

# SEX DIFFERENCES IN OVER-THE-COUNTER SLEEP AID USE IN OLDER ADULTS

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## ABSTRACT

**OBJECTIVES:** Over-the-counter (OTC) sleep aids are widely self-administered and are generally safe, but their primary ingredients (diphenhydramine and doxylamine [DPH/DOX]) may pose risks, especially in older adults who may use these products outside of their label recommendations. This analysis characterizes the use of DPH/DOX for sleep disturbances by age and sex in older American adults.

**METHODS:** Data were taken from the 2013 US National Health and Wellness Survey (NHWS), a cross-sectional, internet-based, IRB-approved annual survey of adults (n=75,000). Stratified sampling was used to represent the demographic make-up of the general population in age, sex, and ethnicity. Weights were applied using age, sex, ethnicity, and education to reflect the US population. Respondents reporting regular sleeplessness symptoms and insomnia/sleep difficulties (SD) were included in the analysis. Comparisons between sexes were made using chi-square tests for categorical variables and t-tests for continuous variables.

**RESULTS:** Of the projected 41.3 M (n=16,500) adults aged ≥65, 15% (3.8 M aged 65-74; 2.6 M aged 75+) reported regular sleeplessness symptoms and insomnia/SD. More women were affected; 67% of patients aged 65-74 (2.5 M) and 73% of patients aged 75+ (1.9 M) were female ( $p < 0.05$ ). Approximately 1.1 M patients aged 65+ self-reported using a product containing DPH/DOX. Women were more likely to use DPH/DOX than men (21% [526 K] vs. 12% [150 K] aged 65-74 [ $p < 0.05$ ]; 19% [348 K] vs. 11% aged 75+ [76 K] [ $p > 0.05$ ]). However, men using DPH/DOX reported taking it more mean days per month (14.4 vs. 11.3 aged 65-74 [ $p < 0.05$ ]; 18.4 vs. 13.7 aged 75+ [ $p > 0.05$ ]).

**CONCLUSIONS:** An estimated one million adults aged 65+ self-reported using DPH/DOX, many on a regular basis. Women composed a larger proportion of users, though men reported using these products more frequently. Further study on the use and safety of these OTC agents in older populations is recommended.

## INTRODUCTION

- While good quality sleep is essential, use of sleep aids across all populations is of some controversy. Recently, the US Food and Drug Administration revised dosing recommendations for common prescription (Rx) sleep aids, lowering the recommended initial doses and specifically the dose for women.<sup>1</sup>
- Although sleep issues affect people of all ages, there are additional health considerations in the elderly population, such as a potential relationship between sleep disturbance and dementia.<sup>2</sup>
- Over-the-counter (OTC) sleep aid use has not been widely studied, although it is of special concern in the elderly due to the anticholinergic properties of the primary ingredients, diphenhydramine or doxylamine (DPH/DOX).
- Anticholinergic effects include greater risk of confusion, dry mouth, and constipation. Other drugs with anticholinergic properties are prescribed for conditions common in the elderly, and the effects may stack with each drug, leading to an increased risk of cognitive impairment.<sup>3</sup>

## OBJECTIVE

- The objective of this study was to identify the differences in OTC sleep aid use among older men and older women.

## METHODOLOGY

### Sample

- Data were taken from Kantar Health’s 2013 US National Health and Wellness Survey (NHWS), a cross-sectional, internet-based, IRB-approved annual survey of adults (n=75,000).
- A random stratified sampling framework was used to represent the demographic composition of the US regarding sex, age, and ethnicity, including n=16,500 respondents aged 65+ years.
- Weights were applied using the US Census to reflect the adult population in terms of age, sex, education, and ethnicity.
- The study was approved by the Essex Institutional Review Board (Lebanon, NJ, USA).

