THE GERONTOLOGICAL SOCIETY OF AMERICA
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OTC SLEEP AIDS AND SLEEP HEALTH IN OLDER ADULTS

Grand Hyatt • Washington, DC
Wednesday and Thursday, October 16-17, 2013

Program Agenda

The October 2013 National Summit on OTC Sleep Aids and Sleep Health in Older Adults will be a full-day conference in Washington, DC. The Summit is intended to raise understanding of issues and risks related to OTC sleep aid use in older adults, and frame future efforts to address barriers affecting health care professionals, older adults, and caregivers. Stakeholders convening for the Summit draw from the public and private sectors; trade, professional, and advocacy organizations; and academia. Thought leaders with varied interests, experience, and expertise in OTC sleep aids and sleep health in older adults will be participating. The Summit is an effort of The Gerontological Society of America (GSA) and supported by Pfizer.

Objectives of the 2013 National Summit on OTC Sleep Aids and Sleep Health in Older Adults

- Increase understanding of sleep health and OTC sleep aid use in older adults (ages 65 years and older).
- Identify opportunities for improving understanding among health care practitioners, consumers, and caregivers regarding use of OTC sleep aids in older adults.
- Enable networking to create new connections and deepen existing relationships with individuals having a common interest in older adult sleep health and sleep aid use.

WEDNESDAY, OCTOBER 16, 2013

6:00 PM–8:00 PM **Registration and Networking Reception**
Grand Hyatt—Cabin John Room

THURSDAY, OCTOBER 17, 2013

7:00 AM–8:00 AM **Registration and Breakfast**
Grand Hyatt— Wilson Room

8:00 AM–8:30 AM **Welcome and Why We Are Here**
Grand Hyatt—Constitution Rooms D/E
James C. Appleby, RPh, MPH, Executive Director and CEO
The Gerontological Society of America

Annette Schmidt, Senior Director of Strategic Alliances and Business Development
The Gerontological Society of America

8:30 AM–9:45 AM **Introduction of the Workgroup, Stakeholders, and the Goals for the Day**
Steven M. Albert, PhD, *Workgroup Chairperson*
Professor and Chair, Department of Behavioral and Community Health Sciences
Graduate School of Public Health, University of Pittsburgh

9:45 AM–11:00 AM **Uncovering Stakeholder Experience and Perception Regarding OTC Sleep Aids and Sleep Health in Older Adults**
Facilitator: Judy Klein

Participants will work in small groups to kick-start engagement in discussions and networking by using "investigative journalism" techniques to address the following questions:

- What are 3 to 5 key reasons or benefits relevant to you or your organization for improving sleep health in older adults?
- What do you believe to be the key issues older adults face on OTC sleep aid use?
- What are the greatest barriers you face in your organization to support improved OTC sleep aid use in older adults?
- What are 3 to 5 key ways you or your organization could contribute to achieve safe use of OTC sleep aids in older adults?

11:00 AM–11:15 AM **Wiggle Break**

11:15 AM–12:30 PM **State of Knowledge About Sleep Health in Older Adults**
Speaker: Phyllis Zee, MD, PhD
Professor of Neurology, Neurobiology, and Physiology
Director, Sleep Disorders Center
Northwestern University

Roundtable groups will discuss questions posed by Dr. Zee and share their top 1 to 2 themes and/or surprises uncovered.

12:30 PM–1:00 PM **Networking Lunch**
Grand Hyatt—Wilson Room

1:00 PM–2:00 PM **State of Knowledge About OTC Sleep Aid Use by Older Adults**
Speaker: Thomas Roth, PhD
Director of Research and Division Head
Sleep Disorders and Research Center
Henry Ford Health System

Roundtable groups will discuss questions posed by Dr. Roth and share their top 1 to 2 themes and/or surprises uncovered.

2:00 PM–3:00 PM **Call to Action to Improve Safe Use of OTC Sleep Aids—Now and in the Future**
Moderator: Steven M. Albert, PhD, *Workgroup Chairperson*
Panel: James A. Owen, PharmD, BCPS; Deborah A. DiGilio, MPH; Joan Enstam Baird, PharmD, CGP, FASCP

Lively, moderated discussion among panelists representing varied perspectives; includes time for participants to pose thought-provoking questions to panelists.

3:00 PM–3:15 PM	**Wiggle Break**
3:15 PM–4:45 PM	**Prioritize Topics for Future Emphasis** Facilitator: Judy Klein Participants break out into small groups to develop proposals (*posters*) for improving older adult sleep health and use of sleep aids. Led by Panel Discussants, Workgroup, and Facilitators.
4:45 PM	**Closing Remarks: Reflections of the Day and Next Steps**
5:00 PM	**Adjournment**

OTC SLEEP AIDS AND SLEEP HEALTH IN OLDER ADULTS

OTC Sleep Aids and Sleep Health in Older Adults

Research Is Needed to Better Understand and Promote Safe and Effective Use

THE GERONTOLOGICAL SOCIETY OF AMERICA

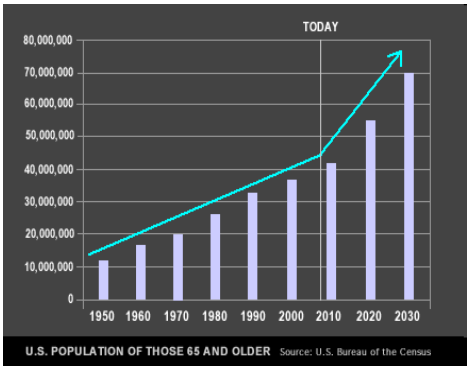
Pfizer

OTC SLEEP AIDS AND SLEEP HEALTH IN OLDER ADULTS

Welcome

James C. Appleby, RPh, MPH, Executive Director and CEO

1 out of every 9 Americans is 65 or older



US Bureau of the Census 2008 population estimates.

- Boomers span 18 years — born from 1/1/1946 to 12/31/1964
  - Oldest turned 65 on January 1, 2011
  - Youngest boomers are 49
- More 65+ Americans than the populations of New York, London, and Moscow — **combined**
  - Living longer
  - More racial/ethnic diversity
- 7,000 to 10,000 people turning 65 **every day** for the next 16 years

The Gerontological Society of America

- Oldest, largest national/international professional membership organization
  - 5,600 interdisciplinary members touching all facets of aging
- Mission
  - Promote multi- and interdisciplinary research in aging
  - Translate and disseminate research findings
  - Promote/advocate for education/awareness on aging across disciplines
  - Foster application of research into policy development
- Sections
  - Biological Sciences (BS)
  - Health Sciences (HS)
  - Behavioral and Social Sciences (BSS)
  - Social Research, Policy, and Practice (SRPP)

The Gerontological Society of America

- **Our vision:**
  - *To be recognized as the preferred, trusted, credible partner for our research, knowledge, and unique collaborations across all disciplines leading to important innovative solutions in the field of aging*
- **Our focus:**
  - *Advancing innovation in aging to identify solutions that address unmet needs through our credible, trusted, respected members, affiliates, offerings, and collaborations*

International Membership

- Members from 45 countries; in addition to the United States, top countries include:

Australia
Brazil
Canada
China
Germany
Hong Kong
Israel
Italy
Japan
Netherlands
South Korea
Sweden
Taiwan
United Kingdom

GSA and Affiliates

- **Oldest/largest international, interdisciplinary scientific organization in aging**
- **Association for Gerontology in Higher Education**
  - **Academic institutions with programs in gerontology and/or geriatrics**
- **National Academy on an Aging Society**
  - **Non-partisan policy institute**

Stakeholder Organizations

OTC SLEEP AIDS AND SLEEP HEALTH IN OLDER ADULTS

Welcome

Annette Schmidt, Senior Director of Strategic Alliance & Business Development

OTC SLEEP AIDS AND SLEEP HEALTH IN OLDER ADULTS

Introduction of the Workgroup, Stakeholders, and the Goals for the Day

Steven M. Albert, PhD, Workgroup Chairperson

OTC Sleep Aids and Sleep Health

Introductions

- Name
- Organization
- Title/Role
- What are your goals for the day?

1 to 2 minutes, please

Summit Agenda

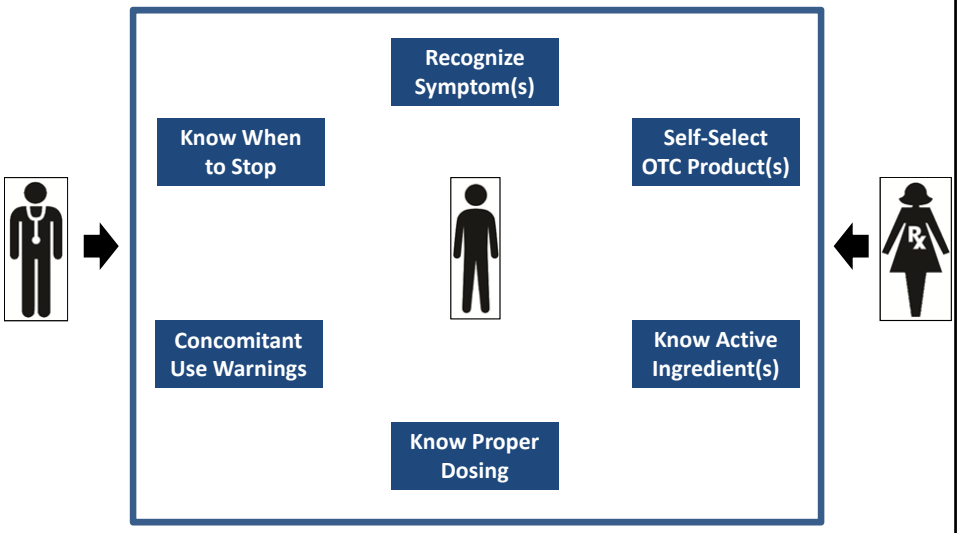
9:45 AM – 11:00 AM	Uncovering Stakeholder Experience and Perception Regarding OTC Sleep Aids and Sleep Health in Older Adults
11:00 AM – 11:15 AM	Wiggle Break
11:15 AM – 12:30 PM	State of Knowledge About Sleep Health in Older Adults
12:30 PM – 1:00 PM	Networking Lunch
1:00 PM – 2:00 PM	State of Knowledge About OTC Sleep Aid Use by Older Adults
2:00 PM – 3:00 PM	Call to Action to Improve Safe Use of OTC Sleep Aids—Now and in the Future
3:00 PM – 3:15 PM	Wiggle Break
3:15 PM – 4:45 PM	Prioritize Topics for Future Emphasis
4:45 PM – 5:00 PM	Closing Remarks: Reflections of the Day and Next Steps

OTC Medication Behavior

42% of older adults use OTC drugs regularly (Qato et al 2008)

- Identify **gaps in research** required to improve OTC medication behaviors of older adults
- Assess **factors that influence older adults' choice of OTC medications**, e.g., health literacy, vision, cognitive strategies, packaging
- Examine **contexts of OTC use**: role of clinicians and lay caregivers
- Identify **emerging technologies** that may support optimal OTC medication practices

The Health Literacy Task of OTC Use



Can you take these products together?

