



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

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

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WHITE PAPER / 2014 UPDATE



Introduction

The use of over-the-counter (OTC) sleep aids by older adults and the implications for the health and well-being of this population presents several complex issues. One out of every eight Americans is 65 years of age or older—a population greater than the *total* population of Canada.¹ The aging baby boomers are turning 65 years old at a rate of 10,000 people every day, dramatically increasing the proportion of the population that has passed this milestone. As adults live longer, it becomes increasingly important to provide the right types of care to enable older adults to optimize their quality of life.

Difficulty getting a good night's sleep increases with age and is common in older adults. Many older adults and their caregivers turn to OTC sleep aids to promote sleep. However, these products are indicated only for occasional difficulty with sleep, and their safety and efficacy in older adults are not well studied. Concerns exist regarding the impact of available OTC sleep aids on the health and safety of older adults, especially if these products are used chronically or in combination with other medication therapies or alcohol.

To engage national stakeholders in a discussion of safe and effective use of OTC sleep aids, The Gerontological Society of America (GSA) has convened a multidisciplinary workgroup and two national summits, all of which have been supported by Pfizer.

An earlier effort, **Promoting Safe and Effective Use of OTC Medications Among Older Adults**, held in partnership with the Consumer Healthcare Products Association in April 2013, looked more broadly at these

issues. Presentations at this conference revealed that there is surprisingly little information in the peer-reviewed literature about how older adults choose and use nonprescription medications. Identified gaps in knowledge include:²

- How does OTC medication use differ from prescription medication use?
- How do attitudes surrounding choice and pattern of use of OTC medications change as a person ages?
- How do different expectations for OTC and prescription medication use affect the behavior of consumers and providers?
- Compared with prescription medications, is it easier or more difficult to ensure safe and effective use of OTC products?

The workgroup on OTC Medication Behaviors of Older Adults proposed several next steps to address these issues:

1. Work with the National Institutes of Health (NIH) to identify funding announcements on OTC medication use in older adults and develop an NIH Request for Applications.
2. Ask gerontology journals to develop special issues and calls for papers on OTC medication use.
3. Improve documentation in national surveys of older adults or in the Centers for Disease Control and Prevention Behavioral Risk Factor Surveillance System.
4. Attempt to optimize standardized U.S. Food and Drug Administration (FDA) labeling of OTC medications so information is presented in a format that is easily accessible to the aging population.

Findings from this meeting were published in a white paper and in a recent article in *The Gerontologist*.³ This publication addressed additional key issues including sleep health literacy and OTC behavior, decision making and OTC sleep medication use among older adults, the role of clinicians in OTC medication behavior, older adult OTC behavior and family care, and the use of technology to promote optimal use of OTC medications.

A national summit, held by GSA in October 2013, focused specifically on OTC Sleep Aids and Sleep Health in Older Adults. This summit began with participants discussing their perceptions regarding these issues using a nominal group process. These conversations were followed by a review of available data on sleep health and OTC sleep aids in older adults. The summit continued with a panel discussion on opportunities to improve safe use of these products and concluded with the development of strategies to address the various issues raised during the summit.

The group suggested a wide range of research, education, advocacy, and policy initiatives to support the overall goal of improving sleep aid use by older adults. Dozens of potential research topics related to sleep health and sleep aid use were identified. Although there are many important gaps in knowledge, summit participants noted that available data have not been widely disseminated; they recommended a multipronged education strategy that targets patients, family caregivers, and health care providers. In addition, summit participants called for the development of tools to support appropriate sleep aid use. Finally, the group suggested several policy initiatives to support sleep health and recommended modeling sleep health efforts on other successful public health campaigns.

A follow-up national summit, convened by GSA in June 2014, retained the focus on OTC Sleep Aids and Sleep Health in Older Adults, and provided updates and in-depth analysis of key issues raised during the April and October 2013 meetings. Information from the June 2014 summit is presented in this white paper.



Tweets From #OTCSleep

@sleepfoundation to launch Sleep Health Journal in 2014—to accompany its annual sleep polls: <http://sleepfoundation.org/sleep-polls-data/sleep-in-america-poll/2014-sleep-in-the-modern-family/...> #OTCSleep

Aging and Sleep Disturbance

Sleep is a biological imperative. Most people spend approximately one third of their lives sleeping. David M. Cloud, MBA, chief executive officer of the National Sleep Foundation (NSF) discussed findings from the national Sleep in America Poll. Each year the poll focuses on a different topic related to sleep. For example, the 2014 poll, Sleep in the Modern Family, looks at how the use of electronics affects sleep.

