OTC Sleep Aids Use and Sleep Health in Older Adults

Improve safe use through research, education, advocacy, and policy

Welcome

James C. Appleby, RPh, MPH, Executive Director and CEO
1 out of every 9 Americans is 65 or older

- 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

US Bureau of the Census 2008 population estimates.

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

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

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

GSA National Summit on OTC Sleep Aids Use and Sleep Health in Older Adults
Introduction of the Workgroup, Stakeholders, and the Goals for the Day

Steven M. Albert, PhD, Workgroup Chairperson
Workgroup Members

Steven M. Albert, PhD (Workgroup Chair)
Professor and Chair
Department of Behavioral and Community Health Sciences
Graduate School of Public Health
University of Pittsburgh

Morris Lewis (ex officio)
Senior Director, External Affairs
Pfizer Consumer Health

Thomas Roth, PhD
Director of Research and Division Head
Henry Ford Health System
Sleep Disorders and Research Center

Michael Toscani, PharmD
Research Professor
Fellowship Director
Rutgers Institute for Pharmaceutical Industry Fellowships
Ernest Mario School of Pharmacy

Michael V. Vitiello, PhD
Professor, Psychiatry & Behavioral Sciences, Gerontology & Geriatric Medicine, and Biobehavioral Nursing
Co-Director, Center for Research on Management of Sleep Disturbances
Co-Director, Northwest Geriatric Education Center

Phyllis C. Zee, MD, PhD
Professor of Neurology, Neurobiology and Physiology
Director, Sleep Disorders Program
Northwestern University Feinberg School of Medicine
Summit Agenda

10:30 AM – 11:30 AM RESEARCH UPDATE: Kantar Health’s National Health and Wellness Survey on Sleep Characteristics in Older Adults
11:30 AM – 11:45 AM Wiggle Break
11:45 AM – 12:30 PM EDUCATION UPDATE: Sleep Health and Older Adults Education and Awareness
12:30 PM – 1:15 PM Networking Lunch
1:15 PM – 2:30 PM ADVOCACY UPDATE: Why Is Improved Sleep Health Important for Older Adults?
2:30 PM – 3:00 PM POLICY UPDATE: Call to Action to Improve Safe Use
3:00 PM – 3:15 PM Wiggle Break
3:15 PM – 4:15 PM TRANSLATE TO PUBLIC, POLICY, AND PRACTITIONERS
4:15 PM – 4:30 PM Closing Remarks: Reflections of the Day and Next Steps

Origins of Summit

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

National Summit I: OTC Sleep Aids and Sleep Health in Older Adults
October 2013

White Paper: Sleep Health and the Appropriate Use of OTC Sleep Aids in Older Adults
November 2013

Press Briefing: Fact Sheets and FAQs about OTC Sleep Aids and Sleep Health in Older Adults
November 2013

Webinar: Sleep Health and the Appropriate Use of OTC Sleep Aids in Older Adults
January 2014

National Summit II: OTC Sleep Aids and Sleep Health: Research, Education, Advocacy
June 2014

GSA National Summit on OTC Sleep Aids Use and Sleep Health in Older Adults
Next Steps for Summit

National Summit II: OTC Sleep Aids and Sleep Health in Older Adults: Research, Education, Advocacy
June 2014

GSA Symposium November 2014

Publication: “Sleep Health & Appropriate Use of OTC Sleep Aids in Older Adults”;
Web-based educational modules
November 2014

Congressional Briefing

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

Promoting Safe and Effective Use of OTC Medications: CHPA-GSA National Summit

Steven M. Albert, PhD, Laura Bix, PhD, Mary M. Bridgeman, PharmD, Laura L. Carstensen, PhD, Margaret Dyer-Chamberlain, MALD, Patricia J. Neafsey, PhD, and Michael S. Wolf, PhD

Older adults aged 65 and older comprise 13% of the population but account for 34% of prescription (Rx) and 30% of nonprescription over-the-counter (OTC) medication use in the United States (National Center for Patient Information and Education, n.d.). Regular use of OTC medications among older adults in the National Social Life, Aging, and Health Project (NSHAP) was estimated to be as high as 47.2% in people aged 75–85 (Qano et al., 2008). Based on the nationally representative NSHAP, 4% of U.S. older adults’ medication regimens include a potentially major drug–drug interaction, and half of these involve a nonprescription medication.
Health Literacy and OTC Behavior

How can we reinforce lay understanding of OTC medications to stress active ingredients rather than symptom relief? Or, short of this change, how can we make active ingredients more salient to consumers in Drug Facts labeling? What changes in marketing of OTC products would such a change entail?

Decision Making and OTC Medications among Older Adults

What organization of OTC information in the Drug Facts label best allows older adults to appreciate risks and appropriate use? Visual displays, packaging, readability, andchunking of information will all need to be considered.

The Role of Clinicians in OTC Medication Behavior

What are the best ways to get clinicians to elicit OTC medication use and ensure that this information is properly recorded in the patient health record? How can current pharmacist medication therapy review be extended to cover OTC use?

Older Adult OTC Behavior and Family Care

What sorts of patient and caregiver clinical education will best support safe and effective OTC medication use? Effective education geared to caregivers may also improve caregiver OTC literacy.

Technology to Promote Optimal Use of OTC Medications

How can human factors be more effectively incorporated in the design of automated medication reminders or point-of-use education? How can we appropriately modify policy factors that constrain adequate integration of OTC medication data in the patient electronic health record?

Promoting Safe and Effective Use of OTC Medications: CHPA-GSA National Summit

Steven M. Albert, PhD,1,2 Laura Bla, PhD,3 Mary M. Stilgenbauer, PharmD,2
Laura L. Carsten, PhD,2 Margaret Dyer-Chamberlain, MALS,3 Patricia J. Neuford, PhD,2 and Michael S. Wolf, PhD2

Funding Priorities

Finally, the GSA-CHPA OTC Behavior workgroup as a whole was asked to consider funding initiatives that could push this research agenda forward. The workgroup endorsed the following funding initiatives:

1. An NIH request for funding in the area of OTC medication behaviors and aging;
2. Funding to support publication of papers investigating OTC medication use in appropriate gerontology journals (supplements or special issue);
3. Funding to add questions on OTC medication use and behavior to ongoing national surveys;
4. CMS or FDA funding, perhaps in a partnership from industry, to support research on optimal labeling of OTC medications.

Promoting Safe and Effective Use of OTC Medications: CHPA-GSA National Summit

Steven M. Albert, PhD,1,2 Laura Bla, PhD,3 Mary M. Stilgenbauer, PharmD,2
Laura L. Carsten, PhD,2 Margaret Dyer-Chamberlain, MALS,3 Patricia J. Neuford, PhD,2 and Michael S. Wolf, PhD2
Promoting Safe and Effective Use of OTC Medications: CHPA-GSA National Summit
Shane W. Albert, PhD, MS, Laura R. Ko, PhD, MS, Marc M. Bridgeman, PharmD, LCSW, LCPC, Margaret O’Brien-Chamberlain, MA, PhD, Patricia J. Neild, PhD, and Michael E. White, PhD

www.geron.org/otc

GSA National Summit on OTC Sleep Aids Use and Sleep Health in Older Adults
The risks and benefits of OTC sleep aids for the treatment of disturbed sleep in older adults have not been examined in randomized controlled trials. Nevertheless, a substantial body of data has identified risks associated with these products and several authoritative sources caution against their use.

The Gerontological Society of America suggests FDA consider OTC medication review and labeling that would address and be responsive to evolving science specific to safety risks of medication use associated with the aging process.

Sleep Health Among Older Adults: Many Unknowns

- Prevalence of sleep disturbance (vs. insomnia)
  - Relation to age, medical status, daily environment
- How older adults use OTC products to treat sleep disturbance
  - Relative to Rx and non-pharmacologic therapies
- Efficacy of OTC therapies
- Role of pharmacists in counseling and product choice
Sleep Therapies: Neglected Area

- “Rigorous scientific data supporting a beneficial effect were not found for the majority of herbal supplements, dietary changes, and other nutritional supplements popularly used for treating insomnia symptoms.”

