posting newly developed resources, the website could include links to other existing information and resources. (The website also could be used to conduct surveys or recruit individuals for additional research initiatives.)

Education to Health Care Providers

Key areas for professional education include topics on the importance of sleep, issues associated with poor sleep, and available treatment options. Understanding how to evaluate and address the anticholinergic burden of medications was seen as a critical area for education.

Education could be disseminated to health care providers through continuing education programs, articles, and special issues in professional journals and publications. Many of the tools that are useful for

patients, such as brochures, 1-page information sheets, and checklists also could be targeted to health professionals.

Summit participants recommended developing a package of educational information to be integrated into the curricula of health professional schools to support understanding of sleep health and use of OTC sleep aids in older adults. The group also suggested that professional organizations could develop practice guidelines to support appropriate clinical practices.

Policy Initiatives

Summit participants recommended several policy initiatives to support sleep health and appropriate sleep aid use. For example, the coalition could create a national screening day to promote community screening events focused on sleep health to attract media attention and support the launch of educational initiatives. Tools that are developed through the coalition could be promoted and distributed through these events.

The group also recommended efforts to make sleep a quality indicator for groups such as the National Committee for Quality Assurance and the Joint Commission. The impact of sleep on a wide range of health outcomes makes this a logical step. Furthermore, because many financial incentives for health care providers are tied to quality measures, this strategy would be an important mechanism to drive behavior.

Another policy strategy would be to include assessments of sleep health in the annual wellness visits that are now available through Medicare under the Affordable Care Act. The group recommended collaboration with the Centers for Medicare and Medicaid Services to support this change. They encouraged

integration of sleep health in office intake forms to make it a regular part of patient care processes for both Medicare patients and others. They also recommended further exploration of the potential of MTM services to be used to address sleep health issues, including risks of anticholinergic burden and OTC product use.

Finally, participants suggested modeling sleep health efforts on other successful campaigns. For example, the campaign to increase awareness of the importance of pain in the 1990s and 2000s promoted evaluating pain as “the fifth vital sign.” Similarly, sleep could be promoted as “the sixth vital sign.” They also recommended the use of public service announcements modeled on those used to create awareness about annual influenza vaccinations.

Summary

OTC sleep aid use by older adults is widespread, however available evidence suggests that these agents offer little benefit and carry substantial risks. During the 2013 National Summit on OTC Sleep Aids and Sleep Health in Older Adults, participants worked to increase understanding of sleep health and OTC sleep aid use in older adults. Through a series of presentations and discussions, participants identified opportunities for improving education about this important topic among health care providers, patients, and caregivers, and identified many potential research opportunities and policy initiatives to promote sleep health. The information emerging from this meeting may be used to guide a variety of initiatives intended to support safe and effective management of sleep disturbances in older adults.

The Gerontological Society of America provides information and resources related to its work on OTC product use and sleep health at www.geron.org/otc. This webpage contains white papers and handouts from the recent summits, a webinar, and the current issue of the *WHAT'S HOT* newsletter on OTC sleep aid use by older adults. Information about these projects also will be disseminated at a press briefing during the 2013 Annual Scientific Meeting.

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