The amount of sleep needed for optimal health varies somewhat from person to person, and there is no specific amount that applies universally. Some individuals may require 9 hours of sleep each night to function at their best, while others may be able to perform optimally after only 7 hours of sleep. However, available data indicate that many adults operate under a sleep deficit that results from variety of causes. Data from the NSF reveal that Americans sleep an average of 6 hours and 31 minutes each night, but report that they need an average of 7 hours and 13 minutes to function at their best. National efforts are underway to develop recommendations for the appropriate amount of sleep time at every life stage.

A good night's sleep is elusive for many adults. Data indicate that 50 million to 70 million Americans have chronic or occasional sleep disturbance.⁴ Furthermore, 28 % of adults report frequent insufficient sleep.⁵ While occasional sleeplessness lasting a few weeks is common, many people have sleep problems that persist for much longer. Insomnia can last for months or years.⁶

Sleep may be disrupted for a variety of reasons including extrinsic and intrinsic factors. Extrinsic factors include a lack of periodic environmental stimuli (e.g., lack of exposure to sunlight), inactivity, and ambient factors such as excessive noise and light. In institutional settings, nursing care activities throughout the night can disrupt sleep. Intrinsic factors include patients' illnesses such as dementia, depression, or other medical illnesses and their associated symptoms (e.g., pain). Many medications used to manage conditions that increase in prevalence with advancing age also can interfere with sleep. Age-related changes in sleep are another intrinsic factor. These changes



Tweets From #OTCSleep

Check out this list of
drugs & substances
associated with
sleeplessness.
#OTCSleep Have the
sleep conversation.

can include alterations in the internal circadian clock as well as an increase in the prevalence of primary sleep disorders.

The prevalence of disturbed sleep has been shown to increase with age. Aging interacts with genetic susceptibility to sleep problems to increase the risk of sleep disturbances. Other contributing factors include declining health, medications, institutionalization, stress, and normal changes in circadian rhythms and sleep depth associated with aging.^{7,8}

The 2003 Sleep in America Poll focused on Sleep in Aging, and found that 44 % of older adults experience disturbed sleep at least a few nights each week. Another study of reports from more than 9,000 adults older than age 65 years found that many reported symptoms of sleep disturbance including difficulty initiating or maintaining sleep (43 %), nocturnal waking (30 %), insomnia (29 %), daytime napping (25 %), waking too early (19 %), and waking without feeling rested (13 %).⁹ While symptoms of poor sleep overlap, results from surveys suggest that sleep disturbance is common among older adults.

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.⁴ Alarmingly, in one survey, 4.7 % of adults reported falling asleep while driving in the past 30 days.⁵

The healthiest of older adults experience much less sleep disturbance than those who are not as healthy.^{9,10} The more chronic medical conditions individuals have, the worse their sleep will be.¹¹ 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 diseases, mood disorders, cognitive decline, pain conditions, and neurologic disorders.¹² Comorbid medical and psychiatric conditions likely contribute to the development of sleep disturbances more than aging contributes.

Rates of disturbed sleep are even higher among individuals with dementia and their family caregivers.¹³ Recent research indicates that there may be a bidirectional relationship between sleep loss and dementia. For example, sleep deprivation increases amyloid- β in the brain, and can result in chronic accumulation of amyloid- β . (Accumulation of amyloid- β in the brain appears to initiate a cascade of key events in the pathogenesis of Alzheimer's disease.¹⁴) As amyloid- β accumulates, increased wakefulness and altered sleep patterns develop.¹⁴

The impact of poor sleep, especially nighttime wandering, in individuals with dementia is a major contributing factor to family caregivers' decisions to institutionalize older adults. In one study of 1,855 elderly men, insomnia was the strongest predictor of both mortality and nursing home placement, compared with age, problems with activities of daily living, self-assessed health, income, cognitive impairment, depression, and whether respondents were living alone.¹⁵

In elderly adults, the effects of poor sleep extend even further. Documented impacts of poor sleep in elderly adults include:^{16–20}

- 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).

- 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 pervasive impact on health and well-being, sleep difficulties in older adults are under-recognized in medical practice and as a result undertreated. A survey conducted by Ancoli-Israel and Roth found that adults who reported having insomnia were unlikely to discuss it with their health care provider. Only 5 % of respondents said that insomnia was a primary reason for visiting a health care provider, and 26 % said it was a secondary reason. Fully 69 % of respondents never discussed their sleep disturbances with a health care provider.²¹ These data point to the need for health care providers to be more proactive about gathering information about patients' sleep health.