“Reasons You Can’t Fall Asleep”

- You Slept In Saturday And Sunday
- It’s A Full Moon
- Your Room Is Too Cold -- Or Too Hot
- You’re Not Wearing Socks
- It’s Too Quiet
- You’re Afraid Of The Dark
- You Ate Steak For Dinner
- You’re Exhausted
- You Share A Bed

Huffington Post, 9 Surprising Reasons You Can’t Fall Asleep. http://www.huffingtonpost.com/2014/05/02/women-men-sleep-differences_n_5242333.html?1399033326
Understanding Older Drivers: An Examination of Medical Conditions, Medication Use, and Travel Behavior

April 2014

Tables 5 and 6 taken together suggest that a substantial number of older people are taking over-the-counter medications. The extent to which purchasers ask a pharmacist or their own physicians about the impacts of non-preservation medications is unknown. But an AAA FTS report (2009) found that many drivers were unaware of the risks of most medications; moreover, doctors and other medical professionals rarely warned drivers about these risks.

National Sleep Foundation Convenes Expert Panel to Review Sleep Time Recommendations

WASHINGTON, D.C. (March 24, 2014)—The National Sleep Foundation (NSF) has convened the Sleep Time Recommendations Expert Panel (STREP) to update its recommendations for appropriate sleep times at every life stage. The NSF anticipates its recommendations to be released in January 2015.
GSA Summit on OTC Sleep Aids Use and Sleep Health in Older Adults

### 2013 International Bedroom Poll

**Summary of Findings**

**United States**
- Average time slept work nights: 6h 31m
- Average sleep needed to function best: 7h 13m
- Less sleep than needed on workdays: 56%
- Good night sleep every/almost every night: 44%
- Schedule/Routine allows adequate sleep: 72%

**Canada**
- Average time slept work nights: 7h 3m
- Average sleep needed to function best: 7h 23m
- Less sleep than needed on workdays: 53%
- Good night sleep every/almost every night: 43%
- Schedule/Routine allows adequate sleep: 70%

**Mexico**
- Average time slept work nights: 7h 6m
- Average sleep needed to function best: 8h 15m
- Less sleep than needed on workdays: 40%
- Good night sleep every/almost every night: 40%
- Schedule/Routine allows adequate sleep: 66%

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### Insomnia and Sleep Disturbance

**Common Conditions**

- Altered Sleep Regulation & Circadian Rhythms
- Medical, Neurologic, & Psychiatric Conditions
- Psychosocial Factors

- Difficulty Initiating & Maintaining Sleep
- Chronic Pain
- Pulmonary Disease
- Late-Life Stressors
- Depression
- SDB (Sleep Apnea)
- Restless Legs

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GSA Summit on OTC Sleep Aids Use and Sleep Health in Older Adults
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.
Indications for Sleep Medications

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

Beers Criteria

<table>
<thead>
<tr>
<th>Organ System/Therapeutic Category/Drug(s)</th>
<th>Recommendation, Rational, Quality of Evidence (QG) &amp; Strength of Recommendation (SR)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Anticholinergics (excludes TAs)</td>
<td>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.</td>
</tr>
<tr>
<td>1st generation antihistamines (as single agent or as part of combination products)</td>
<td>Use of diphenhydramine in special situations such as acute treatment of severe allergic reaction may be appropriate. QG = High (Hydralazine and Phenelzine), Moderate (All others); SR = Strong</td>
</tr>
<tr>
<td>Diphenhydramine (oral)</td>
<td></td>
</tr>
<tr>
<td>Promethazine</td>
<td></td>
</tr>
<tr>
<td>Triprolidine</td>
<td></td>
</tr>
<tr>
<td>Antipsychotics</td>
<td>Avoid. Not recommended for prevention of extrapyramidal symptoms with antipsychotics; more effective agents available for treatment of Parkinson disease. QG = Moderate; SR = Strong</td>
</tr>
<tr>
<td>Haloperidol</td>
<td></td>
</tr>
<tr>
<td>Thiothixene</td>
<td></td>
</tr>
</tbody>
</table>

• 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 Aids (n = 1,256)
- Unisom SleepTabs (doxylamine): 22%
- Unisom SleepGels (diphenhydramine): 21%
- ZzzQuil (diphenhydramine): 7%
- Nytol (diphenhydramine): 6%
- Sominex (diphenhydramine): 5%
- MidNite (herbal): 2%
- Other: 38%

Module 6: Inadequate Sleep

I would like to ask you a few questions about your sleep patterns.

1. On average, how many hours of sleep do you get in a 24-hour period? Think about the time you actually spend sleeping or napping, not just the amount of sleep you think you should get.

2. Do you snore?

3. During the past 30 days, for about how many days did you find yourself unintentionally falling asleep during the day?  
   (297-298)

4. During the past 30 days, have you ever nodded off or fallen asleep, even just for a brief moment, while driving?  
   (299)

Population-Based Estimates of Poor Sleep Health: BRFSS 2006

A)

SLEEPDIST

B)

TIREDNESS

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Rehabilitating Sleep
Commentary on Martin et al. Poor self-reported sleep quality predicts mortality within one year of inpatient post-acute rehabilitation among older adults. SLEEP 2011;34:1715-1721.
Marcia E. Braun, PhD; Nalaka S. Gooneratne, MD, MSc

Social Jetlag and Obesity

What Older People Do about Sleep Problems

Table 1. Percentage of Study Participants Who Participated in Each Activity to Treat Their Sleep Complaints and Had Discussed Their Sleep Complaints with Their Healthcare Provider

<table>
<thead>
<tr>
<th>Activity</th>
<th>Participated in Activity</th>
<th>Discussed Sleep Complaints with Health Care Provider</th>
<th>p-value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Medication</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>took pain medicine</td>
<td>40.1</td>
<td>55.1</td>
<td>.03</td>
</tr>
<tr>
<td>took an over-the-counter sleep aid (e.g., NyQuil, TYLEND PM)</td>
<td>30.6</td>
<td>48.2</td>
<td>.07</td>
</tr>
<tr>
<td>took a prescription sleep aid (e.g., Valium, Alprazol, Sonata)</td>
<td>22.1</td>
<td>77.5</td>
<td>&lt;.001*</td>
</tr>
</tbody>
</table>

n=242, mean age 73

Perceived Effectiveness of Diverse Sleep Treatments in Older Adults
Nalaka S. Gooneratne, MD, MSc; ** Aashir A. Patel, MD, MPH; Logan F. Chandler, MD, FAAN; and Kathy G. Bohdan, RN, BSN

GSA Summit on OTC Sleep Aids Use and Sleep Health in Older Adults
Table 2. Self-Report of Effectiveness of Each Activity

<table>
<thead>
<tr>
<th>Activity</th>
<th>Perceived Effectiveness, Mean ± Standard Deviation</th>
</tr>
</thead>
<tbody>
<tr>
<td>Prescription sleeping medicine</td>
<td>2.5 ± 1.2</td>
</tr>
<tr>
<td>Change room</td>
<td>2.1 ± 1.2</td>
</tr>
<tr>
<td>Read</td>
<td>2.0 ± 1.2</td>
</tr>
<tr>
<td>Radio or television</td>
<td>2.0 ± 1.1</td>
</tr>
<tr>
<td>Change room temperature</td>
<td>2.0 ± 1.1</td>
</tr>
<tr>
<td>Over-the-counter sleep medicine</td>
<td>1.9 ± 1.3</td>
</tr>
<tr>
<td>Took a nap the next day</td>
<td>1.9 ± 1.1</td>
</tr>
<tr>
<td>Took medicine for pain</td>
<td>1.9 ± 1.1</td>
</tr>
<tr>
<td>Bath or message</td>
<td>1.8 ± 1.0</td>
</tr>
<tr>
<td>Alcohol</td>
<td>1.8 ± 1.0</td>
</tr>
<tr>
<td>Spoke to someone</td>
<td>1.8 ± 1.2</td>
</tr>
<tr>
<td>Exercise</td>
<td>1.7 ± 1.3</td>
</tr>
<tr>
<td>Snack</td>
<td>1.7 ± 1.1</td>
</tr>
<tr>
<td>Drink liquid other than alcohol</td>
<td>1.6 ± 1.0</td>
</tr>
<tr>
<td>Relaxation exercises</td>
<td>1.5 ± 1.2</td>
</tr>
<tr>
<td>Cigarette</td>
<td>1.3 ± 1.6</td>
</tr>
<tr>
<td>Meditain</td>
<td>1.3 ± 1.3</td>
</tr>
<tr>
<td>Vitamins</td>
<td>1.3 ± 1.3</td>
</tr>
<tr>
<td>Acupuncture</td>
<td>1.3 ± 1.5</td>
</tr>
<tr>
<td>Refrained from taking a nap the next day</td>
<td>1.2 ± 1.2</td>
</tr>
<tr>
<td>Ear plugs</td>
<td>1.0 ± 1.0</td>
</tr>
</tbody>
</table>

0-4 = maximum effectiveness; n=242, mean age 73

Perceived Effectiveness of Diverse Sleep Treatments in Older Adults

Nikolai S. Gurevitch, MD, MSC; Aishah Tavirah, MD; Nihar Patel, MD, MPH; Lavanji M. M. Madhurangan, PhD; Darcy Naderiz, MD; Erica Owens, MD, PhD; and Kathy G. Rahardja, RN, PhD.

