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SCIENTIFIC INVESTIGATIONS

Declining trend in use of medications for sleep disturbance in the United States from 2013 to 2018

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Study Objectives: Recent initiatives to discourage overprescription of sleep medications have increased awareness of their potential adverse effects; however, it is unknown whether these efforts translated into a decline in use of these medications in the United States. We assessed recent national trends in the use of medications used for sleep disturbance.

Methods: We used data from n = 29,400 participants in the 2013–2018 National Health and Nutrition Examination Survey. At each of three waves of in-person assessments, participants presented prescription bottles for all medications used in the prior month. Interviewers recorded each medication and participants self-reported duration and reasons for use. We identified all medications used for sleep disturbance and categorized medications into two categories: Food and Drug Administration–approved sleep medications and those used off-label for sleep disturbance. We examined changes in the prevalence in use of these medications across the study period.

Results: The odds of using medications for sleep disturbance decreased 31% between 2013 and 2018 (odds ratio = 0.69, 95% confidence interval = 0.51–0.93, $P = .015$). This trend was driven by declines in use of Food and Drug Administration–approved medications for sleep disturbance, especially for medium- and long-term duration of use. Notably, among those age 80+ years, we observed an 86% decline (odds ratio = 0.14, 95% confidence interval = 0.05–0.36, $P < .001$) in use of Food and Drug Administration–approved sleep medications over the study period.

Conclusions: Use of prescription medications for sleep disturbance declined nationally, suggesting a possible effect of efforts to curb overprescription and encourage judicious use of these agents. Future research needs to examine whether these changes have coincided with improved population sleep health.

Keywords: sleep medications, sleep health, hypnotics, benzodiazepines

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BRIEF SUMMARY

Current Knowledge/Study Rationale: Previous studies show the use of medications for sleep disturbance has increased over the past 2 decades. However, in recent years, there have been a number of efforts to encourage deprescribing of these agents and increase access to potentially safer behavioral sleep treatments. To date, it is not known whether these recent developments have changed use patterns of medications for sleep disturbance in the population.

Study Impact: We found a decline in use of medications for sleep disturbance between 2015 and 2018, with particularly decreasing trends in older adults. Findings suggest a possible shift in the ways sleep disturbance is treated.

INTRODUCTION

While sleep disturbances have been historically underdiagnosed and underappreciated, past studies have shown precipitous increases in prescribing and use of sleep medications over the past 2 decades.[1–7] For example, we previously found prescribing of benzodiazepines (BZDs; eg, alprazolam) and non-BZD hypnotics (eg, zolpidem) increased 69% and 140%, respectively, between 1993 and 2010.[7] We also found that long-term prescribing[2] and use[8] of these agents contributed to overall increases in prescribing of these medications. While BZDs are often prescribed for anxiety, a number also have approval for treating sleep disturbance (ie, estazolam, flurazepam, triazolam, etc). Other investigators, using data from health care settings or data representing select groups such as Medicare beneficiaries, show similar increases in prescribing up to as recently as 2015.[1,3,5,6] For example, Agarwal and Landon found that an estimated 7.4% of all office visits in the United States resulted in a prescription for a BZD in 2015.[5] Using data from Medicare claims, Albrecht et al found that rates of claims for sleep medications ranged from

21.0 to 29.6% but remained steady between 2006 and 2013; however, the rate of BZD claims increased 16-fold (from 1.1 to 17.6%) between 2012 and 2013, 2012 being the year when BZDs were included in the Medicare formulary for the first time.[9]

The increased prescribing and use of these medications is at odds with clinical recommendations and concerns about the use of these agents, particularly in vulnerable groups.[10–12] For example, the use of BZDs and other hypnotics has shown to be associated with the risk of motor vehicle accidents,[13] functional and memory impairment,[14] and in older age groups falls and hip fractures.[15–17] Indeed, in 2019, the US Food and Drug Administration (FDA) put a "black box warning" on common non-BZD hypnotics (including eszopiclone, zolpidem, and zaleplon) concerning their dangers.[18]

