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Short Report

The medicalization of sleeplessness: Results of U.S. office visit outcomes, 2008–2015



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ABSTRACT

Previous analysis of U.S. physician office visits (1993-2007) indicated that the medicalization of sleeplessness was on the rise and had potentially negative implications for population health. Our study asks if the medicalization of sleeplessness at the level of patient-physician interaction has persisted over time. Using the most recent years available (2008-2015) of the National Ambulatory Medical Care Survey we calculated nationally representative estimates for four sleeplessness-related outcomes of physician office visits: sleeplessness complaint, insomnia diagnosis, and prescription of benzodiazepine and non-benzodiazepine sedative-hypnotics (NBSH). To test for the significance of the linear trajectory, we ran a series of bivariate linear models. We tested three hypotheses grounded in the medicalization framework: if the medicalization of sleeplessness at the interactional level is continuing at a rate comparable to previous analyses, sleeplessness-related outcomes will continue to increase significantly over time (Hypothesis 1); NBSH prescriptions and insomnia diagnoses will continue to outpace sleeplessness complaints (Hypothesis 2); and insomnia diagnoses and use of sedative-hypnotics will increase or remain concentrated among age groups who lack the changing sleep patterns and commonly occurring comorbidities associated with older age (Hypothesis 3). Support for these hypotheses was mixed. Unlike previous analyses wherein all sleeplessness-related outcome trends were positive and statistically significant over time, regression analyses revealed a significant negative NBSH prescription trend 2008-2015 (slope, b = -699,628, P < 0.05). No other associations were significant. Younger age groups were most likely to receive an insomnia diagnosis and NBSH prescription. These trends imply that the medicalization of sleeplessness at the level of patient-physician interaction may be on the decline. We suggest that increasingly negative portrayals of sedative-hypnotics, conservative practice recommendations, and decreased direct-to-consumer advertising for NBSH may decrease consumerism and physician compliance related to the medicalization of sleeplessness. We conclude with a discussion on non-pharmaceutical methods of reducing sleeplessness relevant to population health.

Background

Insufficient sleep has become a well-recognized public health concern (Colten & Altevogt, 2006). Commonly occurring, transient sleep-lessness is often the result of social factors including stress, grief, or aging processes (Moloney, 2017). The tendency of *medicalizing* these normal if uncomfortable life experiences via a medical diagnosis (i.e., insomnia) and treatment with prescription sedative-hypnotics is contentious because it is costly (Conrad, Mackie, & Mehrotra, 2010), fails to address underlying behavioral or social issues (Moloney, 2017), and may heighten population health risks via dangerous side effects (e.g., cognitive impairment, falls, increased all-cause mortality) (American Academy of Sleep Medicine, 2004; Kripke, Langer, & Kline, 2012).

Given these risks, it is important to track trends over time in sleeplessness complaints, insomnia diagnoses, and sedative-hypnotic prescriptions, and examine the forces that shape their trajectories. The present study builds on previous analyses of sleeplessness-related outcomes of U.S. physician office visits, 1993–2007 (Moloney, Konrad, & Zimmer, 2011). We analyze the most recent available data (2008–2015) and assess trends over a 23-year trend arc. We further contribute to the literature by exploring shifts in public perception, practice recommendations, and direct-to-consumer advertising that may influence the medicalization of sleeplessness at the level of patient-physician interaction.

To contextualize our study, we first offer an overview of medicalization, its fueling factors, and related theoretical frameworks. We then

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summarize previous work on the medicalization of sleeplessness before describing our updated analyses. We present our results in contrast to the previous analyses, and end with a discussion on non-pharmaceutical methods of reducing sleeplessness relevant to population health.

1.1. Medicalization

Medicalization is the process by which formerly non-medical issues come to be described, accepted, or treated as medical problems with medical solutions (Conrad, 2007). Medicalization occurs at three, mutually-influential levels: 1) conceptual (medical definitions are created and used); 2) institutional (disease conceptualizations are codified); and 3) interactional (interaction between patient and healthcare practitioner) (Conrad, 2007). The conceptual level has long been considered key to the medicalization process but recent scholarship has highlighted the importance of interactional factors related to patient-practitioner interactions (Clarke et al., 2011; Figert, 2011, pp. 291–307).

The medicalization literature is grounded in social constructionism (Conrad, 1992). Thus, medicalization studies often document the transformation of natural life processes or deviant behaviors into treatable disorders (Davis, 2006). For instance, in the 1970's Conrad documented the rise of hyperkinesis (now ADHD) as a means of controlling certain deviant behaviors in children (Conrad, 1992). Although diagnosis construction may be conflicted and controversial, the processual outcomes are value-laden and impact the illness experience, treatment, stigma (or lack thereof), and health expenditures (Barker, 2008; Brown, 1995; Conrad et al., 2010).