Older Adults, OTC Sleep Aids, and Other Strategies for Addressing Sleep Disturbance

OTC medications are indicated for treatment of occasional sleeplessness, not insomnia. All available OTC sleep aids are first-generation antihistamines (i.e., diphenhydramine and doxylamine), which are approved by the FDA for occasional sleeplessness. 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 insomnia), many patients, including older adults, use them on a regular basis.

Beyond FDA-approved therapies, several dietary supplements, including valerian, tryptophan, and melatonin are used as sleep aids. In general, evidence to support their use is lacking and questions remain about their safety, especially when used chronically.²² Notably, dietary supplements do not receive the same level of scrutiny

from the FDA that OTC and prescription products 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.²³ In other surveys, up to 28 % of patients 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



Tweets From #OTCSleep

“The Brain ‘takes out the trash’ while we sleep” (via @nytimes):
<http://mobile.nytimes.com/2014/01/12/opinion/sunday/goodnight-sleep-clean.html?referrer=&r=0...> #OTCSleep

increase daytime sleepiness and promote future sleep disturbances.²³

Evidence suggests that nonpharmacological treatments for insomnia, such as cognitive behavioral therapies, relaxation techniques, or exercise, are as effective in older adults as they are in other age groups. More research is needed on the efficacy of nonpharmacologic treatments for occasional sleep disturbance, as opposed to insomnia, to determine if these approaches are also equally effective in older and younger adults.

By contrast, patients who meet criteria for insomnia should not use OTC medications and should instead consult their health care provider. After assessing the many sources of insomnia, which

may include pain, apnea, or neurologic conditions, physicians may prescribe prescription hypnotic therapies, such as benzodiazepine receptor agonists, other sedative-hypnotics, and melatonin receptor agonists.

Data on 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 in the past year.²³

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, and peak concentrations tend to be higher in older adults. Data suggest this is the case for diphenhydramine as well. 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).²⁴ However, a study by Scavone et al. found the half-life to range from 4.1 hours in young adults to 7.4 hours in older adults.²⁵ A review article published in 1986 found a reported half-life range for diphenhydramine from 3.3 hours to 9.3 hours.²⁶

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, 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; this appears to be more likely for older adults. Additional data evaluating the pharmacokinetics and pharmacodynamics of diphenhydramine

are needed. In particular, age, sex, and food effects need to be further studied in the older population taking diphenhydramine, and the potential effects of accumulation on cognition and activities such as driving warrant evaluation.

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 insomnia remains unclear. Because diphenhydramine and doxylamine were marketed before the FDA began the OTC drug monograph process in 1972, these drugs were “grandfathered” and not subject to the same requirements for randomized controlled trials that exist today for drugs going through a New Drug Application approval process.²⁷

The risks and benefits of OTC sleep aids for the treatment of disturbed sleep in elderly adults have not been systematically examined in randomized controlled trials. No published controlled trials describe the use of doxylamine for the treatment of sleeplessness.

A study published by Rickels et al. found that diphenhydramine significantly improved patient reports of disturbed sleep, including sleep latency and reports of feeling more rested the following morning. Patients reported that they preferred diphenhydramine to the placebo despite experiencing more side effects.²⁸ This is the most positive published trial supporting the use of diphenhydramine as a sleep aid; other published data using both patient reports and objective measures of sleep are less positive.²⁹

Diphenhydramine has been found to have negative residual effects in older adults. For example, in a nursing home population, Meuleman et al. found significant psychomotor and cognitive function impairments with diphenhydramine compared with placebo for several measures of neurologic function.³⁰ While this study found that

diphenhydramine improved sleep latency, there were no other significant benefits compared with placebo.

Additional concerns about the use of diphenhydramine relate to its anticholinergic effects. 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, such as diphenhydramine, 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.)³¹

National Findings on Sleep Disturbance and OTC Sleep Aid Use Among Older Adults

The National Health and Wellness Survey (NHWS) is an Internet-based self-reported general health survey of adults 18 years of age and older. Approximately 75,000 adults participated in the 2013 wave of the survey, which is projected to reflect the total U.S. adult population of 233.8 million.^{32,33}



Tweets From #OTCSleep
#Pharmacists can
communicate good
sleep practices and the
differences and proper
use of OTC, dietary
supplements and Rx
sleep aids. #OTCSleep

Symptoms of Sleeplessness

Symptoms of sleeplessness were defined as having at least one of the following:

- **Difficulty falling asleep.**
- **Waking during the night and not being able to get back to sleep.**
- **Waking up several times during the night.**
- **Waking up too early (e.g., before the alarm clock).**
- **Poor quality of sleep.**

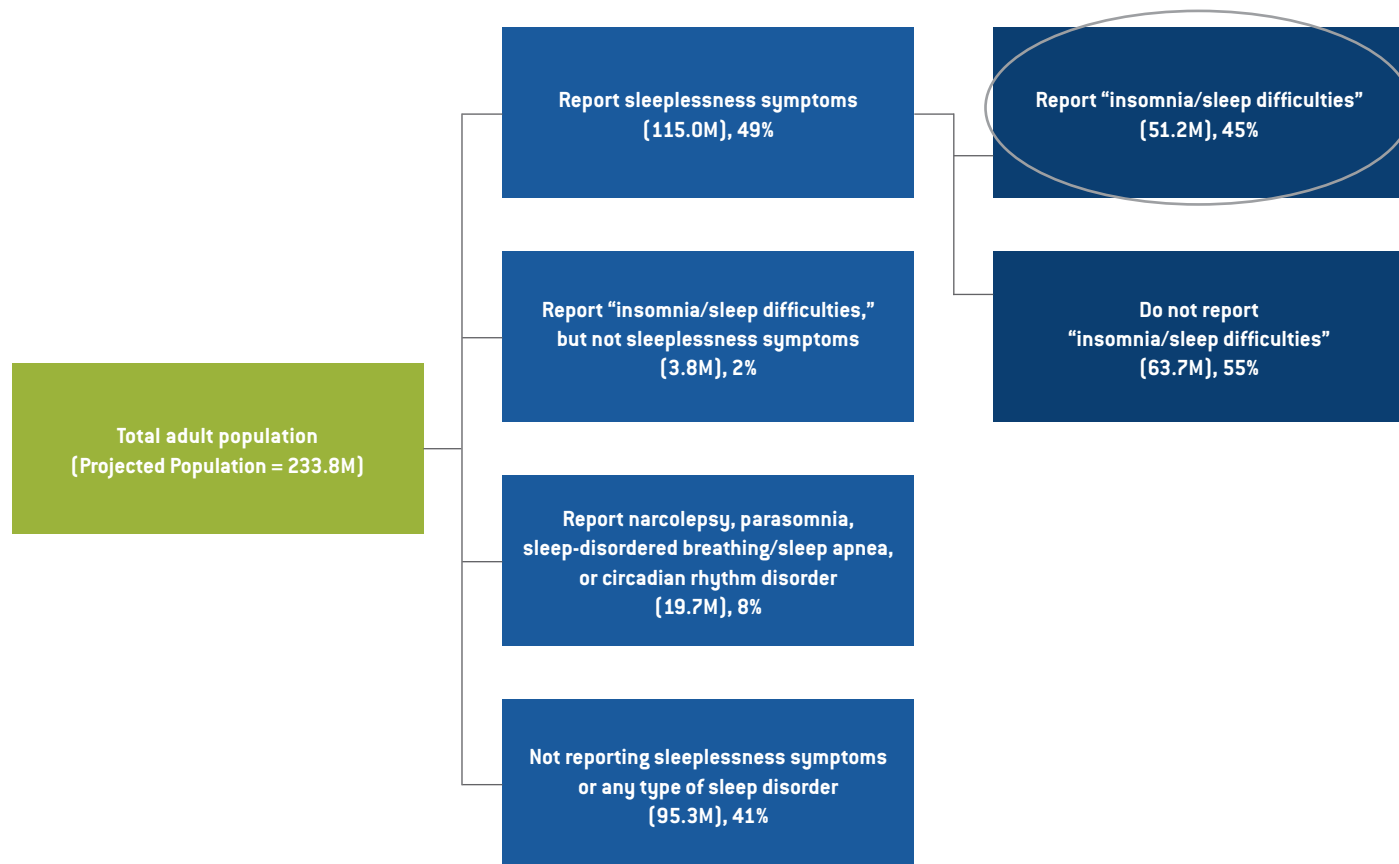
Michael Toscani, PharmD, research professor at the Ernest Mario School of Pharmacy at Rutgers University, and Greg O'Neill, PhD, director of the National Academy on an Aging Society, reported data from the NHWS focusing on sleep characteristics of older adults that have not yet been published.