These concerns prompted a number of efforts in the early to late 2010s to discourage the overprescription of sleep medications and increase access to other, safer sleep treatments. First, deprescribing initiatives were developed and implemented in a number of health care systems (eg, Kaiser and the Veterans Affairs health care systems) with demonstrated success.[19,20] These initiatives sought to taper or discontinue use of potentially inappropriate medications (including sleep medications) in high-risk groups. Second, a number of "digital therapeutics" were developed that delivered behavioral sleep therapies (eg, cognitive behavioral therapy for insomnia) and received considerable attention.[21,22] Historically, access to such behavioral treatments for sleep disturbance has been limited,[23] despite being as effective if not more so as prescription medications with minimal side effects.[24] Third, prescription drug monitoring programs, which required physicians to report prescriptions for controlled substances such as opioids and BZDs, became operational in 17 states in addition to the 33 states with monitoring programs prior to 2010.[25] Finally, health insurance providers began implementing performance measures to monitor and reduce use of high-risk medications, including a number of sleep medications. For example, the Healthcare Effectiveness Data and Information Set program, developed by the National Committee on Quality Assurance, provides a set of performance measures that can be used to compare health care plans and a number of the measures focus on medication management.[26]

Prescribing patterns for sleep medications may be impacted by these initiatives and increased access to behavioral sleep treatments. Identifying changes in trends in prescribing of these medications would inform public policy and treatment of insomnia (eg, resource allocation for more behavioral sleep medicine experts). In this study, we sought to characterize recent US trends in prescription medications reported to be used for sleep disturbance between 2013 and 2018. Using data from the National Health and Nutrition Examination Survey (NHANES), our goal was to examine changes in the annual prevalence of use of these medications and identify whether changes varied by the type of medication (eg, FDA-approved for insomnia, medications used off-label for sleep) and duration of use. Based on our prior research,[2,7,8] we hypothesized that we would see an increase in the use of all medication types for sleep disturbance over the study period, driven by increases in long-term use.

METHODS

Data source

This study used data from the 2013–2014, 2015–2016, and 2017–2018 waves of the NHANES. NHANES, conducted biennially, is a nationally representative cross-sectional survey administered by the National Center for Healthcare Statistics (refer to https://www.cdc.gov/nchs/nhanes/index.htm for data access procedures). At each wave, subjects are asked to complete surveys and undergo a physical assessment. Response rates for the three waves included in our study ranged from 52 to 71%.

Measures

At each interview, participants were asked to bring prescription bottles or pharmacy printouts for all medications used within the past month. Interviewers recorded the medications used, and participants indicated how long they had used the medication. If respondents did not bring prescription bottles or pharmacy printouts they were asked to self-report the medications used. Of all prescriptions reported during our study period, 88.7% were obtained from prescription bottles, 4.6% from pharmacy printouts, and 6.7% via self-report. Beginning in the 2013/2014 wave, participants were also asked to self-report up to 3 health conditions for which the medication was used, and, for the purposes of systematic documentation, their responses were converted to ICD-10-CM codes by NHANES interviewers. In our analysis, we focused on medications participants reported as used for insomnia (ICD-10 code: G47.00) and sleep disorder not otherwise specified (G47.9). We chose to include medications used for sleep disorder not otherwise specified in order to capture medications for transient sleep difficulties that do not rise to the level of insomnia.

We categorized medications as being (1) FDA-approved for sleep disturbance (including zolpidem, suvorexant, butabarbital, quazepam, estazolam, flurazepam, triazolam, tasimelteon, eszopiclone, temazepam, ramelteon, secobarbital, doxepin, and zaleplon) and (2) medications used off-label (ie, any other medication reported to be used for sleep disturbance). For each medication, we also categorized length of use as being short-term (< 6 months), medium-term (6 to 24 months), and long-term (> 24 months).[8] If a participant used more than 1 medication from the above categories, the use duration was based on the medication used for the longest period of time.

In addition to medication use, we also assessed participant age (which we categorized as ≤ 18, 19–49, 50–64, 65–79, and 80+ years), race (non-Hispanic White, non-Hispanic Black, Hispanic, and other), and sex (male, female).

Analyses

We examined trends in the prevalence of use of any medication respondents reported as used for sleep disturbance. Analyses were conducted in 3 stages. First, we examined trends in the prevalence of use for each medication category (ie, FDA-approved, off-label). We employed logistic regression with the respective medication category serving as the outcome and time being the predictor. For the purposes of interpretation, we transformed the time variable to range from a value of 0 (representing the 2013/2014 wave) to 1

(2016–2018 wave) to facilitate interpretation of the beta coefficient for time as the change in odds of medication use across the entire study period (ie, 2013–2018). Second, in order to determine whether trends varied by demographic characteristics, we repeated analyses while stratifying across demographic groups (ie, age, race, and sex). Finally, we repeated analyses in stage 1 but assessed trends based upon use duration (short-, medium-, and long-term use). All analyses were weighted to be nationally representative and account for the complex sampling design of NHANES. Analyses were conducted in Stata SE version 15 (StataCorp, College Station, Texas).