The factors that influence the medicalization process evolve over time. Currently, the primary engines of medicalization are: consumerism (patients challenge medical authority, seek physician compliance), managed care (medical encounter cost-controls), biotechnology (genetics, pharmaceuticals, and direct-to-consumer advertising), and physicians (gatekeepers to treatment) (Barbee, Moloney, & Konrad, 2018; Conrad and Cockerham, 2013; Moloney, 2017). Further, as medicine's cultural and structural contexts continually evolve, scholars have proposed new medicalization-related frameworks including biomedicalization (emphasizes the role of biomedicine and technology in illness and risk assessment) (Clarke et al., 2011), healthicization (individuals are responsible for controlling their health through personal strategies and/or commercially available products) (Hislop & Arber, 2003), and pharmaceuticalization (emphasizes pharmaceutical drugs as solutions to medicalized conditions) (Williams, Seale, Boden, Lowe, & Steinberg, 2008). Although the present work uses the medicalization framework, we revisit these related constructs in our Discussion.

1.2. Medicalization of sleep

According to Williams, the medicalization of sleep is "a complex, contested, partial process in which some aspects of sleep are becoming more medicalized than others" (Williams, Coveney, & Gabe, 2013). Cultural (Hollan, 2013; Williams et al., 2013) and familial (Venn, Arber, Meadows, & Hislop, 2008) factors influence both sleep patterns and remedies for perceived dysfunction, as does the patient-physician interaction (Moloney, 2017). Diagnoses of sleep apnea and the recently recognized "shift-work sleep disorder" remain somewhat contested by patients (Williams et al., 2013; Zarhin, 2015). Sleeplessness, lamented throughout recorded history, appears to be increasingly medicalized at the interactional level (Moloney, 2017).

A qualitative study of sleepless patients and their physicians found that both parties typically recognized sleeplessness as the result of aging processes or life stressors, yet diagnosed the problem as insomnia and (reluctantly) treated it with sedative-hypnotics (Moloney, 2017). Physicians highlighted the role of direct-to-consumer advertising in influencing patients' consumerist behavior (i.e., asking for heavily advertised, newer-generation non-benzodiazepine sedative hypnotics like

Ambien). Physician compliance with patient request was also influenced by multiple constraints (e.g., time, limited non-pharmaceutical resources) (Moloney, 2017).

While quantitative medicalization analyses are rare, a study using the National Ambulatory Medical Care Survey (NAMCS), a nationally representative survey of U.S. physician office visits, revealed that sleeplessness complaints, insomnia diagnoses, and prescriptions for older generation benzodiazepines (BDZ)¹ and newer generation nonbenzodiazepine sedative-hypnotics (NBSH)² increased significantly from 1993 to 2007 (Moloney et al., 2011). The trends were particularly noteworthy among adults ages 18-64⁶ as they lack the changing sleep patterns and increased comorbidities associated with older age (Colten & Altevogt, 2006). Beginning in 2006, insomnia diagnoses began to outpace sleeplessness complaints. NBSH prescriptions grew 30-fold over the study period, far outpacing all other trends. The authors concluded that these trends were indicative of the medicalization of sleeplessness at the level of patient-physician interaction (Moloney et al., 2011). Subsequent analyses of NAMCS indicate that rates of insomnia diagnoses and sedative-hypnotic prescriptions continued to rise between 2008 and 2012 (Ford et al., 2014; Kaufmann, Spira, Depp, & Mojtabai, 2016).

As noted, the forces that influence the medicalization process evolve over time and, since the previous analysis, news media and academic literature have increasingly suggested that sedative-hypnotics are harmful to health. A widely-publicized matched-cohort study from 2012 found that just 18-132 sedative-hypnotic doses increased the hazard of death threefold (Kripke et al., 2012). Even when adjusting for age, gender, smoking, body mass index, ethnicity, marital status, alcohol use, and prior cancer, patients prescribed > 132 doses in a year had substantial elevations in incident cancer and mortality (Kripke et al., 2012). Data from randomized controlled trials suggest multiple mechanisms by which sedative-hypnotics may increase mortality including: acute lethality from higher doses (especially with polypharmacy), impaired motor and cognitive functions leading to accidents and/or falls, and chromosomal damage (Kripke et al., 2012). Although the exact mechanism between sedative-hypnotic use and associated harms remains speculative, numerous organizations, including the Food and Drug Administration, the National Institutes of Health, the American College of Physicians, and the American Academy of Sleep Medicine have issued stronger cautions and revised practice recommendations (National Institutes of Health, 2005; Qaseem, Kansagara, Forciea, Cooke, & Denberg, 2016; Siebern & Manber, 2011).

It is uncertain, however, whether these changes in public perception and practice recommendations have been accompanied by shifts in diagnostic and treatment practices. To our knowledge, no current analyses offer a comprehensive look at recent sleeplessness-related outcomes of physician office visits and compare these outcomes to 1993–2007 trends. To address this literature gap, we ask: Have office-visit outcomes related to the medicalization of sleeplessness persisted over time?

Drawing on the most recent publicly available years of NAMCS (2008–2015) we analyzed: 1) sleeplessness complaint, 2) insomnia diagnosis, and 3) BDZ and NBSH prescriptions. Provisional hypotheses were that: (a) if the medicalization of sleeplessness is continuing at a rate comparable to prior analyses, all study outcomes would continue to increase significantly over time (Hypothesis 1); NBSH prescriptions and

¹ BDZ (e.g., Restoril), introduced in the 1960's to treat anxiety and insomnia, were initially thought to have low risk of dependence and were widely prescribed. Two decades later, BDZ were recognized as addictive and deemed a social problem. Nevertheless, they are still favored by older patients, who may have used them for decades.