Participants in the NHWS reported their experiences regarding various sleep issues, including whether they have “symptoms of sleeplessness” (see box) and whether they experience or have been diagnosed with “insomnia/sleep difficulties.” The survey also asked participants whether they had sleep disorders such as narcolepsy, parasomnia, sleep-disordered breathing/sleep apnea, and/or circadian rhythm disorder; those who responded “yes” were excluded from the sleeplessness analysis.

Approximately 49% of the participants in the NHWS reported that they experience symptoms of sleeplessness. An additional 2% of the surveyed population did not report regularly experiencing these symptoms, however they did report experiencing or being diagnosed with insomnia/sleep difficulties (Figure 1). Extrapolating to the general population, 115 million individuals in the United States experience symptoms of sleeplessness, and an additional 3.8 million have been diagnosed with insomnia/sleep difficulties.

Interestingly, not all individuals who reported symptoms of sleeplessness also said they had insomnia/sleep difficulties, a measure of self-reported sleep disturbance likely to be clinically significant. Among those reporting sleeplessness symptoms:

Figure 1. National Health and Wellness Survey Study Population: Sleep Medication Sub-Study



Source: Reference 33.

- 55 % report no experience of insomnia/sleep difficulties.
- 45 % report experiencing or having been diagnosed with insomnia/sleep difficulties.

Among NHWS respondents with symptoms of sleeplessness who also report insomnia/sleep difficulties, 12 % were 65 years of age and older. Extrapolated to the general population, these findings indicate that 6.3 million older adults (roughly 1 in 6 older adults) fall into this category.

These data suggest that symptoms of sleeplessness for a large number of adults may be mild or severe but are not considered a problem. It is possible that older individuals mistakenly believe that disturbed sleep is a normal part of aging and hence do not report it as

a problem. The differences in reported rates of sleeplessness compared with sleep difficulties are important to consider when conducting research in this field. For example, the rates of specific symptoms varied depending on whether insomnia/sleep difficulties were reported (Table 1). Thus, defining sleep disturbance is a complicated task, making it challenging to compare data across sleep studies that use varying methodologies and questions to identify individuals with sleep disturbances.

Researchers further investigated the use of various sleep aids by this population.³³ Prescription sleep aids were used by 25 % of adults 65 years of age and older with insomnia/sleep difficulties. The most commonly used sleep aid was zolpidem, followed by trazodone (off-label usage), and alprazolam (off-label usage).

In the NHWS, OTC sleep aids and herbal products were used by 37 % of adults 65 years of age and older with insomnia/sleep difficulties.³³ The most commonly used OTC/herbal product was melatonin, followed by “Tylenol products” (which may contain diphenhydramine), and “Benadryl/diphenhydramine.” Diphenhydramine or doxylamine (referred to as DPH/DOX by the researchers) was an ingredient in several other OTC sleep aids that this study population reported using. Overall, 18 % of adults aged 65 to 74 years, and 17 % of adults aged 75 years and older were using DPH/DOX. Extrapolating to the general population, approximately 1.1 million adults 65 years of age and older in the United States are using one of these products as sleep aids.

Product labeling for diphenhydramine and doxylamine advises that patients

Table 1. Reported Rates of Sleeplessness Symptoms

Symptom	Adults With Sleeplessness Symptoms	Adults Reporting Insomnia/Sleep Difficulties
Difficulty falling asleep	56%	73%
Waking during the night and not being able to get back to sleep	42%	54%
Waking up several times during the night	43%	51%
Waking up too early	38%	41%
Poor quality of sleep	34%	45%

Source: Reference 33.

Table 2. Frequency of Diphenhydramine (DPH) and/or Doxylamine (DOX) Use in Past Month Among Adults with Sleeplessness and Reporting Insomnia/Sleep Difficulties, Who Use DPH/DOX

Days per Month	18–64 Years of Age (Projected Population= 7.8M)	65–74 Years of Age (Projected Population= 676K)	75 Years of Age and Older (Projected Population = 424K)
0–14 days	79% (6.1M)	63% (428K)	53% (225K)
15–21 days	10% (770K)	12% (80K)	12% (51K)
22+ days	11% (847K)	25% (167K)	35% (148K)

Source: Reference 33.

should stop use and consult a health care provider if sleeplessness persists for more than 2 weeks. However, a large number of older adults are using these medications chronically. When older adults using DPH/DOX were asked how many times they used these products, more than a quarter of older adults (including more than a third of those age 75 and older) responding to the NHWS reported using them 22 or more days in the past month (Table 2). The number of older adults using DPH/DOX frequently was much higher than among those younger than 65 years of age. Only approximately one third of those using OTC sleep aids or herbals reported that they were satisfied with the product. Importantly, 33% of those 65 to 74 years of age and 44% of those older than 75 years of age were using at least one other anticholinergic medication.