Acetaminophen 500 mg

Acetaminophen 650 mg

41%

Acetaminophen 500 mg
Diphenhydramine HCl 25 mg

37%

Acetaminophen 325 mg
Chlorpheniramine maleate 2 mg
Dextromethorphan hydrobromide 10 mg
Phenylephrine hydrochloride 5 mg

40%

Acetaminophen 250 mg
Aspirin 250 mg
Caffeine 25 mg

38%

Key Problem in OTC Behavior

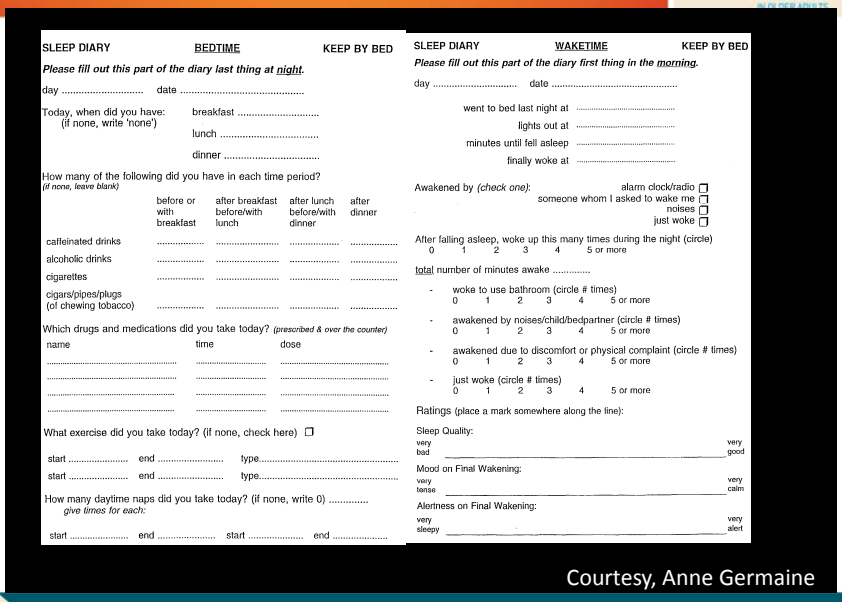
Unintentional Misuse Among Older Adults

- 24% take more than recommended maximum dose for OTC product (Wolf et al 2012)
- 46% of adults misuse OTC products by concomitant use (Wolf et al 2012)

Sleep and OTC Behaviors

- 44% of older adults experience disturbed sleep at least a few nights each week (National Sleep Foundation 2013)
- 23% report taking sleep medications in past 4 weeks (NHANES 2013)
- 15% to 18% use OTC sleep aid; 40% concurrently taking 1+ anticholinergic medication (Kantar 2013)

Sleep Diary: Text



SLEEP DIARY BEDTIME KEEP BY BED

Please fill out this part of the diary last thing at night.

day ..... date .....

Today, when did you have: (if none, write 'none')
breakfast .....
lunch .....
dinner .....

How many of the following did you have in each time period? *(if none, leave blank)*

	before or with breakfast	after breakfast before/with lunch	after lunch before/with dinner	after dinner
caffeinated drinks	.....	.....	.....	.....
alcoholic drinks	.....	.....	.....	.....
cigarettes	.....	.....	.....	.....
cigars/pipes/plugs (of chewing tobacco)	.....	.....	.....	.....

Which drugs and medications did you take today? *(prescribed & over the counter)*

name	time	dose
.....	.....	.....
.....	.....	.....
.....	.....	.....
.....	.....	.....

What exercise did you take today? (if none, check here) ❒

start ..... end ..... type.....
start ..... end ..... type.....

How many daytime naps did you take today? (if none, write 0) .....
give times for each:

start ..... end ..... start ..... end .....

SLEEP DIARY WAKETIME KEEP BY BED

Please fill out this part of the diary first thing in the morning.

day ..... date .....

went to bed last night at .....
lights out at .....
minutes until fell asleep .....
finally woke at .....

Awakened by *(check one)*:
alarm clock/radio ❒
someone whom I asked to wake me ❒
noises ❒
just woke ❒

After falling asleep, woke up this many times during the night (circle)
0 1 2 3 4 5 or more

total number of minutes awake .....

- woke to use bathroom (circle # times)
  0 1 2 3 4 5 or more
- awakened by noises/child/bedpartner (circle # times)
  0 1 2 3 4 5 or more
- awakened due to discomfort or physical complaint (circle # times)
  0 1 2 3 4 5 or more
- just woke (circle # times)
  0 1 2 3 4 5 or more

Ratings (place a mark somewhere along the line):

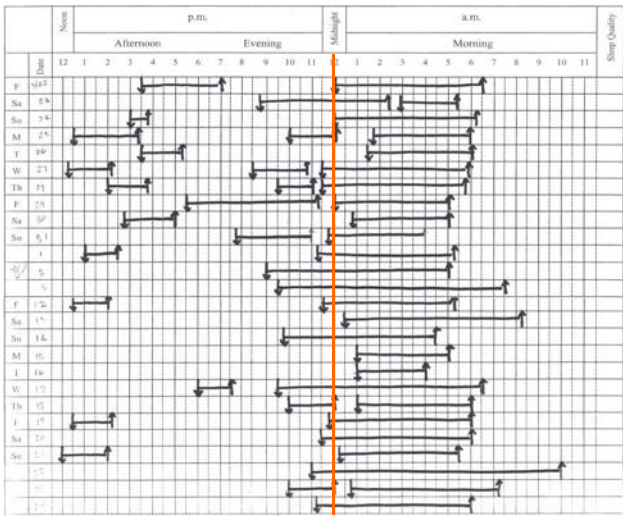
Sleep Quality:
very bad _____ very good

Mood on Final Wakening:
very tense _____ very calm

Alertness on Final Wakening:
very sleepy _____ very alert

Courtesy, Anne Germaine

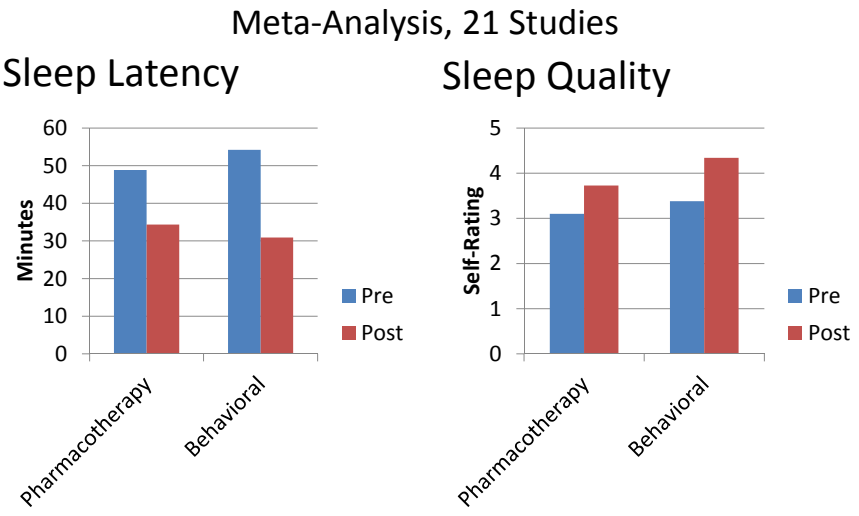
Sleep Diary: Graphic



Courtesy, Anne Germaine

Pharmacotherapy and Behavioral Therapy for Persistent Insomnia

Meta-Analysis, 21 Studies



Smith MT et al. *Am J Psychiatry.* 2002;159:5-11.

To Ensure Safe and Effective Use of OTC Sleep Aids…

- What do we need to know about older adults' actual use of OTC sleep aids?
- What do health care providers need to do?
- How should we educate consumers?
- How can we track OTC use in clinical practice and retail pharmacies?

OTC SLEEP AIDS AND SLEEP HEALTH IN OLDER ADULTS

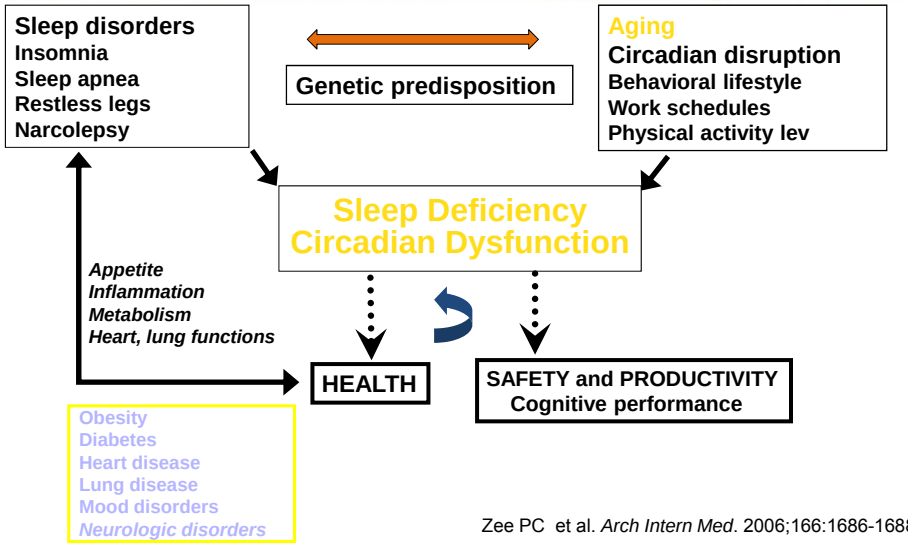
State of Knowledge About Sleep Health in Older Adults

Phyllis Zee, MD, PhD

Why Is Sleep Important?

- **50-70 million Americans have a chronic sleep disorder (IOM 2006)**
- **28% of adults report frequent insufficient sleep; 4.7% report falling asleep driving in the past 30 days (CDC 2008, 2010)**
- **Sleep disorders and deprivation are associated with many deleterious health consequences (IOM 2006)**
- **Annual direct (medical) and indirect (accidents, lost productivity, etc.) costs total hundreds of billions of dollars (IOM 2006)**

Sleep, Circadian Rhythms, and Health



Zee PC et al. *Arch Intern Med*. 2006;166:1686-1688.