² NBSH (e.g., Ambien), FDA-approved for insomnia in 1992, were promoted through multi-million dollar advertisements as being safer than BDZ. However, these claims have since been questioned and, as noted in this manuscript, prescription recommendations have grown increasingly conservative.

insomnia diagnoses would continue to outpace sleeplessness complaints (Hypothesis 2); and insomnia diagnoses and use of sedative-hypnotics would increase or remain concentrated among age groups who lack the changing sleep patterns and comorbidities associated with older age (Hypothesis 3).

Methods

NAMCS data are collected annually by the National Center for Health Statistics. Approximately 3000 randomly-chosen physicians participate each year in a multi-stage, geographically clustered probability sample. Office visits serve as the unit of analysis.

Consistent with the previous analytic period (Study 1, 1993–2007), NAMCS used the International Classification of Diseases, 9th Revision, Clinical Modification (ICD-9-CM) (ICD-9-CM, 1996) for 2008–2015. Key outcomes of interest, matching those of the previous analysis, were:

- Sleeplessness as reason for office visit (defined as complaints of "can't sleep," "trouble falling asleep," or "sleeplessness" [NCHS code 1135.1]).
- Insomnia diagnosis (ICD-9 codes: 78059, 78056, 78055, 78052, 78050, 32780, 32709, 32702, 32701, 32700, 30749, 30748, 30747, 30746, 30745, 30742, 30741, 30740).
- Prescription of sedative-hypnotics (BDZ and NBSH) FDA-approved for insomnia. (Rasu, Shenolikar, Nahata, & Balkrishnan, 2005) (Please see Table 1).

To maintain consistency with Study 1 and examine whether the medicalization of sleeplessness persisted over time at the interactional level, we used svy commands in Stata Version 15 (StataCorp LP, College Station, TX) to calculate means with 95% confidence intervals for the outcomes of interest (complaint, diagnosis, and prescriptions). We then computed national estimates (in millions) for each outcome for the present study (Study 2, 2008-2015). We also estimated rates for each outcome by age group (18-44, 45-64, and \geq 65 years), per 10,000 office visits. To avoid small cell sizes, age group data were combined into two-year increments. We used NAMCS-provided sample weights to adjust for complex survey design. To test for the significance of the linear trajectory, we ran a series of bivariate linear models by regressing estimates for each outcome of interest on year. The regression coefficients reflect average change in each of the four outcomes annually over Study 2. Linear correlation coefficients were calculated to examine the strength of the association. Population estimates with 95% confidence intervals, regression coefficients (slopes), and correlation coefficients are reported in Tables 2 and 3, respectively.

Starting in 2012, the NAMCS sampling design changed, splitting the office-based physician component from the Community Health Center (CHC) component. As a result, 2012–2015 NAMCS public data files only include data on visits to office-based physicians. To accommodate this change, data on CHC visits for the 2008–2011 study period were

 $\begin{tabular}{ll} \textbf{Table 1} \\ \textbf{Benzodiazepine} \ \ \text{and} \ \ \text{nonbenzodiazepine} \ \ \text{sedative hypnotics approved for insomnia by the Food and Drug Administration (Rasu et al., 2005).} \\ \end{tabular}$

Brand Name	Generic Name	NAMCS Medication Code
Benzodiazepines		
Prosom	Estazolam	d00915
Dalmane	Flurazepam	d00238
Doral	Quazepam	d00917
Restoril	Temazepam	d00384
Restoril	Temazepam	d00397
Non-benzodiazepines		
Ambien, Ambien CR	Zolpidem	d00910
Sonata	Zaleplon	d04452
Lunesta	Eszopiclone	d05421
Rozerem	Ramelteon	d05578

excluded from analyses. To compare Study 2 trends with Study 1 trends, national estimates for the outcomes of interest for Study 1 were re-calculated to exclude CHC visits. These changes resulted in slightly lower national estimates relative to those previously published (see Fig. 1). (Moloney et al., 2011)

Results

1.1. Sleeplessness-related outcomes of physician office visits, over time

To provide a 23-year trend arc, we first describe results from Study 1 (1993–2007) (Moloney et al., 2011) and then results from the current analyses (Study 2, 2008–2015). Fig. 1 provides a graphic representation of trends 1993–2015. Study 2 results are presented in Table 2.

During Study 1, complaints of sleeplessness approximately doubled (from 2.7 million to 5.7 million). Throughout Study 2, sleeplessness complaints remained relatively stable (5.4 million in 2008, 5.7 million in 2015). Insomnia diagnoses, however, steadily increased over 23 years, from 800,000 in 1993 to 6.1 million in 2007, and from 6.6 million in 2008 to 9.4 million in 2015. Near the end of Study 1 (in 2006), insomnia diagnoses began to outpace sleeplessness complaints. This trend persisted throughout Study 2.

In Study 1, BDZ prescriptions increased from about 2.5 million to 3.7 million; NBSH prescriptions increased from 540,000 to 16.2 million. During the 23-year period, NBSH prescriptions were on the rise, peaking in 2011 at 22 million, before subsequently declining. In 2015, just 14.5 million NBSH prescriptions were written.