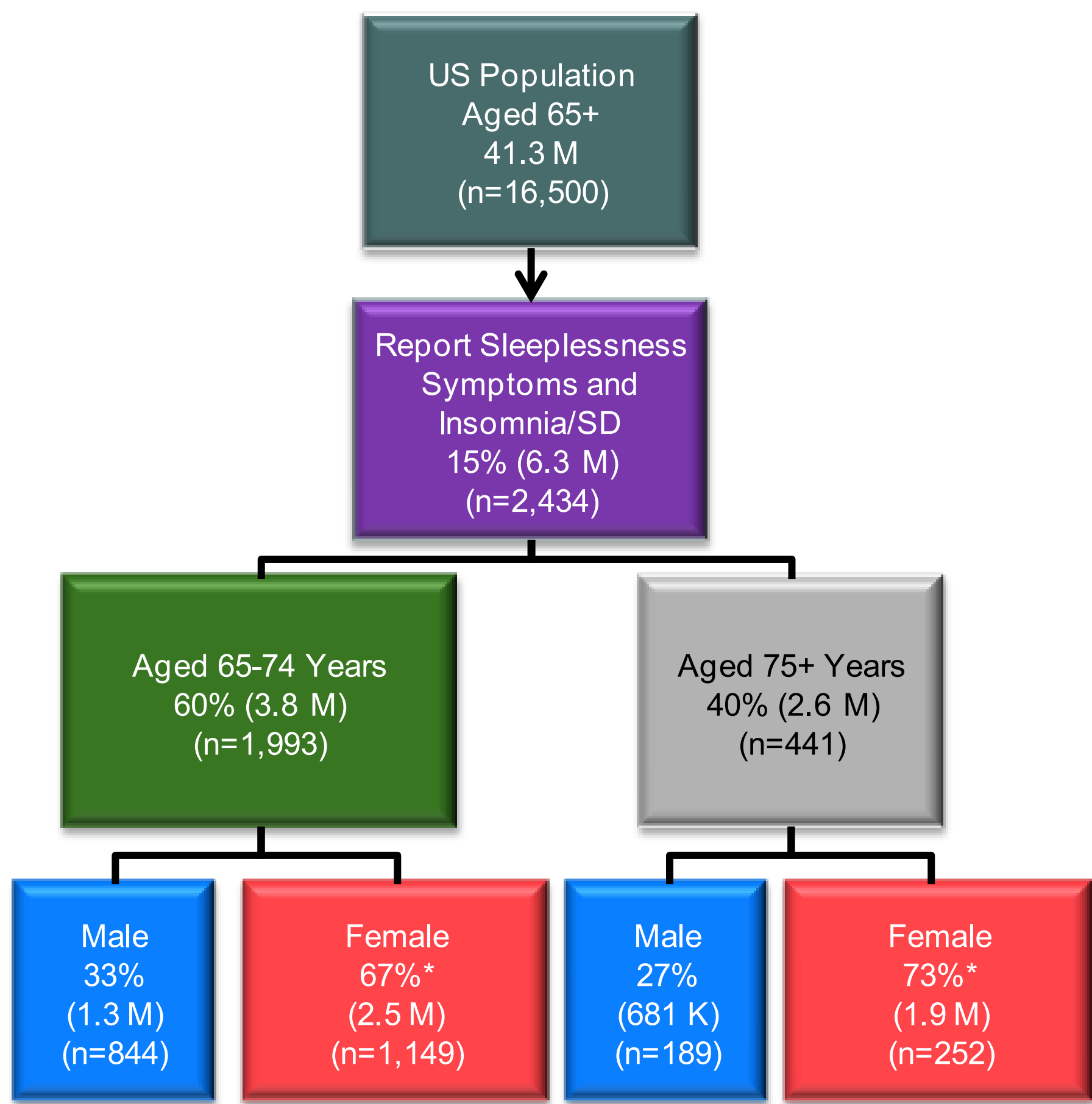
### Measures

- Respondents indicated whether they had experienced a list of comorbidities in the past 12 months, including insomnia and sleep difficulties (insomnia/SD). Respondents indicating insomnia/SD were asked about OTC use specifically for that condition.
  - All respondents were asked if they regularly experience a list of sleep symptoms or problems. Respondents indicating any of the following symptoms were considered to have “sleeplessness symptoms”:
    - 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
  - Survey respondents included in this analysis were those who reported both insomnia/SD and sleeplessness symptoms and were aged 65 and older. Those also indicating experiencing narcolepsy, parasomnia, sleep-disordered breathing/sleep apnea, or circadian rhythm disorder were excluded from the analysis.
  - If individuals indicated using an OTC/herbal product for insomnia/SD, they were given the opportunity to specify the type of product and days using each product in the past month. Products with DPH/DOX as an active ingredient were included in the DPH/DOX analyses.
  - Alcohol use and frequency was asked of all respondents.
  - Respondents were considered to be using an anticholinergic medication if they indicated elsewhere in the survey using an Rx that had suspected or confirmed anticholinergic properties per the Anticholinergic Cognitive Burden List developed by the Healthy Aging Brain Center.<sup>4</sup>
- ### Analyses
- Bivariate comparisons between sexes within each age group were made using chi-square tests for categorical variables and t-tests for continuous variables.