RESULTS

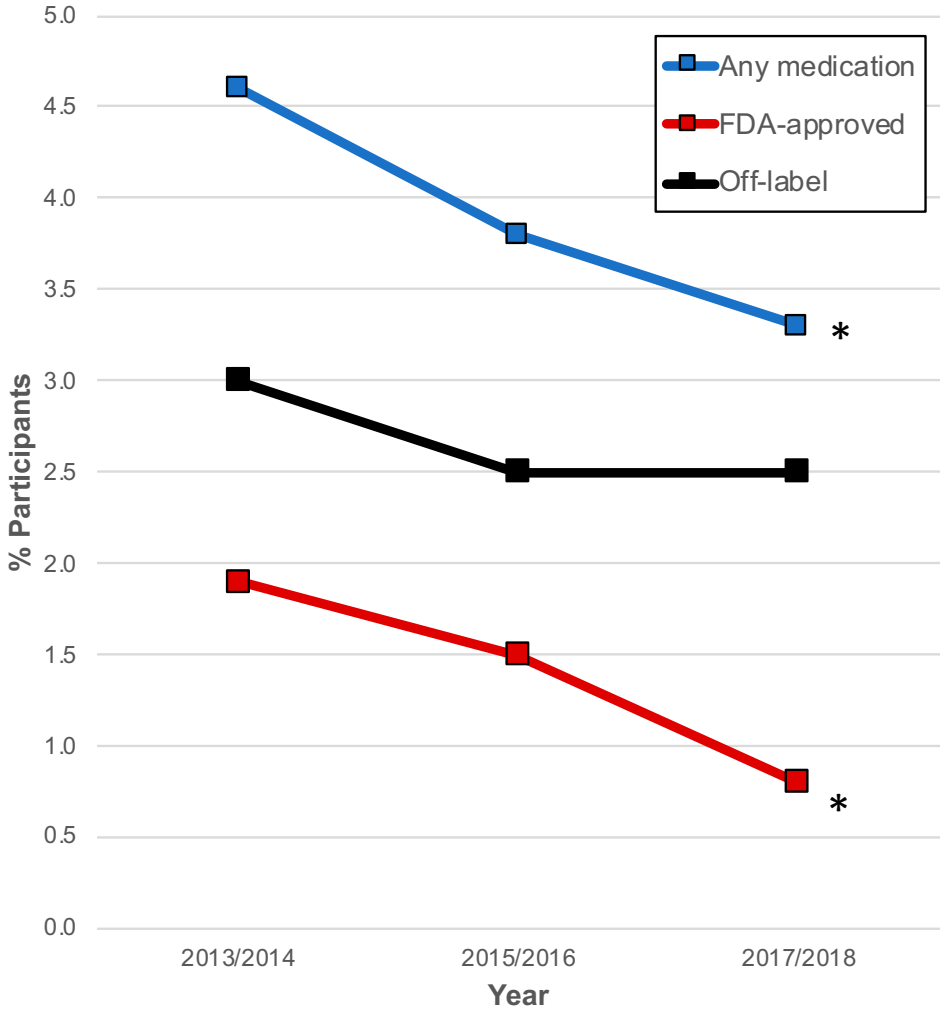
Overall trends

The odds of medication used for sleep disturbance decreased by 31%, from 4.6% of participants in 2013/2014 to 3.3% in 2017/2018 (odds ratio [OR] = 0.69, 95% confidence interval [CI] = 0.51–0.93). While the odds of use of medications for sleep disturbance decreased for all medication types (ie, FDA-approved, medications used off-label), the strongest and statistically significant decrease, of 55%, was for FDA-approved sleep medications (OR = 0.45, 95% CI = 0.34–0.59) (**Figure 1**).

Trends stratified across demographic characteristics

For any medication used for sleep disturbance, we observed a 38% decline in the odds of use among those aged 50–64 years (OR = 0.62, 95% CI = 0.40–0.96) and a 54% decline in those age 80+ years (OR = 0.46, 95% CI = 0.22–0.94). Additionally, we saw declines in the odds of use among non-Hispanic Whites (OR = 0.68, 95% CI = 0.49–0.93) and males (OR = 0.51, 95% CI = 0.35–0.74). Declines were seen in most other categories (except among Hispanics), although these trends were not statistically significant. These trends were exclusively driven by

Figure 1—Trends in use of medications for sleep disturbance, National Health and Nutrition Examination Survey, 2013–2018.