JAGS 2014;29(5-6):305-311

Advocacy Model for Our Efforts?

Join us for Congressional Sleep Health & Safety Briefing

Sleep Research Society
Tuesday, April 8, 2014
Sleep for Health & Safety
1-340 Rayburn House Office Building
April 10, 2014 at 12:00pm

AASM & SRS congressional briefing a success

American Academy of Sleep Medicine
Thursday, April 17, 2014

The AASM and SRS recently conducted a successful congressional briefing that was attended by numerous legislative staffers and co-hosted by Rep. Hank Johnson (D-GA) and Rep. Mike Honda (D-CA). The briefing, titled Sleep for Health & Safety, was held on April 10. At the briefing, Rep. Honda spoke about the importance of supporting more funding for NIH and the need for more training for law officers to detect drowsy drivers.
Social Media 101

Kelsey Heinze, Member Engagement and Social Media Manager

Say What?

#OTCSleep

2014 OTC Sleep Aids Use and Sleep Health in Older Adults
The Gerontological Society of America
Cliff Notes, Please

Tweet [verb] \ˈtwēt\: The action of posting a message of 140 characters or less onto Twitter

*Kelsey tweeted about the conference she was attending in Washington, DC.*

Hash-tag [noun] \ˈhāsh-, tag\: a word or phrase preceded by the symbol # that categorizes the tweet

*Kelsey tweeted using the hashtag #OTCSleep so others could follow that topic throughout the day.*

Hand-le [noun] \ˈhan-dəl\: Twitter username

*Kelsey’s handle is @geronsociety.*

Show Me

@geronsociety: Learning about the research gaps in #OTCSleep research and the role of clinicians. Follow along!

@sallysmith: What technologies are being developed to help with #OTCSleep behaviors?

#OTCSleep
Let’s go viral. Use your knowledge, share your thoughts, answer questions.

Your job? To educate and inform.

150,000 people

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RESEARCH UPDATE
Sleep Characteristics of Older Adults: Findings from the National Health and Wellness Survey

Michael Toscani, PharmD, and Greg O’Neill, PhD

#OTCSleep
Project Objective

• To investigate self-reported sleeplessness symptoms and problems among adults (18+ years of age) in the United States, using data from Kantar Health’s National Health and Wellness Survey (NHWS).

NHWS Method and Sample

- Data Collection
  + Survey administered via the Internet since 2002
  + Data collected during Q1–Q3 2013
- Sample
  + Adults 18+ years of age
  + Sample drawn from the Internet panel maintained by Lightspeed Research and its partners
  + Invitations to participate sent to a sample stratified according to:
    - Gender
    - Age
    - Race
- Results are projected to reflect the total population using known population incidences for key subgroups
  + Weighting Variables: Gender, age, race/ethnicity and education
  + From 2012 Current Population Survey (Annual Demographics File) of the U.S. Census Bureau
**Study Population**

- Self-report regularly experiencing 1 or more sleeplessness symptoms including:
  - Difficulty falling asleep
  - Waking up during the night and not being able to get back to sleep
  - Waking up several times during the night
  - Waking up too early (such as before the alarm clock)
  - Poor quality of sleep
- Self-report experiencing or diagnosis of “sleep difficulties” and/or “insomnia” (past 12 months)
- Self-report no sleeplessness symptoms, but do report experiencing or diagnosis of “sleep difficulties” and/or “insomnia”
- Self-report no sleeplessness symptoms nor any type of “sleep difficulties”/“insomnia”
- Respondents who report narcolepsy, parasomnia, sleep-disordered breathing/sleep apnea, and/or circadian rhythm disorder excluded from analysis

**Sleeplessness Symptoms in US Adult Population**

- Sleeplessness Symptoms include 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 (such as before the alarm clock)
  - Poor quality of sleep

- Reporting “Insomnia/Sleep Difficulties” (Experiencing or diagnosed) 51.2 M (45%) (n=15,635)
- Don’t report experiencing “Insomnia/Sleep Difficulties” 49.7 M (45%) (n=15,635)
- Don’t report Sleeplessness symptoms but do report experiencing or being diagnosed with “Insomnia/Sleep Difficulties” 3.8 M (8%) (n=1,095)
- Self-report narcolepsy, parasomnia, sleep-disordered breathing/sleep apnea, and/or circadian rhythm disorder 19.7 M (8%) (n=6,625)
- Not Reporting Sleeplessness Symptoms or any type of Sleep Disorder 95.3 M (41%) (n=31,112)

**Results from Kantar Health’s National Health and Wellness Survey (NHWS): US 2013**

Questions reference for this slide include: HH10, HH15, HH20, SQ6
Population with Sleeplessness Symptoms

• 49% of adults report sleeplessness symptoms
• Among those reporting sleeplessness symptoms:
  – 45% report experiencing or diagnosed sleep difficulties/insomnia
  – 55% report no experience of sleep difficulties
  – 33% report daytime sleepiness symptoms

Sleeplessness Symptoms Among Adults Reporting Sleep Difficulties/Insomnia

<table>
<thead>
<tr>
<th>Symptom</th>
<th>18+</th>
<th>18-64</th>
<th>65-74</th>
<th>75+</th>
</tr>
</thead>
<tbody>
<tr>
<td>Difficulty falling asleep</td>
<td>73%</td>
<td>74%</td>
<td>65%</td>
<td>62%</td>
</tr>
<tr>
<td>Waking during the night</td>
<td>54%</td>
<td>52%</td>
<td>63%</td>
<td>63%</td>
</tr>
<tr>
<td>Waking up several times</td>
<td>51%</td>
<td>51%</td>
<td>50%</td>
<td>50%</td>
</tr>
<tr>
<td>Waking up too early</td>
<td>41%</td>
<td>41%</td>
<td>39%</td>
<td>38%</td>
</tr>
<tr>
<td>Poor quality of sleep</td>
<td>45%</td>
<td>48%</td>
<td>28%</td>
<td>26%</td>
</tr>
</tbody>
</table>
Older Adults’ Quality of Life (SF-36 Scores)

<table>
<thead>
<tr>
<th></th>
<th>With Sleeplessness Symptoms</th>
<th>No Sleep Problems</th>
</tr>
</thead>
<tbody>
<tr>
<td>Mental</td>
<td>46</td>
<td>52</td>
</tr>
<tr>
<td>Physical</td>
<td>50</td>
<td>52</td>
</tr>
</tbody>
</table>

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

Current Rx Use Among Adults 65+ with Sleep Difficulties/Insomnia

Report Sleeplessness Symptoms
115.0 M (n=36,168)

Reporting ‘Insomnia/Sleep Difficulties’ (Experiencing or diagnosed)
51.2 M (45%) (n=15,635)

Age 65+
6.3 M (12%) (n=2,434)
Age 18-65
44.9 M (88%) (n=13,201)

Use Rx
1.6 M (25%) (n=615)

No Rx
4.8 M (75%) (n=1,819)

Top 10 Rx Therapies Used

- Ambien (zolpidem): 558 K, 36% (n=212)
- Trazodone Hydrochloride (trazodone hydrochloride): 180 K, 12% (n=77)
- Xanax (alprazolam): 113 K, 7% (n=46)
- Amitriptyline (amitriptyline): 85 K, 6% (n=34)
- Temazepam (temazepam): 84 K, 5% (n=31)
- Lunesta (eszopiclone): 70 K, 5% (n=28)
- AmbienCR (zolpidem tartrate): 62 K, 4% (n=25)
- Restoril (temazepam): 60 K, 4% (n=24)
- Lorcipam (lorazepam): 50 K, 3% (n=21)
- Zolpidem (zolpidem tartrate): 50 K, 3% (n=21)
Who Prescribed Rx for Sleep?