## RESULTS

- Of the projected 41.3 M (n=16,500) adults aged 65+, 15% (6.3 M) reported both regular sleeplessness symptoms and insomnia/SD (**Figure 1**).
  - More women were affected in both age groups; 67% of respondents aged 65-74 (2.5 M) and 73% of respondents aged 75+ (1.9 M) were female (all  $p < 0.05$ ).

Figure 1. Prevalence of Sleeplessness Symptoms and Insomnia/SD by Sex and Age



\*Percentage is significantly greater between sexes of the same age group ( $p < 0.05$ ).

- Within the patient groups examined, distribution of sleeplessness symptoms and other sleep problems varied by age group and sex, although overall women were more likely to experience more symptoms than men in both age cohorts (**Table 1**). Of the sleeplessness symptoms:
  - Women in both age groups were more likely to experience “Difficulty falling asleep” (70.1% vs. 55.8% aged 65-74 [ $p < 0.05$ ]; 66.9% vs. 47.4% aged 75+ [ $p < 0.05$ ]).
  - Women also were more likely to experience “Waking during the night and not being able to get back to sleep,” although the difference was not significant in the aged 65-74 cohort (64.0% vs. 59.8% aged 65-74 [ $n.s.$ ]; 69.1% vs. 47.8% aged 75+ [ $p < 0.05$ ]).
  - Approximately half of both sexes in both age groups reported “Waking up several times during the night” (48.8%-51.7%), approximately a third reported “Waking up too early (such as before the alarm clock)” (36.2%-39.4%), and approximately a quarter reported “Poor quality of sleep” (24.3%-29.2%); none of these differences were statistically significant.