OTC Sleep Aids and Sleep Health

Effects of Aging on Sleep

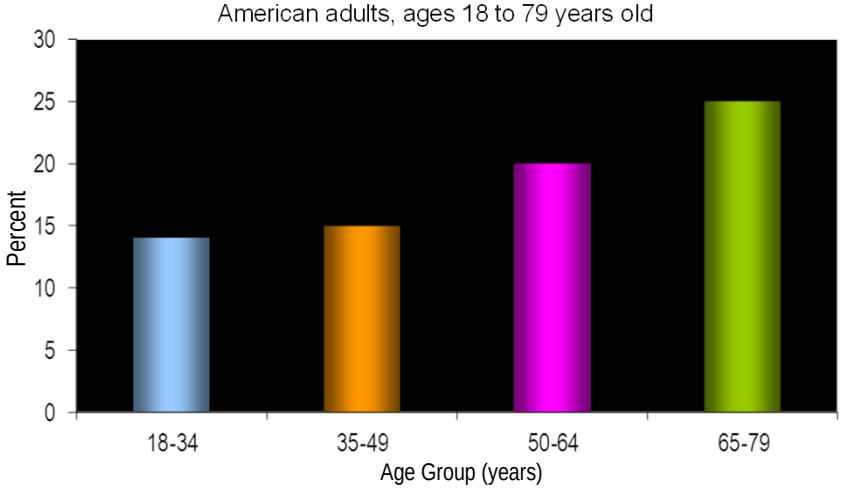
Effects of Sleep (Poor) on Aging

Similarities Between Sleep Loss and Aging

Function	Sleep Loss	Aging
Glucose tolerance	↓	↓
Insulin sensitivity	↓	↓
C-reactive protein	↑	↑
Cardiac sympathetic activity	↑	↑
Plasma norepinephrine	↑	↑
Evening cortisol levels	↑	↑
Plasma TSH levels	↓	↓
Plasma leptin levels	↓	↓
Mood	↓	↓
Vigilance	↓	↓
Subjective alertness	↓	↓
Cognitive function	↓	↓

Prevalence of Insomnia by Age Group

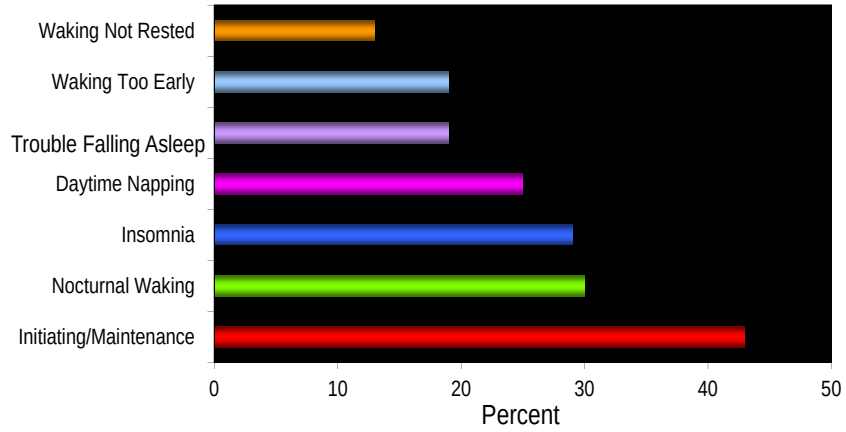
Large-scale community survey of non-institutionalized American adults, ages 18 to 79 years old



Mellenger GD et al. *Arch Gen Psychiatry.* 1985;42:225-232.

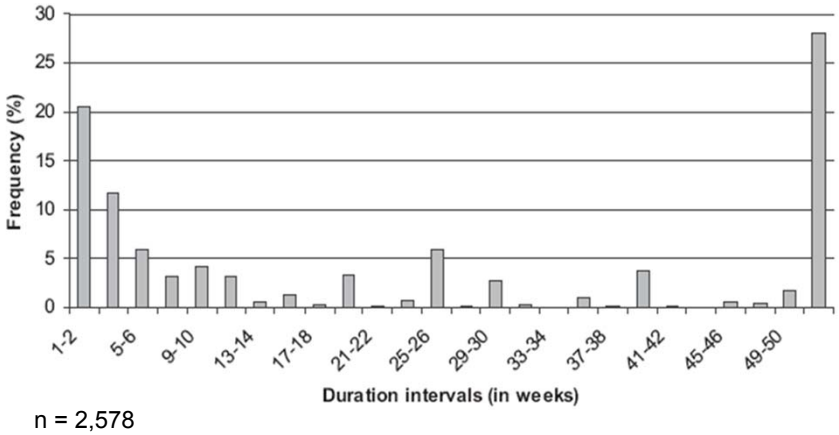
Percent of Sleep Complaints in Older Adults

(n = 9,282; mean age 74 years)



Foley DJ et al. *Sleep.* 1995;18:452-432.

Duration of Insomnia in the National Comorbidity Survey Replication



n = 2,578

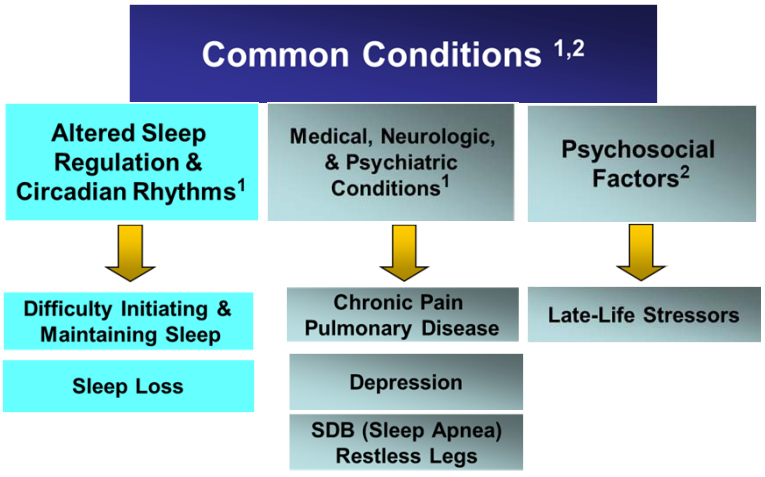
Roth T et al. *Biol Psychiatry*. 2006;60:1364-1371.

Prevalence Rates of Sleep Disturbances in Persons With Dementia and Their Family Caregivers

Caregivers	
McCurry and Teri	68%
Pruchno and Potashnik	22–41% (men), 53–67% (women)
Wilcox and King	67% (women only)
Persons with Dementia	
Carpenter et al.	40%
Craig et al.	42–54%
Lyketsos et al.	20–27%
McCurry et al.	35%
Moran et al.	25%
Pang, et al.	35–54%
Rabins	33%
Ritchie	19–44%
Thommessen et al.	25%

McCurry M et al. *Sleep Med Rev*. 2007;11:143-153.

Possible Underlying Causes of Sleep Disturbance and Insomnia Symptoms



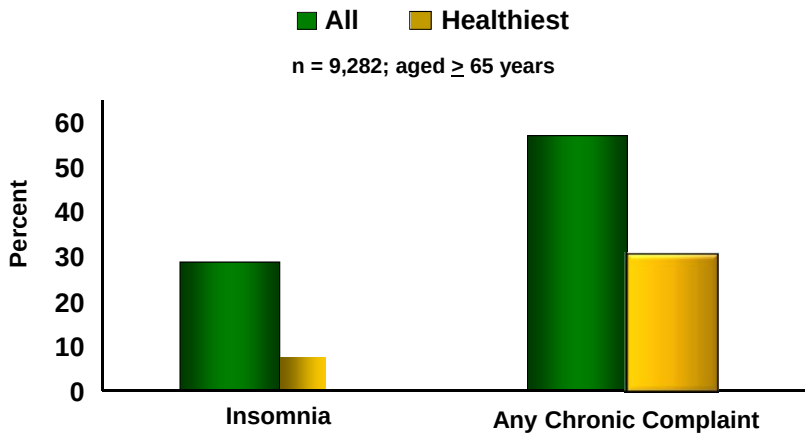
1. Barthlen GM. *Geriatrics*. 2002;57:34-39.
2. Ancoli-Israel S, Cooke JR. *J Am Geriatr Soc*. 2005;53(suppl):S264-S271.

Changes in Sleep With Age

- Meta-analysis of 65 sleep studies in healthy persons
  - 3,557 total subjects ages 5 to 102 years old
- Most age-related sleep changes occur in early and mid-years of human life span
- In healthy older adults:
  - Sleep remains relatively constant from age 60 to mid-90s
    - Except for sleep efficiency which decreases
    - Wake after sleep onset increases
    - Slow wave sleep decreases

Ohayon MM et al. *Sleep*. 2004;27:1255-1273.

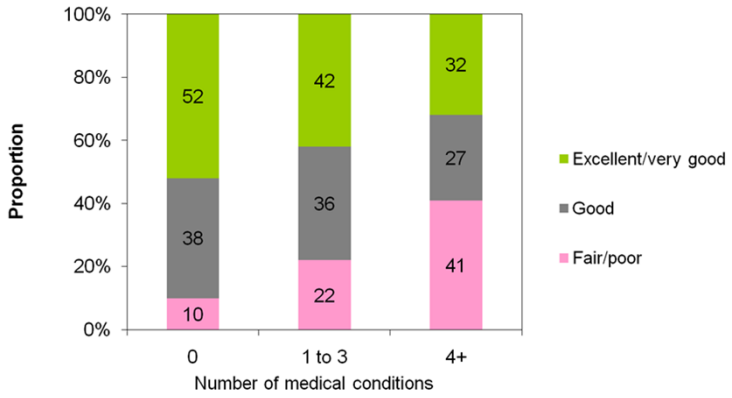
Poor Health Impacts Prevalence of Insomnia in Older Adult Population



Foley DJ et al. *Sleep.* 1995;18:425-432.

Sleep Quality and Medical Conditions

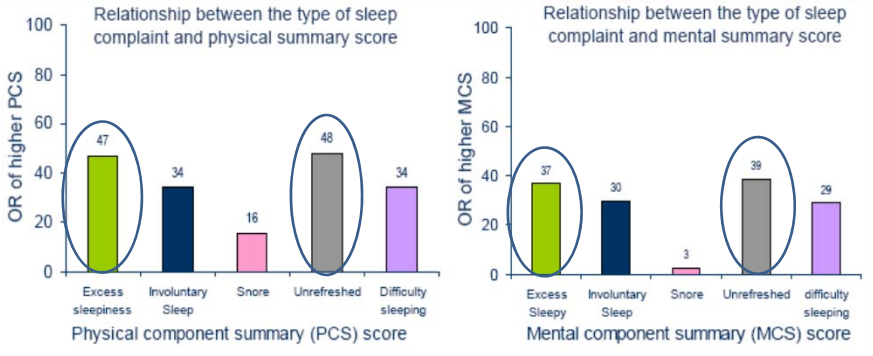
Self-Reported Questionnaire Data From 1,506 Community-Dwelling Adults
Ages 55 to 84 years



Foley D et al. *J Psychosom Res.* 2004;56:497-502.