<table>
<thead>
<tr>
<th>Adults Using Sleep Condition Rx</th>
<th>18-64</th>
<th>65-74</th>
<th>75+</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Primary Care Physician/ GP/Internist</strong></td>
<td>62%</td>
<td>76%</td>
<td>84%</td>
</tr>
<tr>
<td><strong>Psychiatrist</strong></td>
<td>22%</td>
<td>11%</td>
<td>3%</td>
</tr>
</tbody>
</table>

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

Current OTC/Herbal Product Use Among Adults 65+ with Sleep Difficulties/Insomnia

Report Sleeplessness Symptoms 115.0 M (n=36,168)

Report Insomnia/Sleep Difficulties (Experiencing or diagnosed) 61.2 M (46%) (n=15,635)

Use OTC/Herbal Product

Age 65+ 6.3 M (12%) (n=2,434)

Age 18-65 44.9 M (88%) (n=13,201)

No OTC/Herbal Product 4.0 M (63%) (n=1,529)

Top 10 OTC/Herbal Products Used

- Melatonin 782 K 34% (n=296)
- Tylenol Products* 447 K 19% (n=165)
- Benadryl/ Diphendramine* 270 K 12% (n=107)
- Sleep Aid 204 K 9% (n=77)
- Advil PM* 163 K 7% (n=63)
- Valerian 100K 5% (n=38)
- ZzzQuil* 93 K 4% (n=36)
- Teas 90 K 4% (n=34)
- Unisan* 75 K 3% (n=28)
- Midnite 73 K 3% (n=23)

*Contains diphendramine or doxylamine

Results from Kantar Health’s National Health and Wellness Survey (NHWS), US 2013
Questions reference for this slide include: DE10, HH10, HH15, HH20, SD75, SD80
### Sleep Treatment Combinations

<table>
<thead>
<tr>
<th>Adults Reporting Sleep Difficulties/Insomnia</th>
<th>18-64</th>
<th>65-74</th>
<th>75+</th>
</tr>
</thead>
<tbody>
<tr>
<td>Rx Only</td>
<td>15%</td>
<td>21%</td>
<td>17%</td>
</tr>
<tr>
<td>OTC Only</td>
<td>12%</td>
<td>12%</td>
<td>12%</td>
</tr>
<tr>
<td>Herbal Only</td>
<td>10%</td>
<td>9%</td>
<td>12%</td>
</tr>
<tr>
<td>Rx + OTC</td>
<td>2%</td>
<td>2%</td>
<td>3%</td>
</tr>
<tr>
<td>Rx + Herbal</td>
<td>2%</td>
<td>2%</td>
<td>2%</td>
</tr>
<tr>
<td>OTC + Herbal</td>
<td>3%</td>
<td>3%</td>
<td>3%</td>
</tr>
<tr>
<td>Rx + OTC + Herbal</td>
<td>~1%</td>
<td>~1%</td>
<td>~1%</td>
</tr>
<tr>
<td>No Product</td>
<td>54%</td>
<td>49%</td>
<td>51%</td>
</tr>
</tbody>
</table>

### OTC Use Among Adults with Sleep Difficulties/Insomnia

<table>
<thead>
<tr>
<th>DOX/DPH Users</th>
<th>18-64</th>
<th>65-74</th>
<th>75+</th>
</tr>
</thead>
<tbody>
<tr>
<td>15%</td>
<td>15%</td>
<td>16%</td>
<td></td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>OTC pain reliever/sleep aid</th>
<th>18-64</th>
<th>65-74</th>
<th>75+</th>
</tr>
</thead>
<tbody>
<tr>
<td>9%</td>
<td>11%</td>
<td>12%</td>
<td></td>
</tr>
</tbody>
</table>
Adults Currently Using DPH/DOX for Sleep Problems

<table>
<thead>
<tr>
<th>Age Group</th>
<th>Usage Rate</th>
</tr>
</thead>
<tbody>
<tr>
<td>18–64</td>
<td>4%</td>
</tr>
<tr>
<td>65–74</td>
<td>3%</td>
</tr>
<tr>
<td>75+</td>
<td>2.5%</td>
</tr>
</tbody>
</table>

\[ n = 690,775 \quad 447,633 \]

Estimated: 1.14 Million Adults 65+

2014 OTC Sleep Aids Use and Sleep Health in Older Adults

The Gerontological Society of America
### Days Using OTCs, Among Adults Taking DPH/DOX

<table>
<thead>
<tr>
<th>Days Using OTCs</th>
<th>18-64</th>
<th>65-74</th>
<th>75+</th>
</tr>
</thead>
<tbody>
<tr>
<td>0 days</td>
<td>12%</td>
<td>7%</td>
<td>7%</td>
</tr>
<tr>
<td>1-4 days (weekly)</td>
<td>29%</td>
<td>18%</td>
<td>19%</td>
</tr>
<tr>
<td>5-19 days (several times/week)</td>
<td>36%</td>
<td>34%</td>
<td>26%</td>
</tr>
<tr>
<td>20+ days (nearly daily)</td>
<td>24%</td>
<td>41%</td>
<td>49%</td>
</tr>
</tbody>
</table>

### Among Adults Using DPH/DOX, Rx Anticholinergic Use

<table>
<thead>
<tr>
<th>Anticholinergic Use</th>
<th>18-64</th>
<th>65-74</th>
<th>75+</th>
</tr>
</thead>
<tbody>
<tr>
<td>1+ Anticholinergic</td>
<td>24%</td>
<td>36%</td>
<td>45%</td>
</tr>
</tbody>
</table>
### Conditions Ever Experienced, Among Adults Using DPH/DOX

<table>
<thead>
<tr>
<th>Condition</th>
<th>18-64</th>
<th>65-74</th>
<th>75+</th>
</tr>
</thead>
<tbody>
<tr>
<td>Glaucoma</td>
<td>1%</td>
<td>5%</td>
<td>7%</td>
</tr>
<tr>
<td>COPD</td>
<td>1%</td>
<td>8%</td>
<td>5%</td>
</tr>
<tr>
<td>BPH**</td>
<td>3%</td>
<td>26%</td>
<td>37%</td>
</tr>
<tr>
<td>Afib</td>
<td>1%</td>
<td>5%</td>
<td>7%</td>
</tr>
<tr>
<td>Constipation*</td>
<td>6%</td>
<td>5%</td>
<td>10%</td>
</tr>
<tr>
<td>Asthma*</td>
<td>12%</td>
<td>9%</td>
<td>9%</td>
</tr>
</tbody>
</table>

*Condition experienced in past 12 months  
**Males only

### Among Adults Taking DPH/DOX

<table>
<thead>
<tr>
<th></th>
<th>18-64</th>
<th>65-74</th>
<th>75+</th>
</tr>
</thead>
<tbody>
<tr>
<td>Daytime Sleepiness</td>
<td>49%</td>
<td>31%</td>
<td>19%</td>
</tr>
<tr>
<td>Alcohol Use</td>
<td>77%</td>
<td>64%</td>
<td>56%</td>
</tr>
</tbody>
</table>

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

2014 OTC Sleep Aids Use and Sleep Health in Older Adults  
The Gerontological Society of America
## Alcohol Use, Among Adults Taking DPH/DOX, Drink Frequency

<table>
<thead>
<tr>
<th></th>
<th>18-64</th>
<th>65-74</th>
<th>75+</th>
</tr>
</thead>
<tbody>
<tr>
<td>Daily</td>
<td>7%</td>
<td>10%</td>
<td>29%</td>
</tr>
<tr>
<td>4-6 times/week</td>
<td>9%</td>
<td>9%</td>
<td>5%</td>
</tr>
<tr>
<td>2-3 times/week</td>
<td>19%</td>
<td>12%</td>
<td>12%</td>
</tr>
<tr>
<td>Once a week</td>
<td>14%</td>
<td>10%</td>
<td>5%</td>
</tr>
<tr>
<td>2-3 times a month</td>
<td>18%</td>
<td>11%</td>
<td>12%</td>
</tr>
<tr>
<td>Once a month or less often</td>
<td>32%</td>
<td>47%</td>
<td>37%</td>
</tr>
<tr>
<td>Number of alcoholic beverages you typically drink → One</td>
<td>34%</td>
<td>45%</td>
<td>65%</td>
</tr>
</tbody>
</table>

## Adults with Sleep Difficulties/Insomnia, Using OTCs or Herbals

<table>
<thead>
<tr>
<th></th>
<th>18-64</th>
<th>65-74</th>
<th>75+</th>
</tr>
</thead>
<tbody>
<tr>
<td>Mean days/month using OTC</td>
<td>11</td>
<td>15</td>
<td>17</td>
</tr>
<tr>
<td>OTC Satisfaction</td>
<td>36%</td>
<td>33%</td>
<td>32%</td>
</tr>
</tbody>
</table>
Key Findings

- NHWS data confirm observations from other studies
- Sleeplessness symptoms are very common in U.S. adult population
- Individuals self-report sleep difficulties in different ways—important for HCPs to discuss with patients
- In older adults, off-label use of OTC sleep aids is observed, particularly:
  - With co-existing health conditions
  - Length of therapy use (i.e., ≥2 weeks)
  - Co-administration with 1* anticholinergic
  - Co-administration with alcohol
- Opportunity for educating health care professionals on treatment and safety concerns particularly in older adults