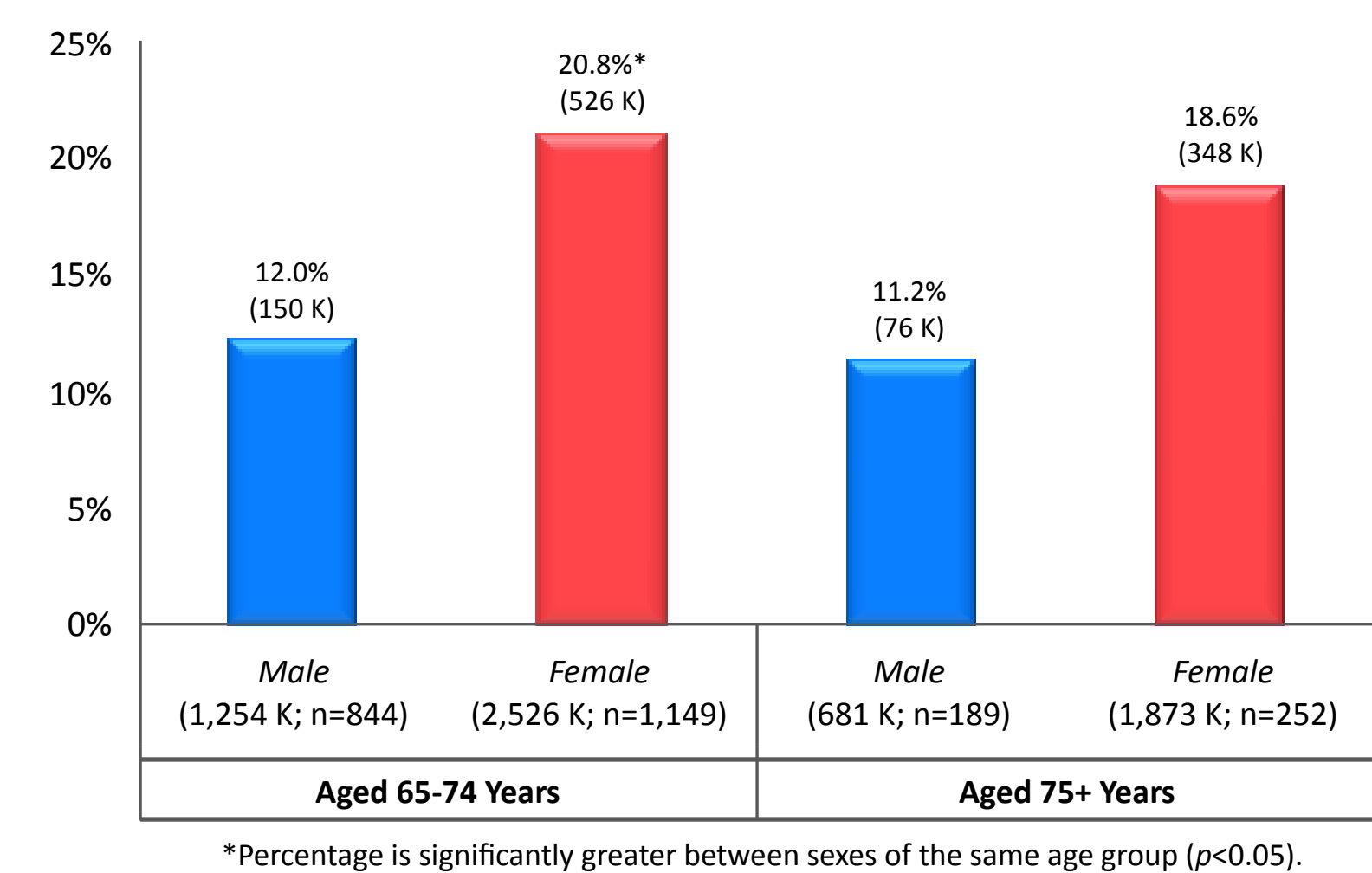
- An estimated 1.1 M adults (17.4% of the patient group) used an OTC sleep aid containing DPH/DOX, 79% (874 K) of whom were female.
  - Within each age cohort, women were more likely to use DPH/DOX (20.8% vs. 12.0% aged 65-74 [ $p < 0.05$ ]; 18.6% vs. 11.2% aged 75+ [ $n.s.$ ]) (**Figure 2**).

Table 1. Sleep Symptoms and Problems Regularly Experienced among Older Adults Reporting Sleeplessness Symptoms and Insomnia/SD by Sex and Age