Sleep: A Marker of Physical and Mental Health

- Odds ratio (OR) of physical or mental health (determined with SF-12) contributing to a sleep complaint



Reid KJ et al. *Am J Geriatr Psychiatry*. 2006;14:860-866.

n = 1,503; age 60-100 years
All significant at *P*<0.001

OTC Sleep Aids and Sleep Health

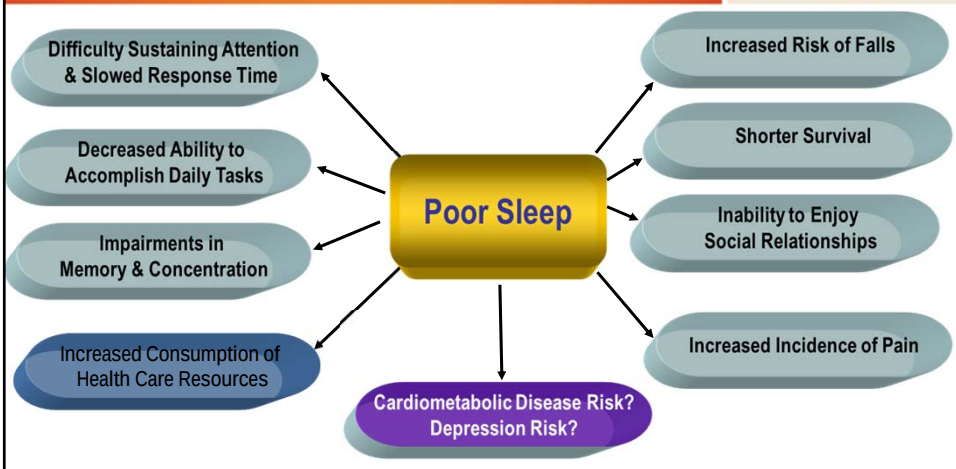
Normal age-associated changes in sleep are

NOT

primarily responsible for increased prevalence of insomnia and other sleep disorders in older adults

Highest contribution is physical and mental health

Impact of Poor Sleep in Elderly Adults



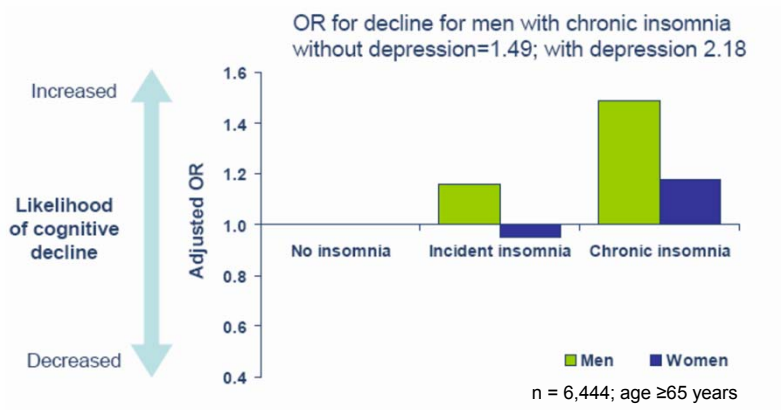
Ancoli-Israel S, Cooke JR. *J Am Geriatr Soc*. 2005;53(suppl):S264-S271.

Insomnia With Short Sleep Duration Is Associated With Health Outcomes

Health Condition	Associated With…		
	Sleep Duration	**Insomnia**	**Interaction**
Hypertension[1]	Yes (≤ 6 hours)	Yes	Yes
Type 2 Diabetes[2]	No	No	Yes (≤ 5 hours)
Neuropsychological test performance[3]	Yes (≤ 6 hours) 5/14 tests	No	Yes 4/14 tests
Mortality[4]	No	No	Yes (< 6 hours, Men only)
Cortisol[5]	No	Yes	Yes (SE < 70%)

[1]Vgontzas AN. *Sleep.* 2009;32:491-497. [2]Vgontzas AN. *Diabetes Care.* 2009;32:1980-1985. [3]Fernandez-Mendoza J. *Sleep.* 2010;33:459-465. [4]Vgontzas AN. *Sleep.* 2010;33:1159-1164. [5]Vgontzas AN. *J Clin Endocrin Metab.* 2001;86:3787-3794.

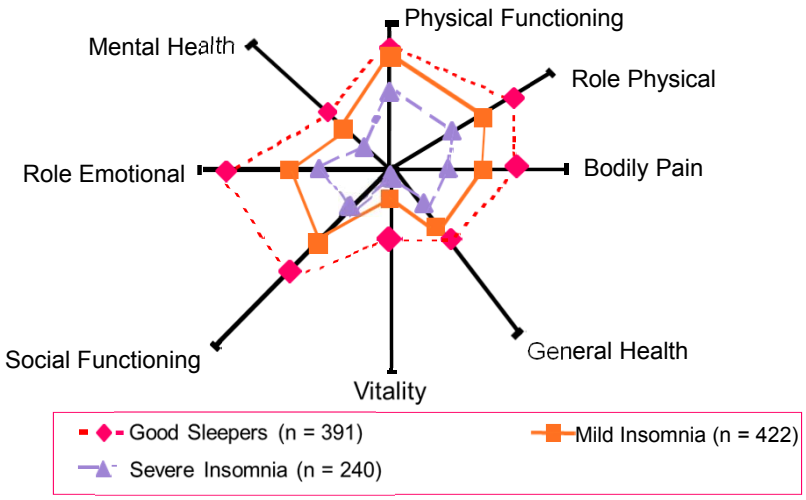
Cognitive Decline and Insomnia in Older Adults



* Adjusted for baseline cognitive function, age, race, education, income, and marital status

Cricco M et al. *J Am Geriatr Soc.* 2001;49:1185-1189.

Impact of Insomnia on Quality of Life



Axes represent subscales of the SF-36. All *P* values < .05 (range .000-.023).

Leger D et al. *Psychosom Med.* 2001;63:49-55

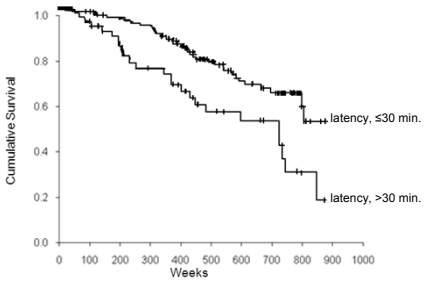
Days-Out-of-Role Associated With Insomnia and Comorbid Conditions in America Insomnia Survey

	Total Sample		Ages 18–34 Yrs		Ages 35–59 Yrs		Ages 60+ Yrs	
	Days[a]	(SE)	Days[a]	(SE)	Days[a]	(SE)	Days[a]	(SE)
Insomnia	.42[b]	(.10)	.12	(.15)	.44[b]	(.12)	.77[b]	(.25)
Cardiovascular Disorders								
Hypertension	.25[b]	(.10)	−.18	(.25)	.28[b]	(.14)	.45[b]	(.20)
Heart disease	.63	(.71)	−.05	(.23)	−1.74	(2.10)	.51	(.70)
Respiratory Disorders								
Seasonal allergies or hay fever	−.18[b]	(.07)	−.06	(.14)	−.06	(.08)	−.66[b]	(.19)
Chronic bronchitis, emphysema, other	−.11	(.15)	−.22	(.12)	−.34	(.21)	.42	(.38)
COPD	.80[b]	(.35)	.04	(.24)	−.17	(.45)	1.12[b]	(.49)
Musculoskeletal Disorders								
Arthritis (osteo or rheumatoid)	.16	(.14)	−.20	(.18)	.54[b]	(.17)	−.36	(.32)
Back or neck pains	.20[b]	(.09)	.16	(.20)	.28[b]	(.10)	.01	(.22)
Other Pain Disorders								
Migraine headaches	.11	(.10)	.05	(.11)	.14	(.16)	.34	(.44)
Other frequent or severe headaches	.19	(.14)	.05	(.16)	.36[b]	(.16)	.27	(.45)
Chronic pain of any sort including muscle, joint or nerve	.48[b]	(.09)	.43[b]	(.17)	.42[b]	(.10)	.66[b]	(.25)

Hajak G et al. *Biol Psychiatry.* 2011;70:1063-1073.

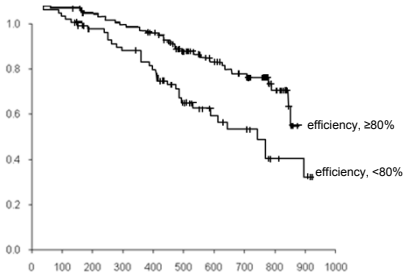
Association Between Sleep Quality and Survival

Survival as a function of sleep latency



Sleep latencies >30 minutes: 2.14x greater mortality risk (*P* = 0.005)

Survival as a function of sleep efficiency

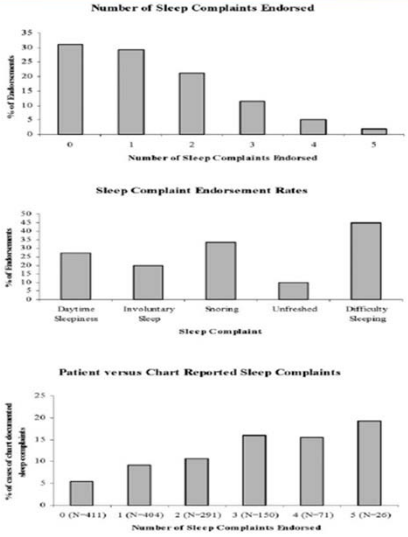


Sleep efficiency <80%: 1.93x greater mortality risk (*P* = 0.014)

Electroencephalographic sleep assessments are controlled for age, sex, and baseline medical burden.

Dew MA et al. *Psychosom Med*. 2003;65:63-73.

Sleep Difficulties in Older Adults: Under-recognized in Medical Practice



Reid KJ et al. *Am J Geriatr Psychiatry*. 2006;14:860-866.

Summary

"Worried About Growing Old? Don't Lose Sleep Over It."

- Healthy aging is associated with changes in sleep and circadian rhythms, BUT does not explain the magnitude of sleep problems in aging
- It is the pathological changes in circadian and sleep and co-morbid medical and psychiatric disorders that result in most sleep complaints in the older adult
- Behavioral treatments, such as light and activity, can improve circadian and sleep function-cognition and health in older adults with and without dementia

Successful Aging

Exercise

Diet

SLEEP

Questions for Discussion

- Identify the top 3 to 5 consequences of poor sleep health in the older adult populations you serve
- Which stakeholders (e.g., primary care physician, caregiver, others) are well-positioned to assist older adults improve their sleep health?
  - Why?
  - What role would they play?

OTC SLEEP AIDS AND SLEEP HEALTH IN OLDER ADULTS

State of Knowledge About OTC Sleep Aid Use by Older Adults

Thomas Roth, PhD

Types of Sleep Aids

- Prescription drugs
- Herbal supplements
- Alcohol

- OTC drugs

Indication

- Prescription hypnotics
  - Treatment of insomnia; no limitation on duration
- OTC agents
  - For occasional sleeplessness for 2 to 3 days

Herbal Supplements

- The FDA updated the laws governing the labeling of herbal supplements so consumers now can see labels that explain how herbs can influence different actions in the body
- However, herbal supplement labels still cannot say anything about treating specific medical conditions because herbal supplements are not subject to clinical trials or to the same manufacturing standards as prescription or OTC drugs
- Example labeling statement: “to promote regular sleep patterns”

US FDA Permitted OTC Sleep Aids

- Diphenhydramine
  - Nytol, Sominex, Tylenol PM, Excedrin PM, Advil PM, Unisom SleepGels, etc.
  - Very weak H1 antagonist; H1/M1 potency ratio low to moderate
  - Pregnancy Category B
  - 1 crossover study in 20 elderly patients with insomnia; decreased only awakenings vs placebo; AEs vs placebo: dry mouth (80% vs 65%), dizziness (25% vs 10%), and headache (20% vs 5%)

Glass JR et al. *J Clin Psychopharmacol.* 2008;28:182-188.