In Study 1, all sleeplessness-related outcomes of physician office visits (complaint of sleeplessness, insomnia diagnosis, BDZ and NBSH prescriptions) increased significantly over time. In Study 2, NBSH prescriptions had a statistically significant negative linear slope over time, reflecting a significant downward prescription trend. The non-significant slopes for all other outcomes suggest that there was no steady increase or decrease in trends. Despite their downward trajectory during 2008–2015, NBSH prescriptions far outpaced all other outcomes in Study 2.

1.2. Sleeplessness-related outcomes of physician office visits over time, by

Throughout Study 1, adults ages 65 years and older were less likely to visit a physician because of sleeplessness or receive an insomnia diagnosis, when compared to those 18–44 or 45–65. As seen in Table 3, these trends continued in Study 2. During Study 2 adults ages 45–64 had the highest rates of sleeplessness, followed closely by adults ages 18–44. Similarly, adults ages 45–64 had the highest rates of insomnia diagnoses until 2014–2015, when they were outpaced by those 18–44.

In Study 1, adults ages 65 + had the highest BDZ prescription rates and this trend continued for Study 2 (BDZ prescription range 2008–2015: 42.1–64.3/10,000 visits). Adults ages 45–64 had a steadily declining rate of BDZ prescriptions ranging from 56.5 prescriptions/ 10,000 visits in 2008-2009 to 29.4 prescriptions/10,000 visits in 2014-2015. The youngest age group (18-44) ranged from 20.5 to 26.1 prescriptions/10,000 visits across Study 2.

NBSH prescription rates, across all age groups, were consistently higher than those of BDZ during Study 2. Like Study 1, adults ages 45–64 had the highest NBSH prescription rates (range 248.9–338.9/10,000 visits) and adults ages 18–44 had the lowest NBSH prescription rates (range 139.5–172.1/10,000 visits). Adults ages 65 + ranged from a high of 278.5 NBSH prescriptions/10,000 visits in 2010–2011 to a low of 164.9 NBSH prescriptions/10,000 visits in 2014–2015. The slopes for all sleeplessness-related outcomes 2008–2015, by age group, were not statistically significant, suggesting a lack of a consistent trend.

Table 2Unweighted numbers and weighted estimates (in millions) along with 95% confidence intervals of sleeplessness-related complaints, insomnia diagnoses, and prescriptions for benzodiazepine and nonbenzodiazepine sedative-hypnotics as a result of physician office visits: United States, 2008–2015

Year	Unweighted No. of Physician Office Visits by Year (Weighted Estimates ^a)	Sleeplessness Complaints, Weighted Estimated No. (95% CI) ^a	Insomnia Diagnoses, Weighted Estimated No. (95% CI) ^a	BDZ Prescriptions, Weighted Estimated No. (95% CI) ^a	NBSH Prescriptions, Weighted Estimated No. (95% CI) ^a
2008	28,741 (768.2)	5.4 (3.7, 7.1)	6.6 (5.2, 8.1)	3.7 (2.7, 4.8)	19.1 (16.3, 21.8)
2009	32,281 (829.6)	5.2 (4.0, 6.4)	6.4 (4.9, 7.8)	4.2 (3.0, 5.4)	19.8 (16.6, 22.9)
2010	31,229 (803.3)	5.5 (4.0, 6.9)	6.1 (4.3, 7.9)	2.7 (1.9, 3.4)	19.1 (16.1, 22.0)
2011	30,872 (763.7)	3.7 (2.7, 4.6)	7.1 (5.4, 8.8)	3.2 (2.3, 4.2)	22.0 (18.0, 25.9)
2012	76,330 (757.6)	4.3 (3.6, 5.0)	6.1 (5.2, 7.0)	3.7 (3.1, 4.4)	16.7 (15.0, 18.3)
2013	54,873 (771.6)	4.0 (3.1, 4.9)	7.1 (5.7, 8.4)	3.1 (2.4, 3.8)	16.8 (14.9, 18.8)
2014	45,710 (745.9)	5.4 (4.4, 6.4)	6.7 (5.5, 7.9)	3.1 (2.3, 4.0)	16.8 (14.9, 18.8)
2015	28,332 (841.2)	5.7 (3.8, 7.6)	9.4 (5.3, 13.6)	1.9 (1.1, 2.8)	14.5 (11.0, 18.0)
Model Statisti	ics ^b				
Slope, b		-6916	277890	- 189,290	-699,628°
Correlation, r		0224	.6319	6576	7367

Note: BDZ = benzodiazepine; NBSH = nonbenzodiazepine sedative hypnotic; CI = confidence interval.

Discussion

This study offers an updated analysis of sleeplessness-related outcomes of U.S. physician office visits and provides some evidence that the medicalization of sleeplessness may be waning at the level of patient-physician interaction. Contrary to the first hypothesis, that sleeplessness complaints, insomnia diagnoses, and sedative-hypnotic prescriptions would continue to increase significantly over time, the only statistically significant trend over the study period was the *reduction* of NBSH prescriptions. The number of NBSH prescriptions in 2015 was approximately 14.5 million, a 34% decrease since the trend's peak of nearly 22 million in 2011. These trends differ substantially when compared to 1993–2007 analyses, when all sleeplessness-related trends over time were positive and statistically significant, and NBSH prescriptions increased 30-fold (Moloney et al., 2011).