	Aged 65-74 Years				Aged 75+ Years			
	Male (1,254 K; n=844)		Female (2,526 K; n=1,149)		Male (681 K; n=189)		Female (1,873 K; n=252)	
	%	Projected (in thousands)	%	Projected (in thousands)	%	Projected (in thousands)	%	Projected (in thousands)
<b>Sleeplessness Symptoms</b>								
Difficulty falling asleep	55.8%	700	70.1%*	1,772	47.4%	323	66.9%*	1,254
Waking up several times during the night	48.8%	612	51.0%	1,289	51.7%	352	49.0%	917
Waking during the night and not being able to get back to sleep	59.8%	749	64.0%	1,618	47.8%	325	69.1%*	1,294
Waking up too early (such as before the alarm clock)	39.4%	494	39.0%	985	36.2%	247	38.0%	712
Poor quality of sleep	27.7%	348	28.2%	712	29.2%	199	24.3%	456
<b>Other Sleep Problems</b>								
Waking up to go to bathroom	54.4%	682	56.5%	1,427	49.6%	338	69.5%*	1,302
Daytime sleepiness	27.7%	347	29.9%	755	26.5%	180	27.5%	515
Pain	20.7%	259	25.6%*	646	14.4%	98	27.1%*	509
Night sweats/hot flashes	9.1%	114	14.8%*	374	3.4%	23	6.9%*	128
Leg cramps/leg problems	18.1%	227	19.8%	499	15.7%	107	27.8%*	520
Difficulty staying awake	7.8%	98	7.1%	179	3.2%	22	5.6%	105

\*Percentage is significantly greater between sexes of the same age group ( $p < 0.05$ ).

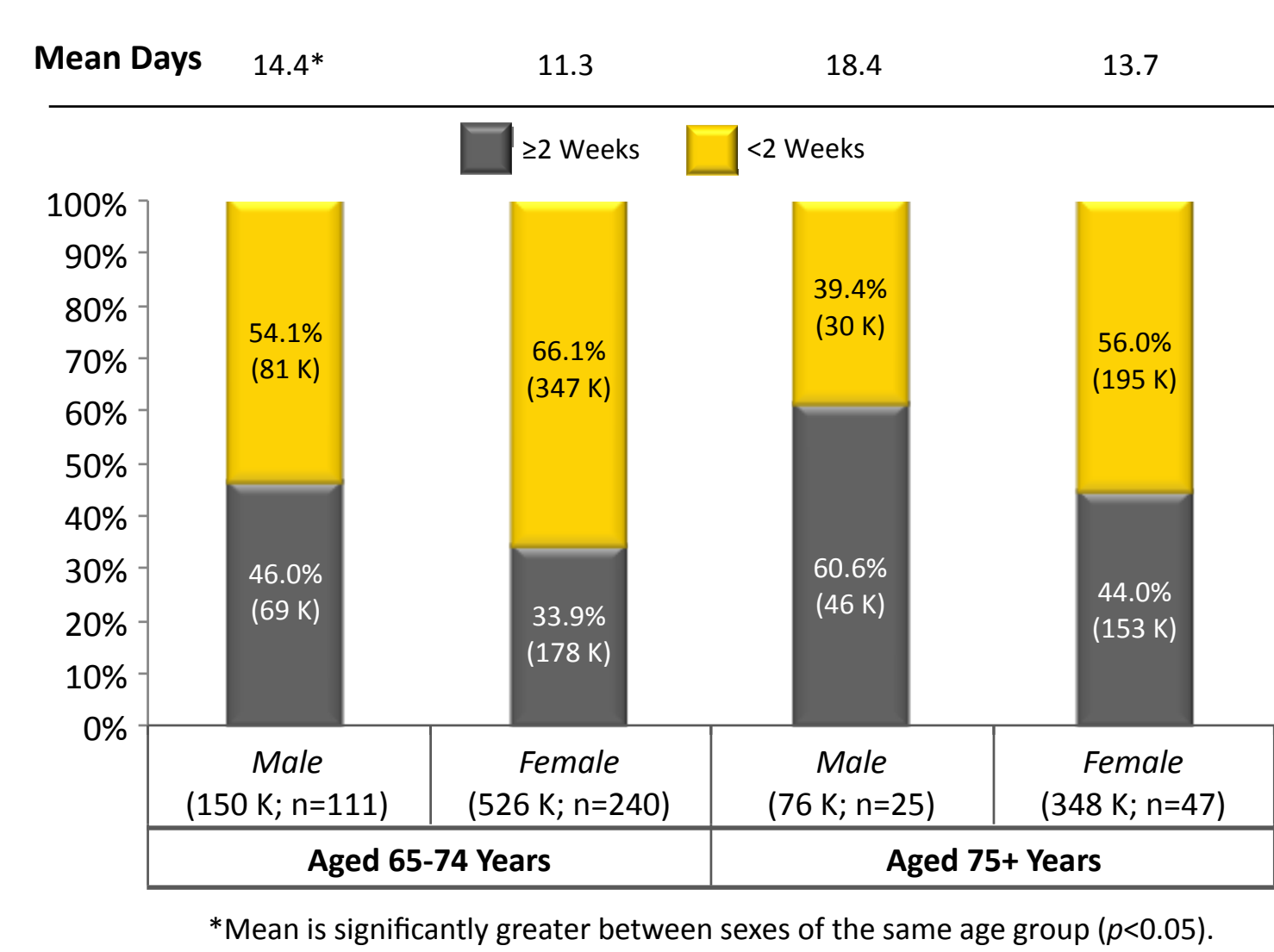
Figure 2. DPH/DOX Use among Older Adults Reporting Sleeplessness Symptoms and Insomnia/SD by Sex and Age