US FDA Permitted OTC Sleep Aids

- Doxylamine
  - Unisom SleepTabs, Equaline Sleep Aid, Good Sense Sleep Aid, etc.
  - Very weak H1 antagonist; H1/M1 potency ratio low to moderate
  - Pregnancy Category B
  - No published placebo-controlled trials

GSA National Summit on OTC Sleep Aids and Sleep Health in Older Adults

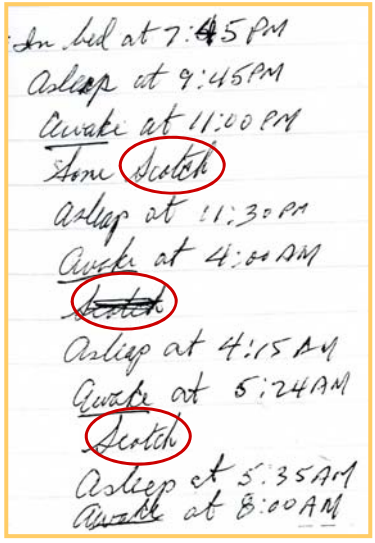
Beers Criteria

TABLE 1: 2012 AGS Beers Criteria for Potentially Inappropriate Medication Use in Older Adults

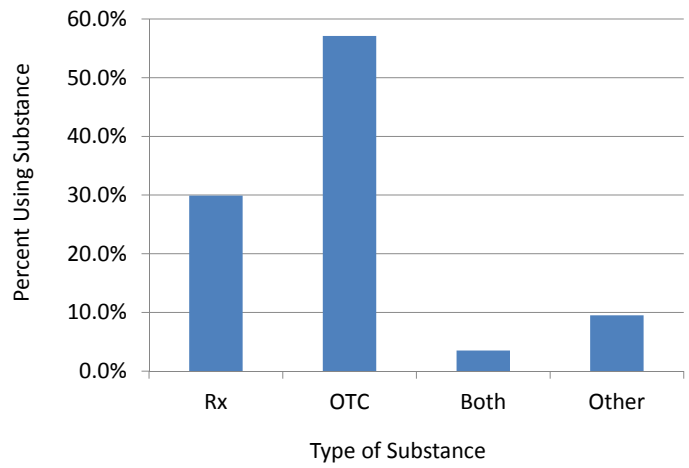
Organ System/ Therapeutic Category/Drug(s)	Recommendation, Rationale, *Quality of Evidence (QE) & Strength of Recommendation (SR)*
Anticholinergics (excludes TCAs)	
First-generation antihistamines (as single agent or as part of combination products) ■ Brompheniramine ■ Carbinoxamine ■ Chlorpheniramine ■ Clemastine ■ Cyproheptadine ■ Dexbrompheniramine ■ Dexchlorpheniramine ■ Diphenhydramine (oral) ■ Doxylamine ■ Hydroxyzine ■ Promethazine ■ Triprolidine	**Avoid.** Highly anticholinergic; clearance reduced with advanced age, and tolerance develops when used as hypnotic; increased risk of confusion, dry mouth, constipation, and other anticholinergic effects/ toxicity. Use of diphenhydramine in special situations such as acute treatment of severe allergic reaction may be appropriate. *QE = High (Hydroxyzine and Promethazine), Moderate (All others); SR = Strong*
Antiparkinson agents ■ Benztropine (oral) ■ Trihexyphenidyl	**Avoid.** Not recommended for prevention of extrapyramidal symptoms with antipsychotics; more effective agents available for treatment of Parkinson disease. *QE = Moderate SR = Strong*

American Geriatrics Society 2012 Beers Criteria Update Expert Panel. *J Am Geriatr Soc.* 2012;60:616-631.

Sleep Diary – May 2006

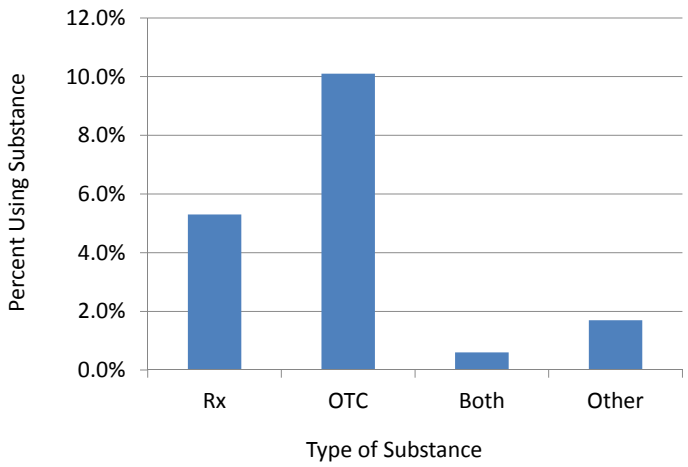


OTC Medication Is Most Commonly Used Sleep Aid Among Non-Elderly Using Sleep Aids



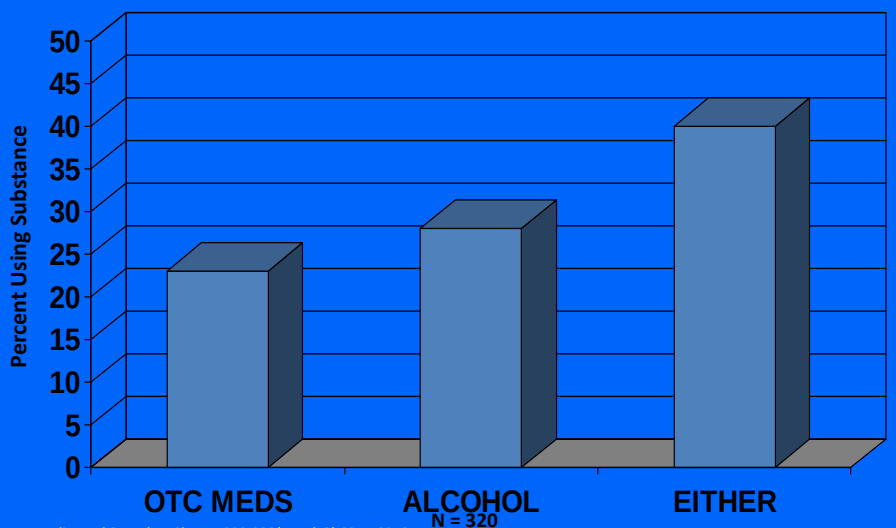
Johnson EO et al. *Sleep.* 1998;21:178-186.

General Population



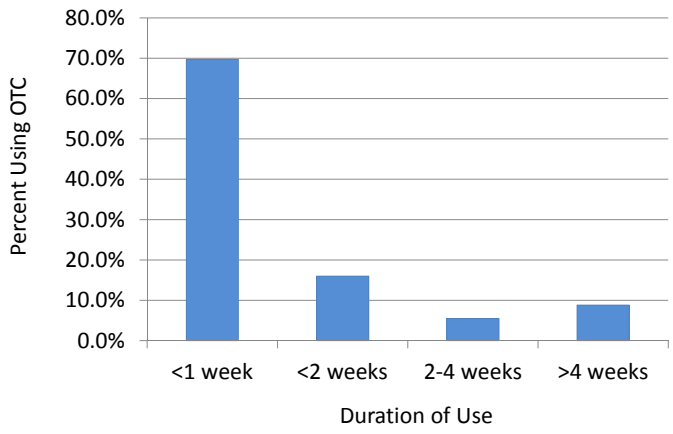
Johnson EO et al. *Sleep.* 1998;21:178-186.

Percent of Patients Using OTCs, Alcohol, or Both



Ancoli-Israel S, Roth T. *Sleep.* 1999;229(suppl 2):S347-S353.

Longest Period of OTC Sleep Aid Use in Non-Elderly Adults



Johnson EO et al. *Sleep.* 1998;21:178-186.

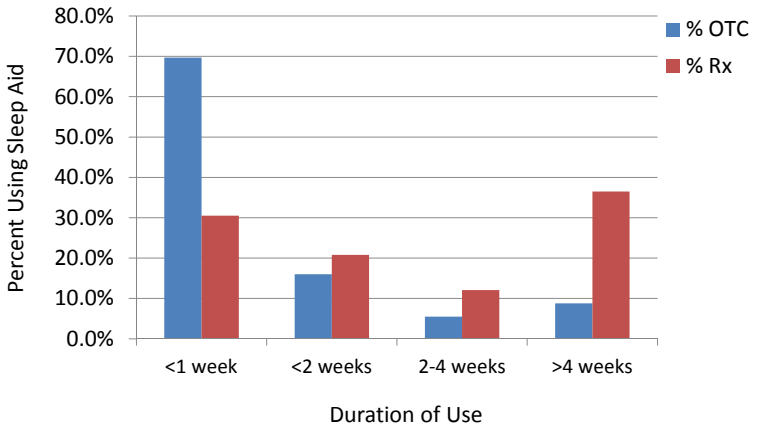
Longest Period of OTC Sleep Aid Use in Elderly Adults (Percent Using OTC)

Number of Days in Last Month

Age	<1	1-4	5-19	20+
60+	9.1%	24.1%	31.2%	35.6%
65+	8.3%	24.7%	31.4%	35.6%
75+	7.4%	19.3%	31.6%	41.7%

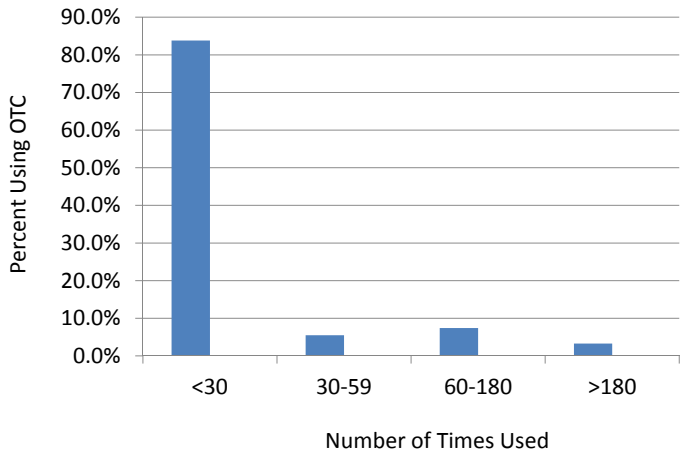
Base: Experiencing sleep difficulties, reporting one or more symptoms of sleeplessness, and use OTC for sleep difficulties
*NHWS US 2012: (SQ6) Thinking of the sleeplessness or difficulty sleeping that you experience, which of the following sleep problems or symptoms do you **regularly** experience ?*
NHWS US 2012: (HH10) Which of the following have you experienced in the past 12 months? <Sleep difficulties>
NHWS US 2012: (SD75) Do you use an over-the-counter or herbal products to treat your sleep condition?
NHWS US 2012: ((SD90) How many days did you use the following product(s) in the past month?