*P < .05. Food and Drug Administration (FDA)–approved medications include zolpidem, suvorexant, butabarbital, quazepam, estazolam, flurazepam, triazolam, tasimelteon, eszopiclone, temazepam, ramelteon, secobarbital, doxepin, and zaleplon. Off-label medications include all other medications reported to be used for sleep disturbance.

Table 1—Trends in use of medications for sleep disturbance stratified by age, sex, and race/ethnicity, National Health and Nutrition Examination Survey, 2013–2018.

	Years[a]			
	2013/2014	2015/2016	2017/2018	Trend (2013–2018)
Medications	n (%)	n (%)	n (%)	OR (95% CI)[b]
All medications used for sleep disturbance				
Age, y				
≤ 18	25 (0.9)	19 (0.6)	22 (0.6)	0.65 (0.30, 1.37)
19–49	86 (3.0)	66 (3.1)	50 (1.9)	0.65 (0.39, 1.11)
50–64	124 (9.7)	73 (6.5)	81 (6.4)	0.62 (0.40, 0.96)
65–79	59 (8.0)	61 (7.3)	66 (7.0)	0.87 (0.51, 1.47)
80+	36 (12.7)	26 (7.6)	29 (6.5)	0.46 (0.22, 0.94)
Race				
Non-Hispanic White	213 (6.0)	132 (5.0)	141 (4.2)	0.68 (0.49, 0.93)
Non-Hispanic Black	50 (2.9)	35 (1.9)	41 (2.2)	0.74 (0.45, 1.23)
Hispanic	44 (1.8)	58 (1.6)	44 (2.0)	1.13 (0.66, 1.94)
Other	23 (2.6)	20 (1.9)	22 (1.4)	0.54 (0.28, 1.05)
Sex				
Male	125 (3.9)	101 (2.4)	96 (2.1)	0.51 (0.35, 0.74)
Female	205 (5.3)	144 (5.0)	152 (4.4)	0.81 (0.58, 1.15)
FDA-approved[c]				
Age, y				
≤ 18	—	—	1 (0.0)	—
19–49	31 (1.1)	21 (1.1)	9 (0.3)	0.40 (0.18, 0.88)
50–64	57 (4.8)	26 (2.2)	26 (1.8)	0.33 (0.20, 0.54)
65–79	21 (3.0)	30 (4.4)	27 (2.6)	0.85 (0.39, 1.85)
80+	19 (7.2)	12 (3.9)	5 (0.7)	0.14 (0.05, 0.36)
Race				
Non-Hispanic White	83 (2.6)	54 (2.2)	38 (1.2)	0.47 (0.34, 0.66)
Non-Hispanic Black	17 (1.0)	13 (0.7)	11 (0.5)	0.49 (0.24, 1.03)
Hispanic	20 (0.8)	15 (0.3)	12 (0.4)	0.40 (0.16, 0.98)
Other	8 (0.9)	7 (0.5)	7 (0.3)	0.31 (0.07, 1.32)
Sex				
Male	47 (1.7)	30 (0.9)	27 (0.5)	0.27 (0.13, 0.54)
Female	81 (2.2)	59 (2.1)	41 (1.2)	0.57 (0.39, 0.84)
Off-label[d]				
Age, y				
≤ 18	25 (0.9)	19 (0.6)	22 (0.6)	0.65 (0.30, 1.37)
19–49	56 (1.9)	50 (2.2)	42 (1.6)	0.83 (0.44, 1.56)
50–64	82 (6.2)	48 (4.3)	56 (4.6)	0.72 (0.37, 1.41)
65–79	40 (5.5)	36 (3.9)	43 (4.9)	0.89 (0.43, 1.83)
80+	18 (5.8)	18 (4.9)	24 (5.8)	0.99 (0.44, 2.24)
Race				
Non-Hispanic White	146 (4.0)	89 (3.3)	108 (3.2)	0.79 (0.50, 1.23)
Non-Hispanic Black	33 (1.9)	24 (1.3)	31 (1.7)	0.92 (0.50, 1.68)
Hispanic	26 (1.0)	44 (1.3)	33 (1.7)	1.61 (0.71, 3.66)
Other	16 (1.7)	14 (1.4)	15 (1.2)	0.66 (0.24, 1.80)