\*Percentage is significantly greater between sexes of the same age group ( $p < 0.05$ ).

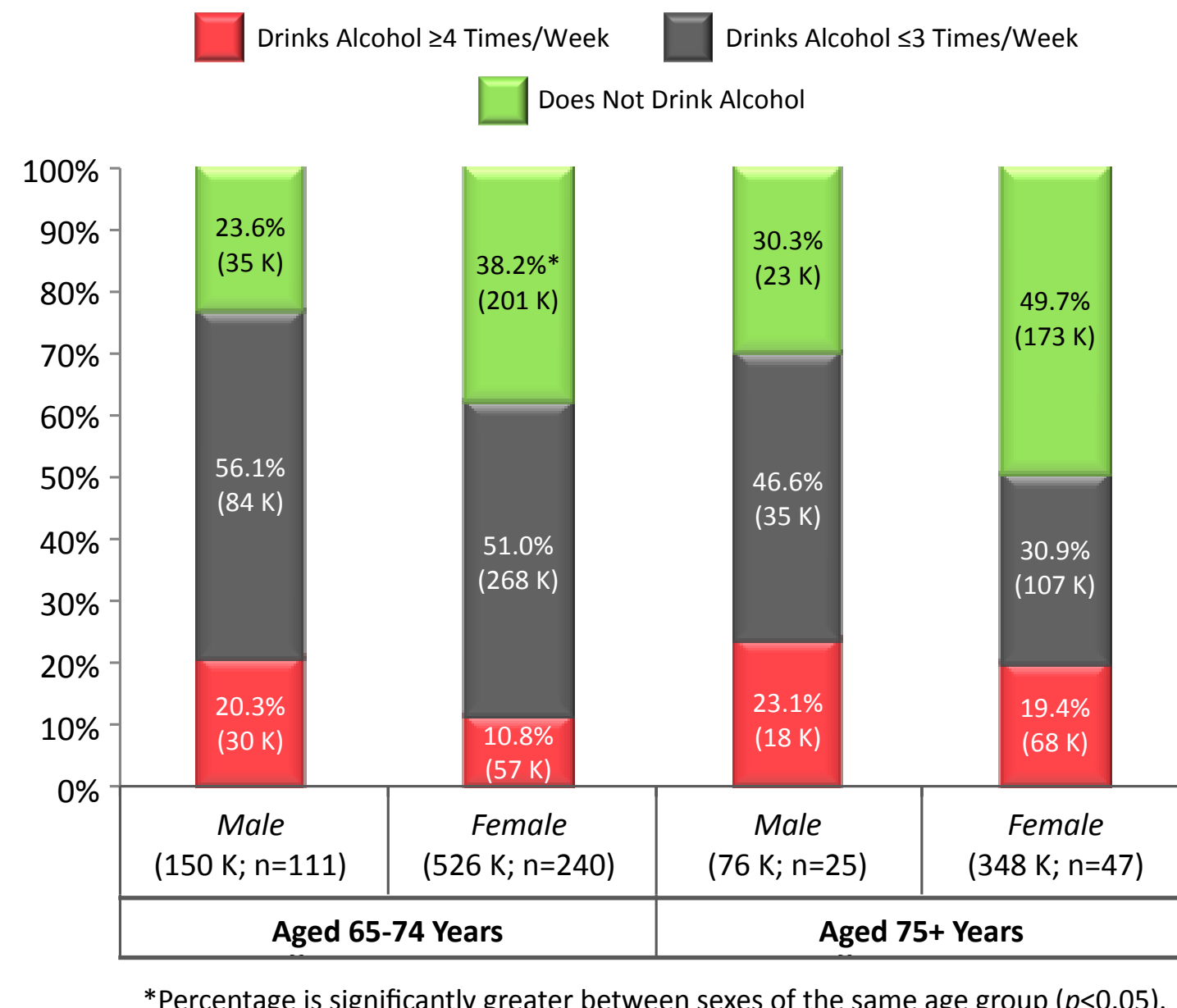
- Although women were more likely to use DPH/DOX, men reported using the products more frequently.
  - Men in both age groups reported using DPH/DOX more mean days per month (14.4 vs. 11.3 aged 65-74 [ $p < 0.05$ ]; 18.4 vs. 13.7 aged 75+ [ $n.s.$ ]) (**Figure 3**).
  - Additionally, more men than women in both age groups reported using DPH/DOX products for more than 2 weeks, which is against recommended label use (46.0% vs. 33.9% aged 65-74 [ $n.s.$ ]; 60.6% vs. 44.0% aged 75+ [ $n.s.$ ]).
- Alcohol use also was highly prevalent among DPH/DOX users, although concomitant use is against label recommendations.
  - Among DPH/DOX users, men were both more likely to drink in general (76.4% vs. 61.8% aged 65-74 [ $p < 0.05$ ]; 69.7% vs. 50.3% aged 75+ [ $n.s.$ ]) and more likely to drink nearly daily (20.3% vs. 10.8% aged 65-74 [ $n.s.$ ]; 23.1% vs. 19.4% aged 75+ [ $n.s.$ ]) (**Figure 4**).
- Using Rx with anticholinergic properties was common in DPH/DOX users.
  - Women in both age groups were more likely to use these Rx than men (33.4% vs. 29.4% aged 65-74 [ $n.s.$ ]; 47.1% vs. 30.3% aged 75+ [ $n.s.$ ]) (**Figure 5**).