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

EDUCATION UPDATE
Sleep Health and Older Adults: Education and Awareness

Michael V. Vitiello, PhD
GSA Silver Market Training Modules

- Based on GSA’s 2012 publication *Communicating with Older Adults: An Evidence-Based Review of What Really Works*
- Online training modules designed to help pharmacy professionals meet the needs of their aging patients
- Each installment runs less than 25 minutes and offers expert information and time-tested techniques to help pharmacists and technicians work efficiently and respectfully across the counter
- Useful to anyone interacting with older adults

www.geron.org/communicating

Currently Available
- 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

Coming Soon
- 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*
GSA Silver Market Training Modules

• Module Format
  – Pre and post test questions
  – Introductory information, objectives, and resources
  – Case studies

Sleep Health and Sleep Disturbance in Older Adults

• Objectives
  – Recognize that poor sleep quality is associated with a wide variety of adverse consequences
  – Appreciate that poor sleep quality is not a necessary part of aging
  – Recognize that sleep disturbance in older adults is often multifactorial in nature
  – Appreciate that disturbed sleep in older adults often occurs in the context of co-morbid illnesses
  – Recognize that sleep disturbances in older adults can significantly impact health and quality of life and warrant appropriate diagnosis and treatment
  – Appreciate that most sleep disturbance, regardless of cause, in older adults can be treated
• Case Studies
  – The Worried Well – someone who is “not sleeping as well as he or she used to” but who upon questioning has some age-related sleep change but whose nighttime sleep is age-appropriate and whose daytime function is undisturbed
  – Acute Insomnia with clear precipitating factor; e.g., recent death of a family member
  – Chronic Insomnia with unclear etiology – patient presents with symptoms of both sleep onset but more pronounced sleep maintenance, who also snores and is overweight but not obese and has well-controlled hypertension

• Objectives
  – Recognize and communicate the benefits of good sleep to older adults and their caregivers
  – Recognize and communicate good sleep hygiene practices
  – Recognize and communicate the differences among OTC, dietary supplement, and prescription sleep aids
  – Recognize and communicate that diphenhydramine may be inappropriate OTC sleep aid for older adults, and certainly when used chronically
  – Recognize and communicate the risks of combining multiple OTC sleep aids and of combining them with prescription medications
Older Adults and OTC Sleep Aids

• Case Studies
  – Purchasing or asking for a recommendation for an OTC sleep aid – patient should be queried about the nature and duration of his or her sleep disturbance and assuming acute insomnia appropriate for an OTC sleep aid; also query for any current medication use, both prescription and OTC that has known anticholinergic side effects
  – Patient is purchasing a prescription or OTC with known anticholinergic side effects – the patient should be queried about prescription and OTC he or she may already be taking with anticholinergic effects

Launch and Dissemination

• Completion and dissemination by December 2014
• Free access to GSA members
NSF Update

David M. Cloud

June 26, 2014
Washington, DC

Mission

To improve health and well-being through sleep education and advocacy
Goals

- Sleep is used as a vital sign of health by medical professionals and the public
- Biological sleep/wake process is common knowledge
- Workplaces, schools, homes and transportation infrastructures are designed to be sleep-friendly
- Sleep science is rapidly incorporated into products and services
Sleep Time Recommendations
Consensus Expert Panel

Stakeholder Organizations

- American Academy of Pediatrics
- American Association of Anatomists
- American College of Chest Physicians
- American Congress of Obstetricians and Gynecologists
- American Geriatrics Society
- American Neurological Association
- American Physiological Society
- American Psychiatric Association
- American Public Health Association
- American Thoracic Society
- Gerontological Society of America
- Human Anatomy and Physiology Society
- Society for Research in Human Development

Expected press release: February 2015
Sleep Health: Journal of the National Sleep Foundation

- Research on sleep’s role in health promotion
- Manuscripts on sleep, behavior & health
- Population health issues
- Social science perspective on health & sleep
- First issue expected in 2014

Washington Agenda

Long-term Initiatives:
- Sleep health of older adults
- Sleep issues in the military
- OSA and transportation safety (Senate Bill 1941)

Current Active Issues:
- FAA & sleep screening for pilots
- Meaningful use
Online Education Resources

- Sleepfoundation.org
- Select patient education topics
  - Excessive sleepiness
  - Shiftwork sleep disorder
  - Insomnia
  - Non-24
- Sleep Disorders e-book

Sleep as a Vital Sign

- Sleep assessment
  - At every patient visit
  - Tool for population health management
    ➔ Promotes patient engagement
    ➔ Informs clinical decision making
- Improve overall health and health care
- Data
Consumer Electronics Association Partnership

- Standards for Wearable Sleep Trackers
- Promoting Sleep Electronics Innovation

Other NSF Activities

- Drowsy Driving Prevention Week® - November 2-9, 2014
- Sleep Health & Safety - November 7, 2014
- National Sleep Advocacy Roundtable (NSART) - November 7, 2014
- Sleep Awareness Week® - March 1-8, 2015
Questions?

Thank you
Why Sleep Health is Important for Older Adults?
An NIH Perspective

Michael Twery, Ph.D.
National Center on Sleep Disorders Research
Division of Lung Diseases
National Heart, Lung, and Blood Institute, NIH

OTC Sleep Aid Use and Sleep Health in Older Adults Summit
The Gerontological Society of America
Washington, D.C.
June 26, 2014

Sleep Research is Supported NIH-Wide

![Graph showing the number of grants supported by NIH institutes for various fields of research, including Training, Translation, Medicine, Clinical, and Basic. The graph highlights the wide support across different NIH institutes.]
Wake and Sleep: “Bookends Marking each Day”

- **Strands Defining our Personal Life, Who we are.**
  - Leisure (passive/active)
  - Intellect (work, family, spiritual)
  - Other Influences (health, relationships)
  - Contentment

- **What Sleep Adds**
  - “Dreams”, inspiration
  - Learning
  - Memory
  - Vigilance/Judgment
  - Perception of emotions
  - Decision making

Sleep and Risks to Health

- Quality of Life ↓
- Sleep Deficiency
- Sleep Disorder
- Chronic Pain ↑
- Suicide, Depression ↑
- Mortality ↑
- Exercise Response ↓

2014 OTC Sleep Aids Use and Sleep Health in Older Adults
The Gerontological Society of America
Sleep and Risks to Health

- Stroke risk ↑
- CVD risk ↑
- Hypertension risk ↑
- Mortality ↑
- Obesity risk ↑

Does The Lack Of Sleep Lead To Brain Injury?

- Locus Coeruleus
  - Clinical depression
  - PTSD
  - Neurodegenerative disease
  - Cerebrovascular dysfunction
  - Hypersomnia

- SIRT3
  - Energy production
  - Redox responses
  - Protects cell

References:
- R01 HL079003, HL095037, and R01 DK096656
Does The Lack Of Sleep Lead To Brain Injury?

Sleep Disorder => Unfolded Protein Response

Hypoxia
Sleep Deficiency

Feedback Control

ER Stress

Adaptive Response

Unfolded Protein Response
IRE1
PERK
ATF6

Effectors

Death
Cell Fate
Survival

NADPH oxidase2

SLEEP 2013;36(4):481-492
(HL079555, HL096037)

Does The Lack Of Sleep Lead To Brain Injury?

Sleep Deficiency => Impaired CSF Flow

Awake
Reduced Interstitial space
Restricted CSF flow
Metabolites accumulate

Asleep
60% increase in interstitial space
Better CSF flow
Effective clearance of metabolites

Science 2013;342:373-377
(N5078167 and N5078304 to M.N. and N5028642)
Does The Lack Of Sleep Lead To Brain Injury?

Sleep Deprivation => blocks morning dip in Aβ42

CSF concentrations of Aβ42

- Sleep Deprivation: 0.3 hours
- Unrestricted Sleep: 6.4 hours

What is Sleep and What is it good for?

“Sleepiness” Vigilance Performance
8-9 hours of sleep per day
What is Sleep and What is it good for?