Our second hypothesis, that sleeplessness complaints would lag behind insomnia diagnoses and NBSH prescriptions, was supported. In 2011, for instance, NBSH prescriptions outpaced insomnia diagnoses more than 3 to 1, and sleeplessness complaints nearly 6 to 1. Even at their lowest rate of prescription (in 2015) NBSH prescription rates were still 1.5 times higher than insomnia diagnoses, and 2.5 times higher than sleeplessness complaints. Throughout the 2008–2015 analytic period, insomnia diagnoses outpaced sleeplessness complaints; this trend was reversed prior to 2006. Generally, these trends support the medicalization hypothesis that pharmaceutical "solutions" are not always directly linked to formal complaint or diagnosis (Moloney et al., 2011).

Our third hypothesis, regarding age groups and sleeplessness-related outcomes, was also supported. While older age is associated with increased sleep disruption (Colten & Altevogt, 2006), adults ages 65 + in this sample received fewer insomnia diagnoses compared to those 18–44 and 45–64. Across the analytic period, the highest rates of insomnia diagnoses and NBSH prescriptions were observed among adults ages 45–64. Compared to younger adults, those ages 65 + received a BDZ prescription at a higher rate. However, BDZ prescription rates were consistently lower than NBSH prescription rates, for all age groups. Given BDZ's decades-long reputation as a "social problem," these lower rates are not surprising (Gabe & Bury, 1988).

While causal conclusions cannot be drawn from these data, we speculate that two engines of medicalization – consumerism and physicians – may be influencing the medicalization of sleeplessness at the level of patient-physician interaction. Put simply, patients may be less likely to request these drugs, and providers less likely to prescribe them. But why? Factors worthy of consideration include negative public

perception, stricter practice recommendations, and reduced spending on NBSH direct-to-consumer advertising (DTCA).

Shifts in these factors coincide with the precipitous drop in NBSH prescriptions in 2012 (16.7 million, down from nearly 22 million in 2011). Although numerous studies prior to 2012 linked sedative-hypnotic use to dangerous side effects and potential for abuse (Glass, Lanctot, Herrmann, Sproule, & Busto, 2005; Longo & Johnson, 2000), the landmark findings of Kripke, Langer, and Kline demonstrated a clear "dose-response" effect between sedative-hypnotic use and morbidity and mortality hazards (Kripke et al., 2012). These findings, published in early 2012, also generated widespread media coverage and attention-grabbing headlines (e.g., "Researchers: Sleeping Pills Can Kill You," "Here's Why Experts say Sleeping Pills are as Bad as Cigarettes") (Kakade, 2012; Mullur, 2012). The news media increasingly influences American ideas and policy related to health, illness, and treatment (Gollust, Eboh, & Barry, 2012). High-profile media coverage of stories on the deleterious health outcomes associated with drug use (e.g, estrogen/progesterone replacement correlations with breast cancer) has been linked to reduced prescription rates, and this is at least partially attributable to consumers (Haas, Kaplan, Gerstenberger, & Kerlikowske, 2004).

Physicians, too, are influenced by both scientific studies and public perception, particularly when paired with more conservative practice recommendations (Grimshaw et al., 2004). In recent years, the well-documented harms of sedative-hypnotics have resulted in calls to avoid their use as first-line insomnia therapy (Qaseem et al., 2016). Recommendations for older adults are particularly strict. In 2012, the American Geriatrics Society recommended avoiding BDZ for insomnia and imposed stricter limitations (no more than 90 days) on NBSH use (American Geriatrics Society Beers Criteria Update Expert, 2012). In 2015 they updated their recommendations to complete avoidance of all sedative-hypnotics for older adults (American Geriatrics Society Beers Criteria Update Expert Panel, 2015).

Changes in DTCA may also impact prescription rates. As recently described by Barbee and colleagues (Barbee et al., 2018), DTCA for NBSH has fallen off steeply in recent years.³ For context, makers of Ambien and Ambien CR, the most popular of the newer-generation sedative-hypnotics spent \$147 million on DTCA in 2008, a time of economic recessesion (Weinstein, 2013). DTCA expenditures for Ambien CR have since declined, as is common among medications nearing

^a Estimates are provided in millions.

^b For model statistics, b is the regression coefficient (slope) from bivariate linear regression of national estimates for each outcome of interest on year; *r* is the temporal correlation of variable with year.

^c Significant slope at = P < 0.05 as a result of bivariate regression analysis.

 $^{^3\,\}mathrm{BDZ}$ have been generic for decades, and thus are not marketed to consumers.