Furthermore, product labeling for diphenhydramine and doxylamine includes a warning to avoid concomitant use of alcohol. However, 65% of adults aged 65 to 74 years and 54% of those aged 75 years and older reported using both DPH/DOX

and alcohol. (In comparison, 76% of adults 18 to 64 years of age who use DPH/DOX reported using alcohol.) Among individuals using both DPH/DOX and alcohol, 11% of those 65 to 74 years of age and 35% of those 75 years of age and older reported using alcohol on a daily basis.

These data illustrate that off-label sleep aid use by older adults is common, and there is a critical need to provide education to these patients regarding safe use of OTC sleep aids.

Communicating With Pharmacists About Sleep Disturbance and OTC Sleep Aids

Pharmacists are uniquely positioned to provide education to patients purchasing OTC sleep aids, and they may be the only health care providers who interact with patients regarding these OTC purchases.

To address the need for education to support appropriate OTC use by older adults, GSA is developing online training specifically for pharmacy professionals,

called Silver Market Training Modules.

Michael V. Vitiello, PhD, professor of psychiatry and behavioral sciences at the University of Washington, described these efforts, with a focus on training to address sleep issues for older adults.

Silver Market Training Modules are based on GSA's 2012 publication *Communicating With Older Adults: An Evidence-Based Review of What Really Works*. Each module runs less than 25 minutes and offers expert information and time-tested techniques to help pharmacists and pharmacy technicians work efficiently and respectfully with older adults.

Currently available modules include:

- *Pain Management and Older Adults*
- *Communicating Effectively With Older Adults: What Really Works—The Basics of Aging and Communication*
- *Communicating Effectively With Older Adults: What Really Works—Improving Face-to-Face Communication With Older Adults II: Medication Safety*
- *Communicating With Older Adults With Mild Cognitive Impairment*

Modules under development as of August 2014 include:

- *Communicating Effectively With Older Adults: What Really Works—Older Adult Diversity*
- *Improving Face-to-Face Communication With Older Adults I: Medication Adherence*
- *Non-Prescription Medication Reconciliation for Older Adults*
- *Sleep Health and Sleep Disturbance in Older Adults*
- *Older Adults and OTC Sleep Aids*

While all of these modules are related in some fashion to OTC sleep aid use among older adults, the last two listed programs are designed to specifically address these issues.

The learning objectives for the module *Sleep Health and Sleep Disturbance in Older Adults* are:

- To recognize that poor sleep quality is associated with a wide variety of adverse consequences.
- To appreciate that poor sleep quality is not a necessary part of aging.
- To recognize that sleep disturbance in older adults is often multifactorial in nature.

- To appreciate that disturbed sleep in older adults often occurs in the context of comorbid illnesses.
- To recognize that sleep disturbances in older adults can significantly impact health and quality of life and warrant appropriate diagnosis and treatment.
- To appreciate that most sleep disturbance, regardless of cause, in older adults can be treated.

Case studies for this module are designed to demonstrate how to address common challenges for older adults with sleep health issues and include:

- The Worried Well—an older adult reports “not sleeping as well as I used to”; upon questioning, the person has some age-related sleep change but nighttime sleep is age-appropriate and daytime function is undisturbed.
- Acute Sleep Disturbance—a patient with a clear precipitating factor (e.g., recent death of a family member) experiences disturbed sleep.
- Insomnia—a patient presents with symptoms of both sleep onset and more pronounced sleep maintenance insomnia; this patient also snores, is overweight but not obese, and has well-controlled hypertension.

The second module, *Older Adults and OTC Sleep Aids*, has the following learning objectives:

- To recognize and communicate the benefits of good sleep to older adults and their caregivers.
- To recognize and communicate good sleep practices.
- To recognize and communicate the differences among OTC, dietary supplement, and prescription sleep aids.
- To recognize and communicate that diphenhydramine may be an inappropriate OTC sleep aid for some older adults, and certainly when used chronically.
- To recognize and communicate the risks of combining multiple OTC sleep aids and of combining them with prescription medications or alcohol.