“Sleepiness”
Vigilance
Performance
Requires
8-9 hours of sleep
per day

“Biological Timing”
Requires
- Timing
  - night, circadian
- Duration
  - 7-8 hour block
- Quality
  - undisturbed

NIH Map Viewer: “Aging” Research

https://app.nihmaps.org/public/browser/
Insufficient Sleep Is a Public Health Epidemic

CDC, http://www.cdc.gov/features/dssleep/

Persons With Sleep Apnea Symptoms† who Seek Medical Care, Adults 20+, 2005-08

1 = 95% confidence interval. † People who (snore 5 or more nights per week) OR (snort, gasp, or stop-breathing 5 or more nights per week) OR (feel excessively sleepy during the day 10-30 times per month AND usually sleep 7 or more hours per night). Data are age adjusted to the 2000 standard population. The categories black and white exclude persons of Hispanic origin. Persons of Mexican origin may be any race. Respondents were asked to select one or more race categories. The categories black and white include persons who reported only one racial group.

SOURCE: National Health and Nutrition Examination Survey, CDC, NCHS
Sufficient Sleep, Adults, 2011

<table>
<thead>
<tr>
<th>Gender</th>
<th>Total</th>
<th>Female</th>
<th>Male</th>
<th>18-24 years</th>
<th>25-44 years</th>
<th>45-64 years</th>
<th>65+ years</th>
</tr>
</thead>
<tbody>
<tr>
<td>Total</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Female</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Male</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

Note: Data are for adults 18 years and over. Sufficient sleep is defined as ≥8 hours for those aged 18 to 21 years and ≥7 hours for those aged 22 years and older on average during a 24-hour period. Respondents were asked to select one or more races. Data for the single race categories are for persons who reported only one racial group. Persons of Hispanic origin may be any race.

I = 95% confidence interval.

SOURCE: National Health Interview Survey (NHIS), CDC, NCHS

Promoting Sleep Plan Goals at NHLBI

Mechanisms coupling sleep deficiency and disease
1. Circadian genomics
2. Sleep deficiency
3. Breathing problems
4. Cardiometabolic and pulmonary health risks
   - Pregnancy, Shift work
   - Racial/ethnic disparities
   - Hypertension, stroke, CHF
   - Diabetes, obesity

Develop the evidence-base for medicine
- Pilot RCTs
- Ancillary studies
- Chronobiology
- Phase III RCT
- Sudden Death

Translation and dissemination
- Educational Research
- D&E Research
- Healthy People 2020
  - ↑ % sleeping
  - ↑ % medical care
  - ↓ % MV accidents

Reducing the burden of heart, lung, and blood diseases worldwide

2014 OTC Sleep Aids Use and Sleep Health in Older Adults
The Gerontological Society of America
What If – ‘Bending the Curve’ in Sleep Apnea: Innovative Treatment Discovery?

Sources: Sleep Heart Health Study, Punjabi et al; ATS oral presentation, 2012
NHLBI DCI: http://www.nhlbi.nih.gov/health/topics/topics/cpap/

Technologies To Assess Sleep Health Status in Populations (R43/R44)

- RFA-HL-14-013
  - Biomarker panels for the point-of-care assessment of acute sleep deprivation, chronic sleep deficiency, sleep disorders, circadian rhythm abnormalities, risks to health or safety, or as intermediate markers of the efficacy achieved by sleep disorder interventions
  - Participating Sponsors: NHLBI, NCCAM\textsuperscript{5}, FMCSA/DOT\textsuperscript{5}
  - Receipt Dates
    - November 15, 2013, Phase I applications only
    - November 14, 2014, Phase I and II applications
    - November 13, 2015, Phase II applications

\textsuperscript{5}Announcement expected soon
Understanding Older Drivers: An Examination of Medical Conditions, Medication Use, and Travel Behavior

Sandra Rosenbloom, PhD, The Urban Institute
Understanding Older Drivers: An Examination of Medical Conditions, Medication Use, and Travel Behavior

Dr. Sandra Rosenbloom
Robert Santos
Tim Tripplet

The Urban Institute
BACKGROUND

- 90% of those 65+ are drivers
- Almost one out of six drivers on the road are 65+
- Older drivers are among the safest on the road
- BUT they are more likely to be killed or injured due to fragility
Medical Issues

- Older people as they age are more likely
  - to have medical conditions
  - take multiple medications
- Older people are often unaware of the potential impacts of medication
- Medical personnel rarely raise these issues with older drivers

What We (Don’t) Know About Medications and Driving

- No clear relationship between specific medications and crash risks for those over and under 65
- No studies of the interaction of medical conditions and medications
- No consideration of the role of self-regulation by older drivers
Our Research Questions

- What is the relationship between medical problems, medication use, and driving behavior—particularly self-regulation?

- Answers from 2 national studies:
  - 2009 National Household Travel Survey (NHTS)
  - 2011 National Health and Aging Trends Study (NHATS)

### Senior Drivers

<table>
<thead>
<tr>
<th></th>
<th>65' - 69</th>
<th>70' - 74</th>
<th>75' - 79</th>
<th>80' - 84</th>
<th>85 +</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>M</td>
<td>W</td>
<td>M</td>
<td>W</td>
<td>M</td>
</tr>
<tr>
<td>FHWA (2010)</td>
<td>99.2</td>
<td>89.6</td>
<td>96.5</td>
<td>83.2</td>
<td>93.5</td>
</tr>
<tr>
<td>NHTS (2009)</td>
<td>93.5</td>
<td>87.1</td>
<td>92.1</td>
<td>80.5</td>
<td>89.2</td>
</tr>
<tr>
<td>NHATS (2010)</td>
<td>92.2</td>
<td>85.6</td>
<td>89.5</td>
<td>79.9</td>
<td>87.3</td>
</tr>
</tbody>
</table>
**Daily Travel Patterns of Drivers 65+**

<table>
<thead>
<tr>
<th></th>
<th>1990</th>
<th>2009</th>
</tr>
</thead>
<tbody>
<tr>
<td>Vehicle Trips per driver</td>
<td>2.27</td>
<td>2.67</td>
</tr>
<tr>
<td>Vehicle Miles Travelled per driver</td>
<td>14.8</td>
<td>19.7</td>
</tr>
<tr>
<td>Avg. time driving (min.)</td>
<td>30.8</td>
<td>46.4</td>
</tr>
</tbody>
</table>

**Driving Daily by Age and Sex**
Weekly Driving Frequency by Age, WOMEN

Weekly Travel By Drivers 85+ by Sex
### Older People Reporting A Medical Condition (%)
#### By Driver Status, Age, and Sex, 2009

<table>
<thead>
<tr>
<th>Age Range</th>
<th>65-69</th>
<th>70-74</th>
<th>75-79</th>
<th>80-85</th>
<th>85+</th>
</tr>
</thead>
<tbody>
<tr>
<td>Drivers</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>M</td>
<td>11.3</td>
<td>12.6</td>
<td>16.9</td>
<td>21.1</td>
<td>25.4</td>
</tr>
<tr>
<td>W</td>
<td>10.2</td>
<td>10.8</td>
<td>16.0</td>
<td>17.2</td>
<td>25.0</td>
</tr>
<tr>
<td>Non-Driver</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>M</td>
<td>58.3</td>
<td>58.4</td>
<td>59.6</td>
<td>71.9</td>
<td>74.3</td>
</tr>
<tr>
<td>W</td>
<td>51.7</td>
<td>61.0</td>
<td>45.2</td>
<td>61.5</td>
<td>71.5</td>
</tr>
</tbody>
</table>

**Drivers’ Use of Sleep Medications by Age and Sex**

![Bar chart showing the use of sleep medications by age and sex for drivers]
Medication Use and Self-Regulation

<table>
<thead>
<tr>
<th>TAKE MEDICATIONS:</th>
<th>At Night</th>
<th>On Highways</th>
<th>In Bad Weather</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Men</td>
<td>Women</td>
<td>Men</td>
</tr>
<tr>
<td>Sleep Yes</td>
<td>20.8%</td>
<td>42.2%</td>
<td>12.9%</td>
</tr>
<tr>
<td>Sleep No</td>
<td>18.3%</td>
<td>33.5%</td>
<td>9.6%</td>
</tr>
<tr>
<td>Pain Yes</td>
<td>21.3%</td>
<td>38.6%</td>
<td>11.9%</td>
</tr>
<tr>
<td>Pain No</td>
<td>15.8%</td>
<td>16.0%</td>
<td>8.5%</td>
</tr>
<tr>
<td>Prescription Yes</td>
<td>19.3%</td>
<td>37.8%</td>
<td>11.9%</td>
</tr>
<tr>
<td>Prescription No</td>
<td>15.8%</td>
<td>15.8%</td>
<td>10.6%</td>
</tr>
</tbody>
</table>

Income Plays an Unexplained Role

- All measures of auto use go up with income, even among those drivers:
  - with medical conditions
  - taking medication
  - at advanced ages
- All measures of self-regulation go down with increased income
Findings

• Many older drivers report medical conditions and polypharmacy—with important gender differences

• Older drivers in these situations are active drivers—but they also self-regulate their travel significantly

• Income plays an unexplained role in self-regulation

• For more information, or to see the full report, please visit www.AAAFoundation.org
Sleep Disorders in Aging-
What Lies Beneath

Alon Y. Avidan, MD, MPH, UCLA Sleep Disorders Center
Sleep Problems and Aging


Sleep Architecture and Aging

NREM = nonrapid eye movement; SWS = slow wave sleep.
Sleep and Aging: Prevalence of Sleep Disturbances in Elderly

Consequences of Poor Sleep in Aging

NIA, n = 9282 aged ≥65 y.