National weighted estimates of sleeplessness-related complaints, diagnoses, and prescriptions for benzodiazepine and nonbenzodiazepine sedative hypnotics, per 10,000 physician office visits, by age group: United States,

2008-2015												
Years	Sleeplessness as Re	Sleeplessness as Reason for Office Visit, Complaints per 10,000 Visit	laints per 10,000 Visits	Insomnia Diag.	Insomnia Diagnoses, Per 10,000 Visits) Visits	BDZ Prescripti	BDZ Prescriptions, Per 10,000 Visits	Visits	NBSH Prescrip	NBSH Prescriptions, Per 10,000 Visits	0 Visits
	18–44 Years	45–64 Years	≥ 65 Years	18–44 Years	18-44 Years 45-64 Years ≥65 Years 18-44 Years 45-64 Years ≥65 Years 265 Years ≥65 Years ≥65 Years	≥65 Years	18–44 Years	45–64 Years	≥65 Years	18–44 Years	45–64 Years	≥65 Years
		87.3	49.2	84.6	101.0	56.7	24.8	56.5	64.3	163.1	338.9	211.8
2010-2011	75.8	68.5	29.4	92.2	94.9	64.7	20.5	42.2	49	172.1	323.4	278.5
2012-2013	56.7	59.2	46.8	90.8	102.3	74.1	26.1	48.4	58.5	139.5	287.0	218.4
2014-2015	82.1	84.7	45.6	123.1	114.1	73.7	20.5	29.4	42.1	171.0	248.9	164.9
Model Statistics ^a	ics ^a											
Slope, b	2.1	6	e.	5.2	2.3	3	4	-3.8	-2.9	5	-27.4	-10
Correlation, r	4.	4.	.1	.7	6:	6:	2	7	7	<u>.</u> .	6:-	9

Note: BDZ = benzodiazepine; NBSH = nonbenzodiazepine sedative hypnotic.

For model statistics, b is the slop from bivariate regression of variable on year-range midpoint; r is the temporal correlation of variable with year-range midpoint. Ranges are two years.

generic status (Shapiro, 2016). In contrast, makers of Intermezzo, a new NBSH introduced in 2012, spent just \$29 million on the first six months of marketing; sales have been underwhelming (Smith, 2013).

Although we focus here on the office visit interaction and subsequent outcomes, we would be remiss if we did not acknowledge larger forces that influence the medicalization of sleeplessness. Quantitative and qualitative research has identified multiple social and behavioral factors (e.g., career uncertainty, near-constant use of lightproducing technology, worry over children or aging parents) that are closely linked to sleep loss and request for sleep aids (Moloney, 2017; Seidel, Yorgason, Polenick, Zarit, & Fingerman, 2017; Thomee, Harenstam, & Hagberg, 2011). Additional factors, particularly relevant to the United States and its aging, Baby Boom generation, that fuel the multi-billion dollar "Sleep-Industrial Complex" include: enhancement culture (self-transformation through techno-science), commodification of health (creation of niche health-services and products), and a "productivity imperative" (maximizing productivity in a 24/7 work culture) (Barbee et al., 2018). Future research could specifically investigate the extent to which these and other factors contribute to changing attitudes and practices related to sedative-hypnotics.

Additional research might also consider the salience of related theoretical constructs such as pharmaceuticalization (Williams et al., 2008) and healthicization (Hislop & Arber, 2003). The general medicalization framework we have used to interpret these data construes trends in either diagnosis or treatment as indicative of medicalization (Conrad and Cockerham, 2013). However, our analyses might be usefully expanded upon through further consideration of whether, or the degree to which, declines in pharmaceuticalization account for the decline in sedative-hypnotic prescriptions that stand in contrast to rising insomnia diagnoses. It is also possible that declining sedativehypnotic prescriptions are linked to a rise in healthicization, wherein consumers eschew medication and embrace personalized, lifestyle changes intended to improve sleep (e.g., no caffeine after 4PM, no screen time an hour before bed). Importantly, we cannot conclude that our data offer evidence of the demedicalization of sleeplessness as a whole, as we focus on outcomes at the interactional level only (Williams, 2004).

While this analysis provides useful updates on prior research, several limitations should be noted. The NAMCS dataset was neither designed nor intended to measure the medicalization process. The unit of analysis is the office visit, which is not equivalent to patient outcomes. Although NAMCS allows us to track prescription rates over time, we have no way of knowing if prescriptions were filled and medication ingested. We limited the scope of our analyses to only drugs that are FDA-approved for insomnia (Rasu et al., 2005), thus we cannot account for drugs (over-the-counter or prescription) that are primarily intended for other health concerns, but commonly used for sleeplessness (e.g., Benadryl). Future work may wish to analyze a wider range of medications. Further, the elimination of the Community Health Center visits may limit the generalizability of the findings within certain groups, and downwardly bias our estimates.

Despite these limitations, this work contributes to the medicalization literature generally, and the medicalization of sleeplessness literature in particular, by offering quantitative evidence that the medicalization of sleeplessness may be on the decline. To our knowledge, this is the first study to offer an updated look at sleeplessness-related outcomes (i.e., sleeplessness complaint, insomnia diagnosis, prescription of BDZ or NBSH) of physician office visits 2008-2015 and compare these outcomes to 1993-2007 trends, thus providing a 23-year trend arc. Although we speculate that the increasingly negative portrayals of sedative-hypnotics, combined with shifting practice recommendations, and decreased DTCA have led to reduced consumerism and/or physician compliance in the case of sedative-hypnotics for sleeplessness, future research should explore these dynamics in more detail.