Case studies for this module are designed to demonstrate how to address common challenges for older adults using

sleep aids and focus on ensuring patients are using the medications appropriately. The cases include:

- Patient purchasing or asking for a recommendation for an OTC sleep aid—the pharmacy professional queries the patient about the nature and duration of the sleep disturbance. Assuming occasional sleep disturbance (an appropriate use of OTC sleep aids) also query for any current medication use, both prescription and OTC, as well as use of alcohol for sleep.
- Patient purchasing a prescription or OTC sleep aid with known anticholinergic side effects—the pharmacy professional queries the patient about prescription and OTC products that the patient may already be taking with anticholinergic properties.

Implications of Sleep Disturbance in Older Adult Drivers

Safety when driving is a crucial issue affected by insufficient or disturbed sleep. Poor sleep affects function in many ways, including making it more difficult to sustain attention and slowing response time.¹⁶ Drivers with sleep difficulties may be impaired because they are sleepy or experiencing next-day side effects from sleep aids—or a combination of both factors. To better understand these issues, Sandra Rosenbloom, PhD, director of the Innovation in Infrastructure Program at The Urban Institute, provided an overview of medication use, medical conditions, and travel behavior among older drivers.

According to data from the AAA Foundation, older adults are more likely than younger drivers to have medical conditions and take multiple medications. They are also often unaware of the potential side effects of their medications. However, there is no clear relationship between specific medications and crash risk as a function of age.

Dr. Rosenbloom reported that, in 2009, drivers 65 years of age and older took an average of 2.67 trips per day,

drove an average of 19.7 miles per day, and spent an average of 46.4 minutes driving. However, the frequency of driving decreased as individuals aged, and women were less likely to drive daily than men. Regardless of age or sex, drivers were less likely to report having a medical condition than non-drivers.

Older drivers self-regulate (i.e., change their driving patterns) to accommodate their limitations. Available data indicate that more than three quarters of older drivers who take medications report that they have reduced daily travel due to their medical condition. Likewise, many of those who take medications for sleep or pain self-regulate their driving by avoiding driving at night, on highways, and in bad weather. Across all age groups, women are more likely to self-regulate than men. In addition, across all measures of auto use, self-regulation decreases as income increases.

Further research regarding driving behaviors of older adults who experience symptoms of sleeplessness may provide valuable information on how to maximize safe driving in this population.

Advocacy for Sleep Health and the Safe and Effective Use of OTC Sleep Aids

Advocacy can occur at several levels, ranging from sending a tweet to testifying at a Congressional hearing. During the June 2014 summit, participants explored how these strategies can be used to advocate for policies that promote sleep health.

Using Social Media to Advance the Sleep Agenda

A key challenge for advocates is to ensure that their issue of concern is part of the national conversation. Therefore, advocates need to regularly and consistently promulgate their messages. Doing so not only reminds people of the issue, but also helps to position those advocates or their organizations as experts on the issue. As a result, decision makers will consider them to be a valid source of information on the subject.

Kelsey Heinze, manager of Member Engagement and Social Media at GSA,

provided summit participants with a tutorial on strategies to use social media to advance the national conversation on sleep health and OTC sleep aid use in older adults. Ms. Heinze presented an overview of various social media tools and delivered an in-depth tutorial on Twitter, which can be a powerful tool for spreading messages to large audiences. She also educated the audience about the jargon used for Twitter (see box). As part of the session, Ms. Heinze created the hashtag #OTCSleep and encouraged others to follow the topic and tweet using the hashtag. Selected tweets from the meeting are featured throughout this white paper.

Twitter Jargon

Tweet: *[verb]* The action of posting a message of up to 140 characters on Twitter.

[noun] A message of up to 140 characters that is posted to Twitter.

Hashtag: *[noun]* A word or phrase that categorizes the tweet and is preceded by the symbol # (Example: #OTCSleep)

Handle: *[noun]* A Twitter username.

Strategies for Influencing Policies

Once there is a general awareness of an issue, advocates can implement steps designed to influence policy related to that issue. Phyllis Zee, MD, PhD, professor at Northwestern University Feinberg School of Medicine and past president of the Sleep Research Society, described strategies used by advocates for influencing policy.

A crucial first step for influencing policy is to identify the primary and secondary audiences. The primary audience for advocacy efforts is composed of decision makers with authority to modify or introduce policies that the project addresses (e.g., Congress). Secondary audiences include individuals or groups that can influence the decision makers. These audiences include advisors, foundations, societies, patient groups, industry, and media. Once audiences are identified, advocates can work to disseminate their messages to these groups.