### Risks for Nursing Home Placement in Men

<table>
<thead>
<tr>
<th>Risk Factor</th>
<th>Relative Risk</th>
<th>95% CI</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Sleep Disturbances</strong></td>
<td>5.3</td>
<td>1.7-16.1 *</td>
</tr>
<tr>
<td>Age &gt; 74</td>
<td>1.3</td>
<td>0.0-4.3</td>
</tr>
<tr>
<td>ADL Impairment</td>
<td>2.8</td>
<td>0.9-8.6</td>
</tr>
<tr>
<td>Fair-Poor Health</td>
<td>0.8</td>
<td>0.2-2.8</td>
</tr>
<tr>
<td>Low Income</td>
<td>1.4</td>
<td>0.4-4.6</td>
</tr>
<tr>
<td>Cognitive Impairment</td>
<td>4.6</td>
<td>1.4-15.2 *</td>
</tr>
<tr>
<td>Depression</td>
<td>1.0</td>
<td>0.2-4.7</td>
</tr>
<tr>
<td>Living Alone</td>
<td>2.0</td>
<td>0.6-6.2</td>
</tr>
</tbody>
</table>

(Pollak et al, J Comm Health 1990; 15: 123–135)

### Sleep Disorders as Risks for NH Placement

- Increased likelihood for institutionalization
- Irritability
- Impaired motor or cognitive skills
- Disruption of home environment
- Depression, anxiety
- Daytime somnolence
- Increase use of medications & health visits

Chronic Insomnia X 3yrs
Sleeps 4-5 hrs on the average

Difficulties Falling asleep

Was late for his visit with Family MD

Focused on Rx DM. No time to discuss sleep

PSG- No OSA, prolonged sleep latency

Insurance denies Ramelteon

Placed on Zolpidem

Sent for Sleep Study to look at his "sleep architecture"

Was prescribed Ramelteon at 8mg QHS

Sleepy, depressed, irritable next day

Difficulties Falling asleep

Was late for his visit with Family MD
Insomnia continues, feels worse

Told MD that he drove his car at night – no recollection

Finds partially eaten food items in kitchen

Insomnia improves & so is the urge to move

Sleeping 7 hr/night


<table>
<thead>
<tr>
<th>Untreated Insomnia:</th>
<th>Inappropriate Hypnotics:</th>
</tr>
</thead>
<tbody>
<tr>
<td>Depression</td>
<td>Cardiac Side effects:</td>
</tr>
<tr>
<td>Falls &amp; Injury due to poor sleep</td>
<td>Drugs with long t½</td>
</tr>
<tr>
<td>Cognitive Dysfunction</td>
<td>Excessive Sedation</td>
</tr>
<tr>
<td>Excessive Sleepiness</td>
<td>Nonspecific Agents</td>
</tr>
</tbody>
</table>

Cost: Benefit Analysis

Untreated insomnia

Hypnotic Use

Excessive Sleepiness

Cognitive Dysfunction

Falls & Injury due to poor sleep

Depression

Cardiac Side effects:

Drugs with long t½

Excessive Sedation

Nonspecific Agents
Optimal duration of action

- Hypnotics with short t½ for sleep onset insomnia
- Hypnotics with longer t½ taken in the beginning of the night for sleep maintenance insomnia
- Hypnotics with short t½ taken in the middle of the night for middle of the night insomnia

Rapid absorption & Sleep Induction
Address underlying pathophysiology

Sleep Onset  
Sleep Time  
Rise Time

- Minimal adverse effect on sleep physiology
- Minimal effects on Cognition & memory
- No rebound insomnia
- No physical dependence
- No tolerance
- No formation of active metabolites

- No adverse effects on normal sleep architecture
- No respiratory depression
- Safe in patients with respiratory disease (Emphysema)
- No residual effects
- Low potential for abuse & dependence
- No tolerance
- No physical dependence
- No formation of active metabolites

What Do People Take to Try to Improve Their Sleep?

28% use alcohol
Drugs Associated with Insomnia:
- Antidepressants (MAOIs, occasionally SSRIs)
- Asthma, COPD medications (theophylline)
- Corticosteroids (oral prednisone and dexamethasone, IV hydrocortisone)
- Nasal decongestants (pseudoephedrine)
- Histamine Antagonists (cimetidine)
- Antihypertensives (B-blockers)
- Anticholinesterase inhibitors (donepezil)
- Stimulants
- Antineoplastic agents

Substances Associated with Insomnia:
- Alcohol
- Caffeine
- Nicotine
Extrinsic factors

- ↓ periodic environmental stimuli
- Inactivity
- Environmental factors: Excessive noise & light
- Nursing care activities

Intrinsic Factors

- **Illness:**
  - Dementia
  - Depression / medical illness
  - Medications

- **Increased age:**
  - Age-related changes in sleep
  - Changes in the internal circadian clock
  - Increased prevalence of 1º sleep disorders
The Brain ‘takes out the trash’ While We Sleep

New York Times
Sunday Review | OPINION
Goodnight. Sleep Clean.

Sleep Loss and Dementia—A Bidirectional Relationship?

Sleep deprivation increases [Aβ] resulting in chronic accumulation of Aβ
Sleep extension has the opposite effect.

Implications:
- AD & other Neurodegenerative Diseases
- Role of Hypnotics
- Untreated sleep Disorders— OSA
- Consequences of chronic sleep deprivation—Insomnia
- Shift workers, physicians on call

Yo-El S. Ju, Lucey, PB, Holtzman, DM.
Take Home Message

- Spend time going through the sleep history.
- Question about potential comorbidities & impact of sleep disturbance.
- Proper treatment & the type of treatment are critical.

How to Engage with FDA

Stephanie Joseph, MPH
FDA Office of Health and Constituent Affairs
25-Jun-14

GSA OTC Sleep Aids and Sleep Health Summit
Presentation Overview

• About FDA and the Office of Health and Constituent Affairs (OHCA)

• How FDA engages with stakeholders

• Medication safety activities and resources

• How to report problems to FDA (MedWatch)

FDA Regulates $1 Trillion Worth of Products a Year

Safety  Efficacy  Security  Quality
OHCA works to help patients, patient advocates, consumers and healthcare professionals connect with FDA
OHCA’s Role with Stakeholders

- Listen
- Engage
- Educate
- Involve
Health Professional Organizations

- Stakeholder Calls
- Comments to FDA Dockets
- Listening Sessions
- Conferences
- Publishing
- Individual Meetings
- Public Meetings and Workshops
CDER Professional Affairs & Stakeholder Engagement (PASE)

- Engages and assists stakeholders on issues concerning drug development, drug review, and drug safety
- Provides a focal point for health professional organizations, patient advocacy groups, and healthcare systems for drug issues
- Provides enhanced two-way communication and collaboration between CDER and stakeholders
- Contact PASE by email at CDERPASE@fda.hhs.gov or by phone at 301-796-7600

Public Hearing for All Stakeholders

- Over-The-Counter Drug Monograph System-Past, Present, and Future; Public Hearing March 25 and 26, 2014

Transcripts, Summary and FR available at:
http://www.fda.gov/drugs/newsevents/ucm380446.htm
Medication Safety Message for HCPs

FDA reminds health care professionals to stop dispensing prescription combination drug products with more than 325 mg of acetaminophen

FDA is reminding health care professionals to stop prescriing and pharmacists to stop dispensing prescription combination drug products that contain more than 325 milligrams (mg) of acetaminophen per tablet, capsule, or other dosage unit. If a pharmacist receives a prescription for a combination product with more than 325 mg of acetaminophen per dosage unit, FDA recommends that they contact the prescriber to discuss a product with a lower dose of acetaminophen. These products are no longer considered safe by FDA and have been voluntarily withdrawn. We encourage pharmacists to return them to the wholesaler or manufacturer.