Population health may be improved by continued awareness-raising of sedative-hypnotic harms among both doctors and patients. It is also

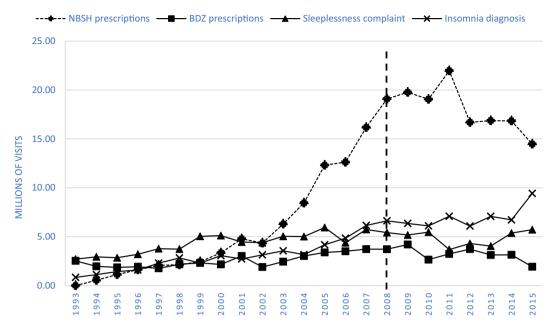


Fig. 1. Sleeplessness-related trends of complaint, insomnia diagnosis, benzodiazepine (BDZ) and nonbenzodiazepine sedative hypnotic (NBSH) prescription as a result of physician office visits: United States, 1993-2015.

imperative to address behavioral or social causes of sleeplessness and treat these root causes with appropriate behavioral or psychological therapies. More broadly impactful, however, would be the implementation of work and school schedules that more closely adhere to shifting circadian rhythms over the life course (e.g., delayed school start time for teenagers), education programs (e.g., sleep hygiene) and eliminating daylight savings time (Barnes & Drake, 2015). Further, the addition of items reflecting the use of effective well-validated and standardized non-pharmacological treatment protocols (e.g., cognitive behavioral therapy) occurring in clinical encounters in national databases like NAMCS would round out the picture for studies of this kind.

Conflicts of interest

None.

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Appendix A. Supplementary data

Supplementary data to this article can be found online at https:// doi.org/10.1016/j.ssmph.2019.100388.

References

American Academy of Sleep Medicine (2004). FDA requests label change for sleep disorder drug products. 2018 https://aasm.org/fda-requests-label-change-for-sleep-disorderdrug-products/, Accessed date: 15 January 2018.

American Geriatrics Society Beers Criteria Update Expert Panel (2012). American Geriatrics Society updated Beers Criteria for potentially inappropriate medication use in older adults. Journal of the American Geriatrics Society, 60(4), 616-631.

Barbee, H., Moloney, M. E., & Konrad, T. R. (2018). Selling slumber: American neoliberalism and the medicalization of sleeplessness. Sociology Compass, 12(10), e12622. Barker, K. K. (2008). Electronic support groups, patient-consumers, and medicalization: The case of contested illness. Journal of Health and Social Behavior, 49(1), 20-36.

Barnes, C. M., & Drake, C. L. (2015). Prioritizing sleep health: Public health policy recommendations. Perspectives on Psychological Science, 10(6), 733-737.

Brown, P. (1995). Naming and framing: The social construction of diagnosis and illness. Journal of Health and Social Behavior, 34-52.

American Geriatrics Society Beers Criteria Update Expert Panel. American Geriatrics Society 2015 updated Beers Criteria for potentially inappropriate medication use in older adults, Journal of the American Geriatrics Society 63(11), 2227-2246.

Clarke, A. E., & Shim, J. (2011). Medicalization and biomedicalization revisited: Technoscience and transformations of health, illness and American medicine, In B. A. Pescosolido, J. K. Martin, J. D. McLeod, & A. Rogers (Eds.). Handbook of the sociology of health, illness and healing: A blueprint for the 21st century (pp. 173-199). New York: Springer.

Colten, H. R., & Altevogt, B. M. (2006). Institute of medicine (U.S.). Committee on sleep medicine and research. Sleep disorders and sleep deprivation: An unmet public health problem. Washington, DC: Institute of Medicine: National Academies Press.

Conrad, P. (1992). Medicalization and social control. Annual Review of Sociology, 18, 209-232

Conrad, P. (2007). The medicalization of society: On the transformation of human conditions into treatable disorders. Baltimore: Johns Hopkins University Press.

Conrad, P. (2013). Medicalization: Changing contours, characteristics, and contexts. In W. C. Cockerham (Ed.). Medical sociology on the move (pp. 195-214). New York: Springer. Conrad, P., Mackie, T., & Mehrotra, A. (2010). Estimating the costs of medicalization. Social Science & Medicine, 70(12), 1943-1947.

Davis, J. E. (2006). How medicalization lost its way. Society, 43(6), 51-56.

Figert, A. E. (2011). The consumer turn in medicalization: Future directions with historical foundations. New York, NY: Springer New York.

Ford, E. S., Wheaton, A. G., Cunningham, T. J., Giles, W. H., Chapman, D. P., & Croft, J. B. (2014). Trends in outpatient visits for insomnia, sleep apnea, and prescriptions for sleep medications among US adults: Findings from the National Ambulatory Medical Care Survey 1999-2010. Sleep, 37(8), 1283-1293.

Gabe, J., & Bury, M. (1988). Tranquillisers as a social problem. Sociological Review, 36(2),

Glass, J., Lanctot, K. L., Herrmann, N., Sproule, B. A., & Busto, U. E. (2005). Sedative hypnotics in older people with insomnia: meta-analysis of risks and benefits. BMJ, 331(7526), 1169.