Longest Period of OTC and Rx Sleep Aid Use



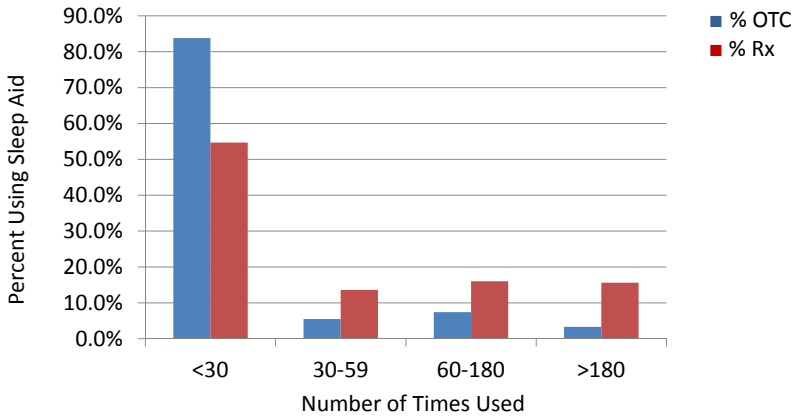
Johnson EO et al. *Sleep.* 1998;21:178-186.

Number of Times OTC Sleep Aid Used



Johnson EO et al. *Sleep.* 1998; 21:178-186

Number of Times OTC and Rx Used



Johnson EO et al. *Sleep.* 1998;21:178-186.

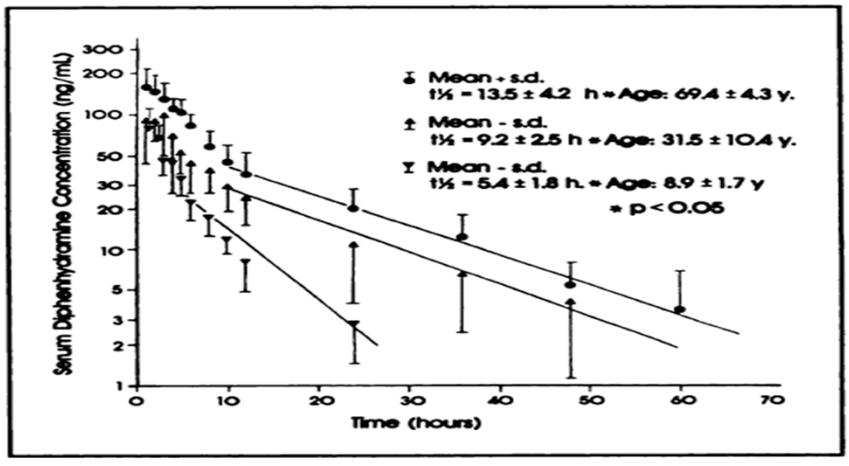
Diphenhydramine Pharmacokinetics and Age

	Elderly Adults	Young Adults	Children
Age* (yrs)	69.4 ± 4.3	31.5 ± 10.4	8.9 ± 1.7
Weight (kg)	71.0 ± 11.4	70.3 ± 9.9	31.6 ± 6.8
Dose (mg)	86.0 ± 7.3	87.9 ± 12.4	39.5 ± 8.4
Cp_{max} (ng/mL)	188.4 ± 54.5	133.2 ± 37.6	81.8 ± 30.2
t_{max} (h)	1.7 ± 0.8	1.7 ± 1.0	1.3 ± 0.5
$t_{1/2}$ (h)	13.5 ± 4.2	9.2 ± 2.5	5.4 ± 1.8
Cl (mL/min/kg)	11.7 ± 3.1	23.3 ± 9.4	49.2 ± 22.8
Vd_{ss} (L/kg)	10.2 ± 3.0	14.6 ± 4.0	17.9 ± 5.9
Vd (Lkg)	13.6 ± 6.3	17.4 ± 4.8	21.7 ± 6.6
AUC (ng/mL/h)	1902 ± 572	1031 ± 437	475 ± 137
MRT (h)	14.8 ± 2.8	11.3 ± 3.1	6.4 ± 1.6

* *Mean ± standard deviation.*

Simons KJ et al. *J Clin Pharmacol*. 1990;30:665-671.

Diphenhydramine Pharmacokinetics and Age



Simons KJ et al. *J Clin Pharmacol*. 1990;30:665-671.

GSA National Summit on OTC Sleep Aids and Sleep Health in Older Adults

Diphenhydramine Pharmacokinetics by Age and Sex

Table I Subject Characteristics and Diphenhydramine Pharmacokinetics

	Young Men (n = 10)	Elderly Men (n = 7)	Young Women (n = 10)	Elderly Women (n = 10)
Subject Characteristics				
Age (yrs)	30.4 ± 5.8	64.3 ± 1.8	29.4 ± 2.4	70.1 ± 1.2
Weight (kg)	73.9 ± 2.2	71.9 ± 5.4	65.4 ± 8.7	69.2 ± 3.6
Height (cm)	177.9 ± 1.3	176.0 ± 1.3	166.7 ± 2.2	169.9 ± 1.9
Diphenhydramine Kinetics				
C_{max} (ng/mL)	35.3 ± 4.2	32.4 ± 6.1	34.7 ± 5.9	26.7 ± 2.9
t_{max} (hrs after dose)	2.1 ± 0.4	2.3 ± 0.3	2.2 ± 0.2	2.7 ± 0.3
$t_{1/2}$ (hrs)	4.1 ± 0.3	7.4 ± 3.0	4.4 ± 0.3	4.9 ± 0.6
Total AUC (ng·hr/mL)	192.5 ± 18.6	160.4 ± 21.8	276.2 ± 71.4	180.9 ± 16.8
Total clearance (mL/min/kg)	28.0 ± 2.8	35.3 ± 4.1	27.7 ± 4.1	32.8 ± 4.2

Values are presented as the mean ± standard error. C_{max}, peak plasma concentration; t_{max}, time of C_{max}; $t_{1/2}$, elimination half-life; AUC, area under the plasma concentration–time curve.

Scavone JM et al. *J Clin Pharmacol*. 1998;38:603-609.

Diphenhydramine Pharmacokinetics by Age and Sex

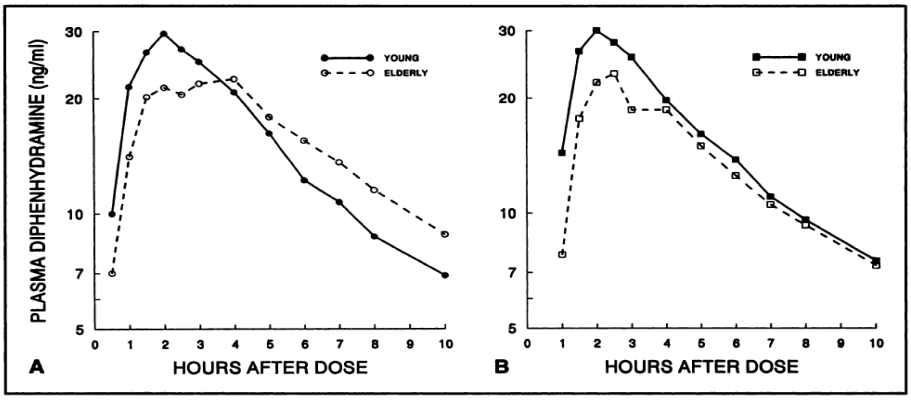


Figure 1. Mean plasma diphenhydramine concentrations at corresponding times (A) in young (●) and elderly (○) men and (B) in young (■) and elderly (□) women.

Scavone JM et al. *J Clin Pharmacol*. 1998;38:603-609.

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Pharmacokinetics Comparison Across Studies

Comparison of Pharmacokinetic Variables for Diphenhydramine Among Published Studies

Reference	Mean Kinetic Variables for Diphenhydramine: Vd (L/kg)*	Half-life (hr)*	Clearance (mL/min/kg)*	Oral Bioavailability
Albert, et al[2] (N = 2)	—	5.6	—	0.50†
Carruthers, et al[3] (N = 6)	3.29	3.3	11.2	0.43
Berlinger, et al[4] (N = 5)	4.17	4.1	12.1	0.61
Spector, et al[5]				
Meredith, et al[6] (N = 8)	8.04	9.3	9.8	—
Present study (N = 10)	4.54	8.4	6.2	0.72

*Kinetic variables after intravenous dosage; †approximation.
Vd = volume of distribution; N = number of subjects.

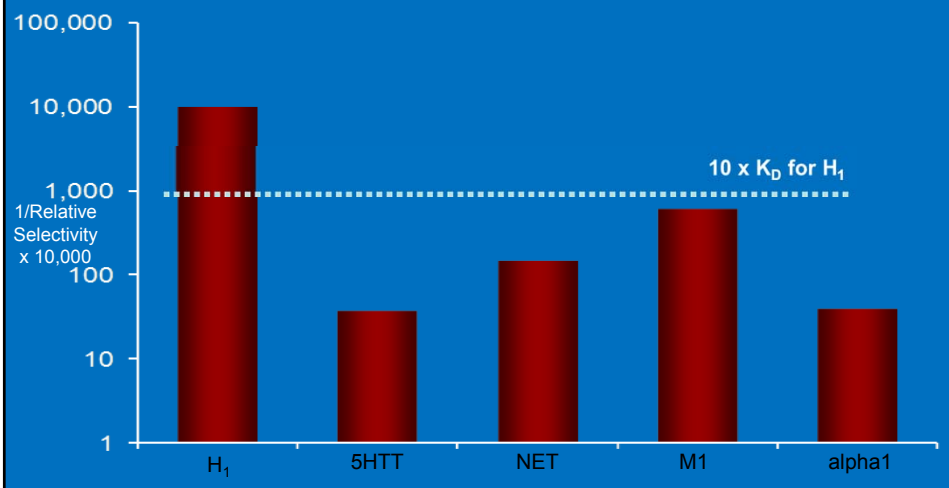
Blyden GT et al. *J Clin Pharmacol*. 1986;26:529-533.