These products were voluntarily withdrawn by the manufacturers at FDA’s request to protect consumers from the risk of severe liver damage, which can result from taking too much acetaminophen.

FDA also asks wholesalers to remove the product codes for all prescription combination drug products containing more than 325 mg of acetaminophen per dosage unit from their ordering systems and return all products to the manufacturers.

Health care professionals who have questions are encouraged to contact the Division of Drug Information at 888.INFO-FDA (888-463-5372) or druginfo@fda.hhs.gov


OTC Medication Safety for Consumers

Understanding Over-the-Counter Medicines

Over-the-counter medicine is also known as OTC or nonprescription medicine. All these terms refer to medicine that you can buy without a prescription. They are safe and effective when you follow the directions on the label and as directed by your health care professional.

The information in this section will help you, working with your health care professional, to choose and use over-the-counter medicine wisely.

Related Resources
- Educational Resources: Understanding Over-the-Counter Medicines includes brochures, pamphlets, public service announcements, and more
- Medisavvy in My Home (MiHM): An interactive educational program about the safe and effective use of over-the-counter medications
- Choosing the Right Over-the-Counter (OTC) Medicine
- The Over-the-Counter Medicine Label
- Tips for Parents

http://www.fda.gov/Drugs/ResourcesForYou/Consumers/BuyingUsingMedicineSafely/UnderstandingOver-the-CounterMedicines/
Medication Safety Information for Older Adults

- Consumer Update: Four Medication Safety Tips for Older Adults
- June 2014

http://www.fda.gov/downloads/ForConsumers/ConsumerUpdates/UCM399867.pdf

Resources for Older Adults

Resources for Older Adults

As You Age…
A Guide to Aging, Medicines, and Alcohol

- Some of your medicines won't mix well with other medications, including over-the-counter medications and herbal remedies.
- Many medications do not mix well with alcohol.

http://www.fda.gov/drugs/resourcesforyou/ucm079522.htm

Patient Tool – Medication Record

4. KEEP A RECORD OF MEDICINES YOU USE

<table>
<thead>
<tr>
<th>DATE</th>
<th>NAME OF MEDICATION</th>
<th>Dosage Information</th>
<th>REASONS</th>
<th>DO YOU TAKE IT REGULARLY?</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

Check items for the ones you use:

- Aspirin or other pain medications
- Blood thinners
- Allergy medications
- Antacids
- Cold medicines
- Cough medicines
- Diet pills
- Supplements
- Prescriptions
- Sleeping pills
- Vitamins
- Minerals
- Herbs
- Others

Keep this in your purse or pocket and show it to your doctor, pharmacist, or nurse.

For more information, go to Drugs@FDA:
http://www.fda.gov/downloads/ForConsumers/ByAudience/ForWomen/UCM304679.pdf
MedWatch Reporting - VOLUNTARY

Clinician Form 3500

Consumer/Patient Form 3500B

“What Kind of Problem Was It?”

“Tell Us What Happened?”

“Name of the Product…”

“Why Was the Person Using the Product?”

MedWatch

• How can MedWatch Reports Result in Improved Product Safety?
  – Update the product label
  – Include a medication guide
  – Request a change in the product’s design, process, packaging, or distribution
  – Request a product recall
  – Safety Communications
  – Public workshops
  – Knowledge about post-market problems helps inform pre-market reviews
MedWatch - Safety Info OUT

• Safety Information Delivered to You
• Subscribe to MedWatch
• Receive emails about product recalls and safety communications

www.fda.gov/medwatch

Summary – OHCA’s Role

• Facilitates FDA engagement with patients, consumers, and health professional organizations
• Advises FDA on stakeholder opinions and views
• Is a resource for stakeholders and provides information about FDA regulatory/safety initiatives and the importance of reporting problems to FDA through MedWatch
• Seeks new opportunities to involve stakeholders in FDA processes
• Understands older adult medication safety is important
Questions?

Thank You

Stephanie Joseph, MPH
U.S. Food and Drug Administration
10903 New Hampshire Avenue
Silver Spring, MD 20993
Phone: 240-402-5098

Stephanie.joseph@fda.hhs.gov
Medication Safety and Older Adults

CDER MANUAL OF POLICIES AND PROCEDURES (MAPP)
6025.2 Good Review Practice: Clinical Review of Investigational New Drug Applications

- assists FDA staff in reviewing INDs during drug development to ensure review completeness and consistency
- December 2013


Elderly Subjects:
Although elderly patients comprise a significant portion of the consumer population for drugs, they are often underrepresented in clinical trials. Data collected from elderly subjects can be of particular value because elderly subjects are more likely to have organ impairment, take a larger number of concomitant medications, and be susceptible to certain drug-related toxicities. In general, subjects over 65 years of age are considered elderly for the purposes of data evaluation, but it is particularly important to have data on subjects 75 years of age and older. For drugs intended for a population that includes the elderly, substantial numbers of elderly subjects should be included in trials by the time of the marketing application. ICH E7 should be consulted about the inclusion of elderly subjects in clinical trials. A recent amendment to this guidance strongly emphasizes the need for exposure of patients above 75 years of age. As noted earlier, arbitrary upper age limits for trial entry are almost never justified and should be discouraged.

MAPP 6025.2 Good Review Practice: Clinical Review of Investigational New Drug Applications
FDA Safety & Innovation Act Section 907

- directed FDA to report on the extent to which demographic subgroups (sex, age, race and ethnicity) participate in clinical trials in marketing applications for drugs, biologics, and devices

- FDA held a public hearing April 2014 to obtain input on the issues and challenges associated with the collection, analysis, and availability of demographic subgroup data

- requires that FDA develop an Action Plan no later than one year following publication of the report


POLICY UPDATE
Call to Action to Improve Safe Use of OTC Sleep Aids for Older Adults—Now and in the Future

Phyllis C. Zee, MD, PhD
Influencing Policy

• Identify audiences
  - **Primary:** Decision makers with the authority to modify or introduce the policies that your project addresses (i.e., Congress)
  - **Secondary:** Individuals or groups that can influence the decision makers (advisors, foundations, societies, patient groups, industry, media)

Congressional Briefing

• **Theme**
  – New information, i.e., white paper, research findings
  – Report of OTC Summit activity
  – NHWS data
  – NSF Education Program

• **Speakers**

• **Congressional Champions**
  – Representative Mike Honda
  – Representative Hank Johnson

• **Call to action**
Sleep: A Health Imperative
A Congressional Briefing on the 2011 NIH
Sleep Disorders Research Plan
May 31, 2012

Phyllis C. Zee, MD, PhD
SRS President

Sleep: A Health Imperative
Congressional Briefing on the 2011 NIH Sleep Disorders
Research Plan
Agenda

Phyllis C. Zee, MD, PhD; President, Sleep Research Society

Congressman Michael Honda; U.S. House of Representatives

Susan Shurin, MD; Acting Director NHLBI

David F. Dinges, PhD; Professor and Chief
Division of Sleep & Chronobiology
University of Pennsylvania School of Medicine

American Academy of Sleep Medicine
American Academy of Neurology
National Institutes of Health
Sleep Advocacy Organizations
Theme
Sleep: A Health Imperative

Sharon Shurin
Deputy Director NHLBI

David Dinges
U of Pennsylvania

Sleep for Health and Safety
A Congressional Briefing
Strategic Opportunities in Sleep and Circadian Research:
Report of the Joint Task Force of the Sleep Research Society
and American Academy of Sleep Medicine

Phyllis C. Zee, MD, PhD; M. Safwan Badr, MD; Clete Kushida, MD, PhD;
Janet M. Mullington, PhD; Allan I. Pack, MBChB, PhD; Sairam Parthasarathy, MD; Susan Redline, MD, MPH; Ronald S. Szymusiak, PhD;
James K. Walsh, PhD; Nathaniel F. Watson, MD

2014 OTC Sleep Aids Use and Sleep Health in Older Adults
The Gerontological Society of America 96
A one-page policy brief allows GSA to communicate the results of research in the form of persuasive recommendations. Research project results: most likely to be read by staffers in policy-making circles. A policy brief’s success depends on how results are presented.
TRANSLATE AND DISSEMINATE TO PUBLIC, POLICY, AND PRACTITIONERS: Prioritize Messages for Future Emphasis

Steven M. Albert, PhD

Now What?

Do you have a Twitter account?

Yes.

No.

Want one?

Yes.

No.

You’re awesome. Go tweet #OTCSleep.

You’re awesome. See Kelsey for help.

Not really but my organization, university, or company has one.

Awesome. Tell them what you learned today and how they can get involved.

#OTCSleep

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