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Table 1—Trends in use of medications for sleep disturbance stratified by age, sex, and race/ethnicity, National Health and Nutrition Examination Survey, 2013–2018. (*Continued*)

	Years[a]			
	2013/2014	2015/2016	2017/2018	Trend (2013–2018)
Medications	**n (%)**	**n (%)**	**n (%)**	**OR (95% CI)[b]**
Sex				
Male	81 (2.4)	78 (1.7)	71 (1.6)	0.65 (0.38, 1.12)
Female	140 (3.6)	93 (3.3)	116 (3.3)	0.93 (0.58, 1.50)

[a]Statistics come from percentages of survey respondents each year that reported use of respective medications. [b]ORs come from logistic regression models and correspond to the difference in odds of using respective medication across the entire study period (ie, 2013–2018). [c]Include zolpidem, suvorexant, butabarbital, quazepam, estazolam, flurazepam, triazolam, tasimelteon, eszopiclone, temazepam, ramelteon, secobarbital, doxepin, and zaleplon. [d]Include all other medications reported to be used for sleep disturbance. CI = confidence interval, FDA = Food and Drug Administration, OR = odds ratio.

declines in odds of use of FDA-approved sleep medications. Of note, among those aged 80+ years, there was an 86% decline in odds of use of FDA-approved sleep medications (OR = 0.14, 95% CI = 0.05–0.36) (**Table 1**).

Trends in duration of use

For all medications used for sleep disturbance, there were declines in the odds of use for all use durations, with medium-term use reaching statistical significance (OR = 0.59, 95% CI = 0.40–0.87). Among FDA-approved medications, there were substantial declines in odds of use for medium- (OR = 0.51, 95% CI = 0.28–0.94) and long-term (OR = 0.45, 95% CI = 0.29–0.70) use durations, whereas no statistically significant change was seen in short-term use. For medications used off-label for sleep, there was a statistically significant decline in the odds of medium-term use (OR = 0.62, 95% CI = 0.41–0.95) (**Table 2**).

DISCUSSION

To our knowledge, this is the first study to show a national decline in use of prescription medications for sleep disturbance.

Table 2—Trends in use of medications for sleep disturbance stratified by self-reported duration of use, National Health and Nutrition Examination Survey, 2013–2018.

	Years[a]			
	2013/2014	2015/2016	2017/2018	Trend (2013–2018)
Medications	**n (%)**	**n (%)**	**n (%)**	**OR (95% CI)[b]**
All medications used for sleep disturbance				
Short-term	60 (0.8)	44 (0.6)	41 (0.6)	0.72 (0.41, 1.27)
Medium-term	113 (1.5)	92 (1.6)	82 (0.8)	0.59 (0.40, 0.87)
Long-term	163 (2.5)	116 (1.8)	130 (1.9)	0.73 (0.52, 1.03)
FDA-approved[c]				
Short-term	19 (0.3)	5 (0.1)	8 (0.1)	0.28 (0.05, 1.41)
Medium-term	35 (0.5)	30 (0.6)	22 (0.2)	0.51 (0.28, 0.94)
Long-term	71 (1.2)	52 (0.8)	37 (0.5)	0.45 (0.29, 0.70)
Off-label use[d]				
Short-term	43 (0.5)	39 (0.5)	33 (0.5)	0.87 (0.43, 1.76)
Medium-term	81 (1.1)	64 (1.1)	60 (0.6)	0.62 (0.41, 0.95)
Long-term	103 (1.5)	72 (1.0)	97 (1.4)	0.94 (0.54, 1.64)

Short-term use = < 6 months; medium-term use = 6–24 months; long-term use = > 4 months. [a]Statistics come from percentages of survey respondents each year that reported use of respective medications. [b]ORs ratios come from logistic regression models and correspond to the difference in odds of using respective medication across the entire study period (ie, 2013–2018). [c]Include zolpidem, suvorexant, butabarbital, quazepam, estazolam, flurazepam, triazolam, tasimelteon, eszopiclone, temazepam, ramelteon, secobarbital, doxepin, and zaleplon. [d]Include all other medications reported to be used for sleep disturbance. CI = confidence interval, FDA = Food and Drug Administration, OR = odds ratio.