Figure 3. Days per Month Using DPH/DOX Use by Sex and Age among DPH/DOX Users



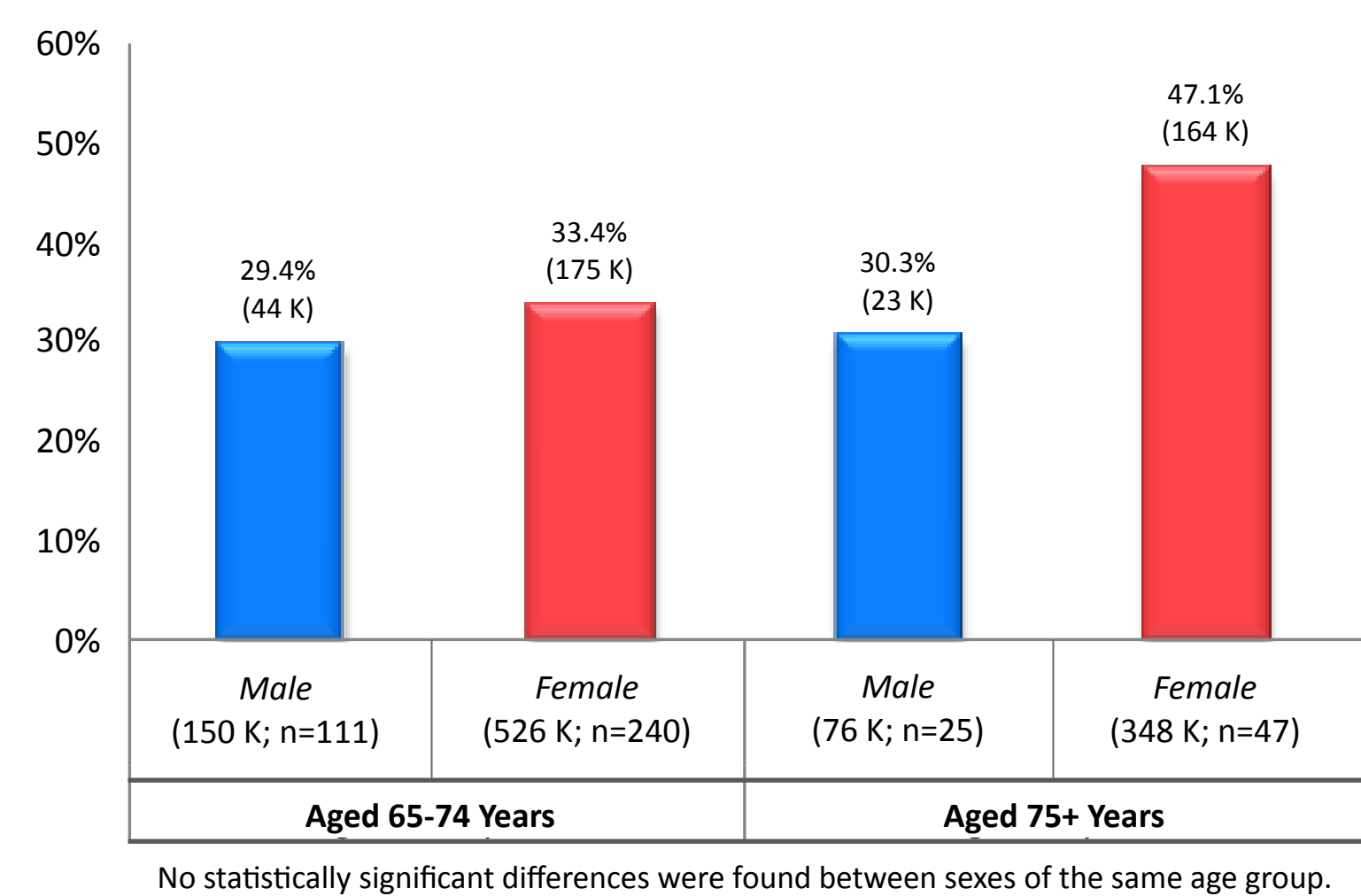
\*Mean is significantly greater between sexes of the same age group ( $p < 0.05$ ).

Figure 4. Alcohol Use by Sex and Age among DPH/DOX Users



\*Percentage is significantly greater between sexes of the same age group ( $p < 0.05$ ).

Figure 5. Anticholinergic Use by Sex and Age among DPH/DOX Users



No statistically significant differences were found between sexes of the same age group.

## LIMITATIONS

- The older population represented in the survey was likely healthier than the general elderly population, as they were noninstitutionalized and able to use the internet to take a survey.
- Data were cross-sectional in nature, and therefore causality cannot be assumed.
- These data were self-reported and therefore subject to recall bias.
- Due to small sample sizes, many comparisons did not show statistical significance.

## CONCLUSIONS

- Sleeplessness and insomnia/SD affect over six million estimated elderly people in the US.
- DPH/DOX use is quite common in the elderly, with over one million estimated users, although the anticholinergic properties of these agents are known to have special risks for this vulnerable population.
- Both sexes are at risk; a larger number of older women use the products and they are more susceptible to health issues. Men are more frequent users and more likely to use alcohol, usage patterns that may be outside of label recommendations.
- These data show a clear need for discussion with older adults about their OTC sleep aid use, with special consideration for concomitant alcohol use, frequency of use, and use of other anticholinergic Rx that may put them at increased risk for cognitive impairment.

## ACKNOWLEDGEMENTS

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