20 Agents With Greatest M1/H1 Binding Affinity Ratio That Cross BBB (Highest Ratio of M1/H1 Inhibition Constants)

Agent	Approximate H1/M1 Binding Affinity	Comments
Pyrilamine	130,000	Highly selective H1 antagonist available OTC for cold and menstrual symptoms
Mirtazapine	5000	Highly selective H1; was in insomnia development by Organon; now Merck owned
Methapyrilene	1800	Was in OTC sleep aides until caused liver cancer in rats with long-term use
Dimethindene	700	S-Isomer potent M2 antagonist; R Isomer responsible for H1 antagonism
Hydroxyzine	590	Relatively low potency anti-H1 with relatively low M1; probably dosed > than needed
Trazodone	550	Low potency anti-H1 with minimal M1; most potent for NE, 5HT2, 5HTT blockade
Doxepin	330	Highly selective H1; Somaxon recently received FDA insomnia indication for 3-6 mg
Tripelennamine	230	Available OTC and often combined with cold medications; relatively H1 selective
Carbinoxamine	220	FDA approved for allergy, vasomotor rhinitis; mild urticaria; angioedema, low anti-M1
Tripelenamine	180	Relatively weak H1; very low M1 antagonism
Isothipendyl	180	Very selective H1 antagonist; Available for allergy and as topical antipruritic
Pyrathiazine	170	Closely related to promethazine; Moderate selectivity
Chlorpheniramine	120	OTC anti-H1; relatively H1 selective; also delayed release; Pregnancy Cat B
Clemastine	62	OTC anti-H1; potent M1; moderate selectivity; long T1/2; Pregnancy Cat B
Alimemazine	53	Somewhat selective; not available in U.S.; antipruritic, anti-emetic; allergy, sedation.
Doxylamine	40	Weak H1 antagonist but no Ach blockade and minimal others; Pregnancy Cat B
Meclizine	26	Very weak H1; very low anti-Ach; used for vertigo/motion sickness
Diphenylpyraline	24	Marketed in Europe for allergy; potent M1 blocker; also dopamine reuptake inhibitor
Diphenhydramine	20	Weak H1 antagonist but low Ach blockade and minimal others; Pregnancy Cat B

Kubo N et al. *Jpn J Pharmacol.* 1987;43:277e82.
Richelson E. *Mayo Clin Proc.* 2001;76:511-527.

Diphenhydramine



Cusack B et al. *Psychopharmacology.* 1994;114:559-565.
Tatsumi M et al. *Eur J Pharmacol.* 1997;340:249-258.

Efficacy of Diphenhydramine in Family Care

SAS-GLM Crossover Analysis of Patients' Daily Questionnaire Items ($N = 96$)

		Drug	Placebo	F-Ratio Treatment	F-Ratio Period
How long did it take you to fall asleep? (0–4)	Week 1	2.07	1.68	9.07**	8.05**
	Week 2	2.36	2.05		
How many times did you wake up during night? (0–4)	Week 1	2.86	2.68	9.69**	12.52***
	Week 2	3.15	2.89		
Time spent awake in bed? (0–6)†	Week 1	1.44	1.84	13.84***	5.96*
	Week 2	1.04	1.60		
How many hours did you sleep? (0–4)	Week 1	1.92	1.68	18.77***	2.18
	Week 2	2.21	1.66		
How much did medication help you sleep? (0–3)	Week 1	1.24	0.92	21.95***	0.83
	Week 2	1.53	0.82		
How deeply did you sleep? (0–3)	Week 1	2.12	1.82	22.95***	4.13*
	Week 2	2.26	1.94		
How was the quality of your sleep? (0–4)	Week 1	2.71	2.39	16.96***	4.26*
	Week 2	2.90	2.53		
How rested did you feel when you woke up? (0–3)	Week 1	1.96	1.86	6.15*	1.64
	Week 2	2.07	1.89		

Rickels K et al. *J Clin Pharmacol.* 1983;23:234-242.

Efficacy of Diphenhydramine and Valerian

Variable	Valerian-Hops	Group Placebo	Diphenhydramine
		Sleep Latency, min	
Sleep diary			
Baseline	35.07 (25.79) 59	27.88 (20.96) 65	25.69 (13.73) 60
Week 2	27.54 (25.02)	23.77 (21.49)	21.62 (12.87)
Week 4	25.89 (28.10)	23.71 (21.19)	22.11 (13.83)
Week 6	25.71 (25.48)	24.50 (17.90)	20.70 (13.80)
Polysomnography			
Baseline	19.48 (21.61) 22	36.04 (43.30) 26	17.77 (19.40) 26
Week 1	15.94 (17.69)	19.50 (29.25)	15.65 (22.64)
Week 2	9.06 (4.95)	18.35 (22.82)	10.46 (9.57)

Morin CM et al. *Sleep.* 2005;28:1465-1471.

Efficacy of Diphenhydramine and Valerian

	Valerian	Placebo	Diph 50 mg
		Sleep Efficiency, %	
Sleep diary			
Baseline	81.32 (8.84) 58	80.13 (9.81) 65	82.59 (7.30) 58
Week 2	84.32 (9.68)	82.57 (11.53)	87.17 (6.55)
Week 4	86.37 (10.17)	83.38 (10.14)	85.62 (8.30)
Week 6	85.00 (10.48)	82.92 (9.67)	86.96 (6.90)
Polysomnography			
Baseline	76.33 (20.39) 22	75.76 (14.62) 26	77.34 (17.77) 26
Week 1	84.97 (13.13)	80.83 (15.84)	84.30 (9.01)
Week 2	84.68 (10.54)	83.72 (10.56)	86.31 (10.94)

Morin CM et al. *Sleep.* 2005;28:1465-1471.

Efficacy of Diphenhydramine and Valerian

	Valerian	Placebo	Diph 50 mg
		Total Sleep Time (min)	
Sleep diary			
Baseline	392.91 (67.66) 58	384.46 (74.71) 65	389.99 (74.95) 58
Week 2	404.88 (67.14)	401.76 (78.35)	419.59 (60.62)
Week 4	418.82 (66.49)	405.75 (71.07)	399.96 (77.04)
Week 6	411.06 (73.62)	399.17 (76.74)	412.85 (82.10)
Polysomnography			
Baseline	340.69 (98.29) 22	335.02 (61.17) 26	347.93 (82.73) 26
Week 1	373. 73 (65.01)	362.69 (74.80)	375.21 (41.09)
Week 2	381.36 (65.95)	370.40 (45.49)	382.77 (49.21)

Morin CM et al. *Sleep.* 2005;28:1465-1471.

Efficacy of Temazepam and Diphenhydramine in Elderly Adults With Sleep Problems

Table 3. Results of Morning Questionnaire

QUESTION*	TEMAZEPAM	DPH	PLACEBO
1 (latency)	1.84†	2.20†	1.80
2 (duration)	1.74	2.15	1.87
3 (number of awakenings)	1.97	2.01	1.90
4 (time spent awake)	1.76	2.04	1.84
5 (overall evaluation)	1.91	2.14	1.83
6 (overall evaluation)	2.66	2.72	2.36

*See Table 1 for wording of questions and meaning of numerical results.
†Different from placebo $p < 0.05$.
DPH = diphenhydramine.

Meuleman JR et al. *Drug Intell Clin Pharmacol.* 1987;21:716-720.

Safety in Elderly Adults

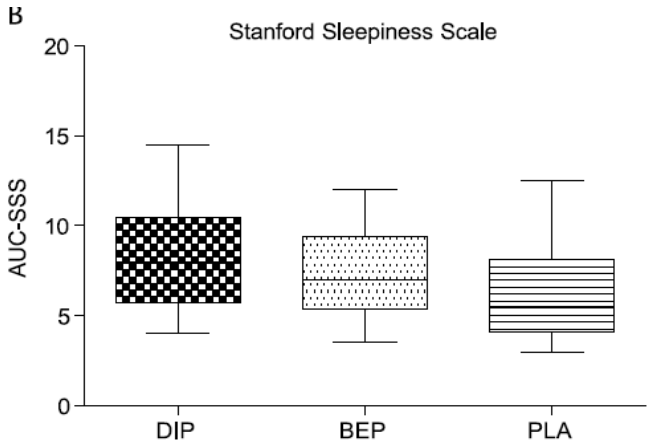
Table 4. Tests of Neurologic Function

NEUROLOGIC TEST	TEMAZEPAM VS. PLACEBO	DPH VS. PLACEBO	
Word list		+	+
Vocabulary		+	+
Tapping board		+	
Cancellation test–time	+		+
Cancellation test–omissions		+	+
Digit span forward		+	+
Digit span reverse		+	
Digit symbol substitution		+	+

Plus sign indicates better score on test during week when this agent was administered.

Meuleman JR et al. *Drug Intell Clin Pharmacol.* 1987;21:716-720.

Residual Sedation of Diphenhydramine 50 mg



Zhang D et al. *J Clin Psychopharmacol.* 2010;30:694-701.

Residual Effect of Diphenhydramine 50 mg on PET

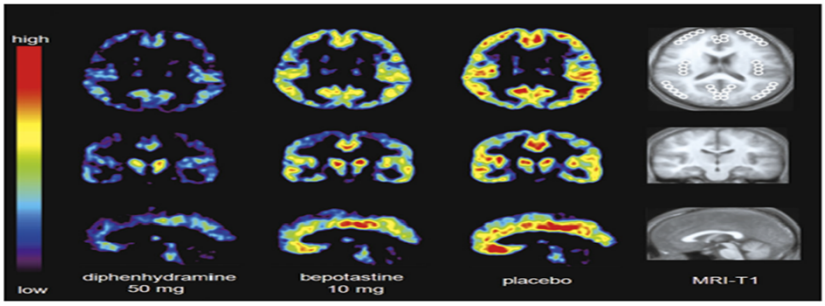


FIGURE 1. Images of BPR of ^{11}C-doxepin in the human brain. The BPR images taken from healthy male subjects (n = 8) using PET 12 hours after oral diphenhydramine 50 mg (left), bepotastine 10 mg (middle), or placebo (right) administration, and their MRI-T1 images (far right) are shown in the transaxial (top), coronal (middle), and sagittal (bottom) sections for each treatment. White circles indicate the ROIs. The brain image of each subject was transformed to fit stereotaxic brain space (spatial normalization) and was averaged across each treatment to generate the mean images. Note that treatment with diphenhydramine results in significantly lower BPRs than the other 2 treatments.

Zhang D et al. *J Clin Psychopharmacol.* 2010;30:694-701.

OTC Sleep Aids and Sleep Health

…And Miles to Go Before I Sleep
—Frost

Questions for Discussion

- How does this information compare with your understanding of the safety and effectiveness of OTC sleep aid use in older adults?
- What information gaps remain that prevent sufficient understanding regarding older adult use of OTC sleep aids?
- How do you believe this information should be used to assist older adults in making informed decisions about OTC sleep aid use?

OTC SLEEP AIDS AND SLEEP HEALTH IN OLDER ADULTS

Grand Hyatt • Washington, DC
Wednesday and Thursday, October 16-17, 2013

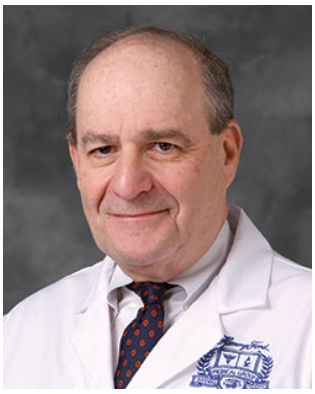
Workgroup

Steven M. Albert, PhD, *Workgroup Chairperson,* is a Professor in the Graduate School of Public Health in the Department of Behavioral and Community Health Sciences at the University of Pittsburgh. He teaches courses on aging as a field of public health, the assessment of quality of life in health and aging, social dimensions of aging, evaluation, and a public health approach to long-term care. He is also the Chair for Research and Science.