We found that over 5 years there was a 31% decline in the odds of use of any medication for sleep disturbance, changing from 4.6% of participants in 2013/2014 to 3.3% in 2017/2018. Although the absolute change is small, when considering the adult population of > 200 million people in the United States, a 1% absolute reduction means over 2 million fewer people reported sleep medication use. The observed trend was driven by a substantial decline in medications approved by the FDA for sleep disturbance, particularly for durations longer than 6 months and among those aged 80+ years. The reduction in usage was apparent in most drug categories, but statistical significance was observed primarily for FDA-approved sleep medications of which the vast majority (74%) were for z-drugs (including zolpidem, zaleplon, and eszopiclone). Of note, these declines were observed before the black box warning from the FDA in 2019.[18]

The reasons for this observed reduction in use of sleep medications nationally remain unclear. Aggressive direct-to-consumer advertising may have driven an increased uptick of sleep pharmacotherapy in prior years; however, many of these agents have now gone off patent, which may have reduced advertising and subsequently, use. Efforts regarding deprescribing have also been ongoing, with promising results seen in many health care settings.[19,20] It is also possible that patient-education efforts may have increased awareness of potential side effects from these medications, perhaps leading to use of other "over-the-counter" sleep aids or melatonin supplements because of perceived safety. With the broad adoption of electronic medical records in some health care systems, medication alerts for sleep medications may have decreased prescribing, at least for long-term use. Public education campaigns and recent media attention about sleep health more broadly may also have contributed to this trend.

Regardless of the mechanism, our results indicate declines in sleep medication use in recent years. Our observed trends were primarily seen with medications used longer than 6 months, suggesting that providers may be prescribing these medications less frequently, are educating patients about the benefits of behavioral sleep treatments, or are more commonly referring patients with sleep disorders to sleep medicine specialists. It is also noteworthy that declines in use were substantial in older age groups (especially in those older than 80 years). This may be reflective of a number of medical organizations strongly discouraging their use among older people. Of note, the American Geriatrics Society's Beers criteria (which during our study period was updated in 2012[27] and 2015[28]) lists medications potentially inappropriate when used by older adults. In the 2012 update, the criteria added long-term use (> 90 days) of non-BZD hypnotics (eg, zolpidem, zaleplon, eszopiclone, etc).[27] In the 2015 update, the > 90 days qualifier was removed and prescribers were advised to avoid any use of these agents.[28]

Increased recognition of the importance of sleep has led to a greater number of patients seeking care for sleep disturbance.[29] Recent clinical guidelines have emphasized behavioral sleep treatment approaches as the first line treatment for insomnia.[11,30,31] Of note, results from randomized trials demonstrate roughly equivalent outcomes between behavioral vs pharmacological approaches with gains from cognitive behavioral therapy for insomnia better maintained over time.[32] Although hypnotic medications are effective and beneficial for some patients, cognitive behavioral therapy for insomnia and other behavioral approaches can be more effective without possible side effects of pharmacotherapy. Unfortunately, NHANES does not collect data on other sleep treatments used (including behavioral approaches and cognitive behavioral therapy for insomnia) and we could not assess whether the observed reduction in sleep medication use coincided with increased use of behavioral therapies. Regardless, we support efforts to make these interventions more accessible, including the development of smartphone- or telemedicine-based strategies.[33]

Despite our study's strengths, we acknowledge a number of limitations. First, because participants in the NHANES self-reported reasons for medication usage, we were unable to confirm prescriber intent for off-label medication use; this limitation is important given the potential stigma attached to the use of BZDs. Relatedly, we did not have objective assessments of sleep disturbance. Second, we were unable to assess the clinical or public health impact of the observed trends. Future research should determine potential population-level impacts on health (eg, neurocognitive outcomes or risk of motor vehicle crashes). Third, we did not evaluate for newer prescription sleep medications approved by the FDA after 2018.

In summary, we found a decline in use of medications for sleep disturbance in recent years. While the reasons for this decline have yet to be determined, our findings suggest possible shifts in the ways sleep disturbance is managed. Future research should assess whether these changes are sustained in later years and whether these changes have resulted in improved clinical outcomes, such as improved sleep and reduced adverse effects often seen with sedating agents, particularly in older adults. Better understanding of how sleep disturbances are treated would improve our ability to address sleep problems more effectively and promote the quality of life for patients.

ABBREVIATIONS

BZDs, benzodiazepines
CI, confidence interval
FDA, Food and Drug Administration
NHANES, National Health and Nutrition Examination Survey
OR, odds ratio

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