Dr. Zee shared examples of a Congressional briefing conducted by the Sleep Research Society in 2012. During this briefing, Dr. Zee and other experts called attention to the health imperative of sleep and reported on recent research and strategic opportunities for sleep research. Additional Congressional briefings on issues pertaining to sleep health in older adults are planned for the future.

Finally, Dr. Zee described how advocates can use policy briefs to further their agendas. A policy brief is a one-page document that communicates persuasive information intended to influence policy decisions. It can be distributed during Congressional briefings as well as to a variety of other audiences. Key points should be summarized in a written format because briefing attendees will not remember everything the advocate says. Furthermore, Senators and Representatives may send staffers to the briefings so the written policy brief can be used to report back to those members of Congress. Leaving decision makers with a physical paper that contains a summary of findings and recommendations helps to reinforce advocacy messages and promotes recall.

FDA Office of Health and Constituent Affairs

Stephanie Joseph, MPH, health programs coordinator at the Office of Health and Constituent Affairs (OHCA) within the FDA Office of External Affairs, explained how stakeholders can interface with the agency. She described two offices within FDA that have roles communicating with outside stakeholders.

OHCA works to help patients, advocates, consumers, and health care professionals to connect with FDA. OHCA's role is to listen, engage, educate, and involve stakeholders; the office maintains a series of webpages describing how to become involved with the agency (www.patientnetwork.fda.gov/get-involved).

Ms. Joseph also described the office of Professional Affairs and Stakeholder Engagement, which is an office within FDA's Center for Drug Evaluation and Research (CDER). This office serves to:

- Engage and assist stakeholders on issues concerning drug development, drug review, and drug safety.
- Provide a focal point for health professional organizations, patient advocacy groups, and health care systems for drug issues.
- Provide enhanced two-way communication and collaboration between CDER and stakeholders.

Beyond these two offices, FDA has many mechanisms for communicating with outside groups. FDA regularly transmits medication safety messages to health care providers and consumers to help promote safe medication use. Messages intended to promote safe medication use among older adults were recently distributed through the following webpages:

- www.fda.gov/downloads/ForConsumers/ConsumerUpdates/UCM399867.pdf
- www.fda.gov/downloads/Drugs/ResourcesForYou/UCM163961.pdf
- www.fda.gov/drugs/resourcesforyou/ucm079522.htm



Tweets From #OTCSleep

The @US_FDA uses a YouTube Channel for consumer information:
<http://bit.ly/1wBZDLm>
#OTCSleep

Tweets From #OTCSleep

Here's an example of a @US_FDA resource for older adults and meds such as #OTCSleep aids
<http://1.usa.gov/1sIsnDA>



Tweets From #OTCSleep
#OTCSleep MT @US_FDA:
JOIN US this June 30
1PM ET for the FDA
Basics Webinar on OTC
Medicines and Drowsy
Driving. <http://go.usa.gov/97qB>

FDA's MedWatch program allows health care providers and patients to submit voluntary reports of adverse events to FDA. (More information can be found at www.fda.gov/Safety/MedWatch.) These reports are monitored by FDA and can be used to gather information about postmarketing safety of medications. Data collected through the MedWatch system can result in future safety communications from the agency.

Regarding the use of OTC sleep aids by older adults, Ms. Joseph noted that FDA is specifically addressing issues related to regulation of OTC products. Currently, these products are regulated through a monograph system, which is a three-phase public rule-making process that was introduced in 1972. In March 2014, FDA held a public hearing to obtain information and comments from the public on the strengths and weaknesses of the current OTC Monograph Process, the feasibility of potential modifications that FDA has identified, and ideas about other modifications or alternatives to this process. This public hearing represents one of many opportunities for individuals who are concerned about safe OTC use by older adults to interact with FDA.

Summary

The use of OTC sleep aids by older adults raises concerns, including adverse events associated with the products, such as anticholinergic activity and residual sedative effects, especially as these may affect safe driving and falls risk. Available data indicate that these products are widely used in the older adult population. Moreover, many older adults do not follow product labeling: they use the product more often or for a longer duration than recommended. Older adults' use of alcohol along with OTC sleep aids is another issue of concern.

Despite these risks, it is important to recognize that untreated sleeplessness has many adverse consequences for older adults. The risks of disturbed sleep are pervasive and interact with numerous disease states, reduce quality of life, and can affect public safety.

Promoting sleep health for older adults is a critical issue for improving health, safety, and quality of life in this population. Through the efforts of the GSA workgroup and summits, a national conversation on topics of sleep health research, education, policy, and advocacy is underway. Ongoing developments are expected to further shed light on strategies that promote the goal of optimal sleep.

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