Dr. Albert's research centers on the assessment of health outcomes in aging and chronic disease, including physical and cognitive function, health service use, and the cost of care, quality of life, and clinical decision making. His recent efforts include investigation of mental health and clinical decisions at the end of life (National Institute of Mental Health) and a study of the cognitive and physical basis of independence in older people (National Institute on Aging). Dr. Albert's current projects include a study of worksite health promotion, modeling of vaccine refusal across the lifespan, and public health surveillance of the end of life. He has completed research on attitudes toward health promotion in culturally insular communities, challenges in assessing quality of life in people with cognitive impairment, and cognitive factors in medication adherence. During 2010-2014, his group is leading a statewide comparative effectiveness trial of primary prevention of falling in old age (Centers for Disease Control and Prevention) and an investigation of functional trajectories at the end of life (National Institute of Nursing Research). His ongoing studies involve medication reviews among older adults in senior housing (The Pittsburgh Foundation) and use of nasal ventilation (ALS Foundation).

During 2009-2011, Dr. Albert was the secretary/treasurer of the Behavioral and Social Sciences section of The Gerontological Society of America. He serves on the editorial boards for the *Journal of the American Medical Directors Association, Internet Journal of Mental Health, Preventive Medicine,* and *Journal of Aging Studies.* He is also a reviewer for the *Journal of Gerontology, The Gerontologist, American Journal of Public Health, Journal of the American Geriatrics Society, Neurology, Journal of Aging and Health, Journal of Cross-Cultural Gerontology, Journal of the American Medical Association,* and *Neuroepidemiology.*

THE GERONTOLOGICAL SOCIETY OF AMERICA



Thomas Roth, PhD, is the Director of the Sleep Disorders and Research Center at Henry Ford Health System in Detroit. His research primarily focuses on sleep processes, including research on sleep loss, sleep fragmentation, and deviation from sleep processes such as pharmacological effects and sleep pathologies. In addition to his position at Henry Ford Health System, Dr. Roth is a Clinical Professor of Psychiatry at the University of Michigan School of Medicine in Ann Arbor.

Dr. Roth has held numerous leadership positions within the field of sleep disorders. His is a past chairman of the National Center on Sleep Disorders Research Advisory Board at the National Institutes of Health. He also is a past president of the United States Sleep Research Society, the American Sleep Disorders Association, and the National Sleep Foundation. Dr. Roth has published over 380 manuscripts, 13 edited volumes, 176 chapters, and 515 abstracts; he also is a past editor in chief of the journal *Sleep.* He received his doctoral degree from the University of Cincinnati in 1970.

Michael Toscani, PharmD, is the Fellowship Administrator for the Rutgers Institute for Pharmaceutical Industry Fellowships and Adjunct Clinical Professor at the Ernest Mario School of Pharmacy. Dr. Toscani is also President of Clinical Solutionz and Consulting Medial Director for KOL, LLC, which are private health care consulting companies. He has held senior management positions in the pharmaceutical, contract research, and health and disease management industries for more than 25 years, and he is a frequent national speaker and author in both the scientific and health care management areas. He currently serves on the editorial boards of the *Journal of Population Health Management* and *Specialty Pharmacy*, and was on the editorial boards of the *Journal of Clinical Outcomes Management, Journal of Clinical Research and Pharmacoepidemiology,* and the *Journal of Osteopathic Medicine.*

Dr. Toscani's scholarly interests include clinical development of new pharmaceutical agents in multiple therapeutic areas; pharmaceutical industry trends; key opinion leader identification and management; the design and implementation of disease management initiatives focused on modifying patient behavior; value assessments; and outcomes studies evaluating the benefits of interventions on patient care. He is active in many charitable and nonprofit organizations. He currently serves as the president of the Central New Jersey Board of Advisors for the American Cancer Society and is the vice chairman of the Foundation Board for Thomas Edison State College. He is a past president and honorary board member of All Access Mental Health (AAMH), a community mental health treatment center in New Jersey. Dr. Toscani received his bachelor of science in pharmacy and doctor of pharmacy degrees from St. John's University College of Pharmacy, and he completed a 2-year postdoctoral research and teaching fellowship in infectious diseases at Hartford Hospital.

Michael V. Vitiello, PhD, is Professor of Psychiatry and Behavioral Sciences, Gerontology and Geriatric Medicine, and Biobehavioral Nursing, and he is Co-Director of the Center for Research on the Management of Sleep Disturbances and Co-Director of the Northwest Geriatric Education Center at the University of Washington in Seattle. He is an internationally recognized expert in sleep, circadian rhythms, and sleep disorders in aging. His research efforts, funded by the National Institutes of Health, focus on the causes, consequences, and treatments of disturbed sleep, circadian rhythms, and cognition in older adults. He is the author of over 450 scientific articles, reviews, chapters, editorials, and abstracts.

Dr. Vitiello is a member of the Board of Directors and the Scientific Program, a co-chair of the Society of Behavioral Sleep Medicine, a member of the Governing Council of the World Sleep Federation, and serves as vice president of the International Sleep Science and Technology Association. He is a past president of both the Sleep Research Society and the Sleep Research Society Foundation, and past chair of the Sleep Disorders Research Advisory Board, National Institutes of Health. He has served as the Scientific Program chair of the Associated Professional Sleep Societies (American Academy of Sleep Medicine and Sleep Research Society), and on the Board of Directors of the National Sleep Foundation. He is a Fellow of The Gerontological Society of America and a founding member of the Society of Behavioral Sleep Medicine and the International College of Geriatric Psychoneuropharmacology. Dr. Vitiello is founding co-editor and editor in chief (for the Americas) of *Sleep Medicine Reviews,* and a member of the editorial boards of the *Journal of the American Geriatrics Society* and *Sleep Medicine.* He has previously served on the editorial boards of *American Journal of Geriatric Psychiatry, Behavioral Sleep Medicine, Journal of Gerontology: Medical Sciences, Journal of Gerontology: Psychological Sciences,* and *Sleep.*

Phyllis C. Zee, MD, PhD, is Professor of Neurology, Neurobiology, and Physiology at Northwestern University. She is also Director of the Sleep Disorders Center and the Accreditation Council for Graduate Medical Education–accredited sleep medicine fellowship training program and Associate Director of the Center for Sleep and Circadian Biology. She earned a doctoral degree in physiology and biophysics and a medical degree from the Chicago Medical School in Illinois. As a National Institutes of Health (NIH) postdoctoral fellow, she conducted basic science studies on the effects of age on circadian rhythms and sleep.

Dr. Zee's career focus has been to translate basic and clinical science in sleep and circadian biology to the practice of neurology and sleep medicine. Her research investigates the effects of age on sleep and circadian rhythms, genetic regulation of circadian sleep disorders, and behavioral interventions to improve sleep and performance. Her current NIH-sponsored research projects include studies to examine the ability of exercise to improve sleep and health in older people with insomnia, phenotypic characterization and genetic analysis of circadian rhythm sleep disorders, relationship between sleep, metabolic and cardiovascular risk, and the effects of age on the neural response to sleep loss. Dr. Zee is active on committees and panels both locally and nationally. She has been on the editorial boards of several journals and is currently an associate editor for the journal *Sleep.* Dr. Zee also is on the Board of Directors of the Sleep Research Society, the National Sleep Foundation, and is the chair of the NIH Sleep Disorders Research Advisory Board.

Morris Lewis, MBA, is Senior Director of External Affairs at Pfizer Consumer Healthcare. He began his career at Pfizer, Inc. in 2003, and led Pfizer's Medicare Part D commercial effort from 2003 to 2008. Thereafter, until joining Pfizer Consumer Health in 2010, Mr. Lewis led public affairs efforts across Pfizer's branded prescription medications. Prior to joining Pfizer, he was involved for 10 years as a consultant to the pharmaceutical industry, primarily on the topics of managed care and disease management; he also spent a number of years in other health care industry positions. Mr. Lewis holds a master of business administration from the Wharton School of Business at the University of Pennsylvania and undergraduate degrees from Washington and Lee University.

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Grand Hyatt • Washington, DC
Wednesday and Thursday, October 16-17, 2013

Reactor Panel

Joan Enstam Baird, PharmD, CGP, FASCP, is the Director of Clinical Affairs for the American Society of Consultant Pharmacists (ASCP) in Alexandria, Virginia. She serves as a resource to ASCP members and staff on issues related to clinical practice and oversees all ASCP activities pertaining to clinical affairs.

Previously, Dr. Baird's work in geriatric pharmaceutical care included consulting and dispensing for two national pharmaceutical services companies. She also has been a clinical pharmacy specialist for two state mental health facilities on the eastern shore of Maryland. Her administrative experience includes work as the program coordinator for the Mental Health Program at the University of Maryland Baltimore School of Pharmacy, where she developed and presented usage reports at the statewide Pharmacy and Therapeutics Committee meetings. These data were used to educate prescribers at the state psychiatric facilities about appropriate use of antipsychotic medications, with an emphasis on reducing polypharmacy through dosage optimization and stepwise prescribing regimens.

Dr. Baird has been an active member of ASCP since 2005. She has participated in the planning and execution of state conferences and other events for the Maryland Chapter of ASCP and has served as the chapter's membership director. She has lectured on safe medication prescribing to geriatric patients to both nursing students and the general public, and has served as an adjunct faculty member of the University of Maryland Eastern Shore School of Pharmacy.

Deborah A. DiGilio, MPH, is the Director of the American Psychological Association Office on Aging. The office promotes the application of psychological science and practice to address the needs and support the strengths of older adults, their families, and caregivers. Her current efforts focus on increasing the availability of mental health services for older adults, building the psychology and aging workforce through expanded education and training opportunities, public education, and advocating for policies that promote positive aging and address the needs of older adults with mental and behavioral health disorders. Ms. DiGilio has worked in the health and aging field for over 30 years, including positions with

George Mason University, AARP, the American Public Health Association, and Kaiser Permanente of the Mid-Atlantic States. Ms. DiGilio is currently on the Board of Directors of the National Alliance for Caregiving and the Coordinating Council of the Eldercare Workforce Alliance, and she is a past chair of the National Coalition on Mental Health and Aging.

James A. Owen, PharmD, BCPS, is the Associate Vice President of Practice and Science Affairs at the American Pharmacists Association (APhA), the national professional society of pharmacists headquartered in Washington, DC. He manages APhA's practice affairs activities including medication therapy management projects and services, directs activities and projects for the APhA Community Pharmacy Residency Program initiative, oversees activities for APhA's Practice and Science Academies, and participates in activities associated with medication safety and quality improvement.

Prior to joining APhA, Dr. Owen was the Director of Clinical Services and Professional Development for Happy Harry's Inc., a regional chain pharmacy organization based in Newark, Delaware, where he developed and initiated clinical service programs, directed activities for training of pharmacy staff, and provided community outreach. His background includes 17 years of experience in community pharmacy practice as a staff pharmacist, pharmacy manager, preceptor, and community pharmacy residency director. Dr. Owen continues to practice part-time as a health-system inpatient pharmacist.

He graduated from the Philadelphia College of Pharmacy and Science with a bachelor of science in pharmacy in 1990 and earned his doctor of pharmacy degree from the Massachusetts College of Pharmacy and Health Sciences in 2007. He is Board Certified in Pharmacotherapy by the Board of Pharmacy Specialties.

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