Gollust, S. E., Eboh, I., & Barry, C. L. (2012). Picturing obesity: Analyzing the social epidemiology of obesity conveyed through US news media images. Social Science & Medicine, 74(10), 1544-1551.

Grimshaw, J. M., Thomas, R. E., MacLennan, G., et al. (2004). Effectiveness and efficiency of guideline dissemination and implementation strategies. Health Technology Assessment, 8(6), 1-72 iii-iv.

Haas, J. S., Kaplan, C. P., Gerstenberger, E. P., & Kerlikowske, K. (2004). Changes in the use of postmenopausal hormone therapy after the publication of clinical trial results. Annals of Internal Medicine, 140(3), 184-188.

Hislop, J., & Arber, S. (2003). Understanding women's sleep management: Beyond medicalization-healthicization? Sociology of Health & Illness, 25(7), 815-837. Hollan, D. (2013). Sleeping, dreaming, and health in rural Indonesia and the urban U.S.:

A culural and experiential approach. Social Science & Medicine, 79, 23-30. ICD-9-CM (1996). International Classification of Diseases, 9th revision, clinical modification.

Medicodehttps://www.cdc.gov/nchs/icd/icd9cm.htm.

Kakade, A. (2012). Experts say sleeping pills are as bad as cigarettes. Aol.com. Aol.com. Kaufmann, C. N., Spira, A. P., Depp, C. A., & Mojtabai, R. (2016). Continuing versus new prescriptions for sedative-hypnotic medications: United States, 2005-2012. American Journal of Public Health, 106(11), 2019-2025.

- Kripke, D. F., Langer, R. D., & Kline, L. E. (2012). Hypnotics' association with mortality or cancer: A matched cohort study. BMJ Open, 2(1).
- Longo, L. P., & Johnson, B. (2000). Addiction: Part I. Benzodiazepines-side effects, abuse risk and alternatives. American Family Physician, 61(7), 2121–2128.
- Moloney, M. E. (2017). 'Sometimes, it's easier to write the prescription': Physician and patient accounts of the reluctant medicalisation of sleeplessness. *Sociology of Health & Illness*, 39(3), 333–348.
- Moloney, M. E., Konrad, T. R., & Zimmer, C. R. (2011). The medicalization of sleep-lessness: A public health concern. *American Journal of Public Health*, 101(8), 1429.
 Mullur, H. (2012). Researchers: Sleeping pills can kill you. Fox 31 Denver News.
- National Institutes of Health (2005). National Institutes of Health State of the Science Conference statement on manifestations and management of chronic insomnia in adults, June 13-15, 2005. Sleep, 28(9), 1049–1057.
- Qaseem, A., Kansagara, D., Forciea, M. A., Cooke, M., & Denberg, T. D. (2016). Clinical guidelines committee of the American College of P. Management of chronic insomnia disorder in adults: A clinical practice guideline from the American College of Physicians. Annals of Internal Medicine, 165(2), 125–133.
- Rasu, R. S., Shenolikar, R. A., Nahata, M. C., & Balkrishnan, R. (2005). Physician and patient factors associated with the prescribing of medications for sleep difficulties that are associated with high abuse potential or are expensive: An analysis of data from the National Ambulatory Medical Care Survey for 1996-2001. Clinical Therapeutics, 27(12), 1970-1979.
- Seidel, A. J., Yorgason, J. B., Polenick, C. A., Zarit, S. H., & Fingerman, K. L. (2017). Are You sleeping? Dyadic associations of support, stress, and worries regarding adult children on sleep. *The Gerontologist*, 58(2), 341–352.
- Shapiro, B. T. (2016). Estimating the cost of strategic entry delay in pharmaceuticals: The case of Ambien CR. *Quantitative Marketing and Economics*, 4(3), 201–231.

- Siebern, A. T., & Manber, R. (2011). New developments in cognitive behavioral therapy as the first-line treatment of insomnia. Psychology Research and Behavior Management, 4, 21, 28
- Smith, L. (2013). Transcept: Purdue fires big marketing guns and FDA issues insomnia drug guidelines that help intermezzo. Smith on Stockshttp://seekingalpha.com/article/ 1126631-transcept-purdue-fires-big-marketing-guns-and-fda-issues-insomnia-drugguidelines-that-help-intermezzo, Accessed date: 13 June 2015.
- Thomee, S., Harenstam, A., & Hagberg, M. (2011). Mobile phone use and stress, sleep disturbances, and symptoms of depression among young adults–a prospective cohort study. *BMC Public Health*, *11*, 66.
- Venn, S., Arber, S., Meadows, R., & Hislop, J. (2008). The fourth shift: Exploring the gendered nature of sleep disruption among couples with children. *British Journal of Sociology*, 59(1), 79–98.
- Weinstein, D. (2013). Purdue puts Intermezzo DCT to bed. Medical Marketing and Mediahttp://www.mmm-online.com/channel/purdue-puts-intermezzo-dtc-to-bed/ article/293546/.
- Williams, S. J. (2004). Beyond medicalization-healthicization? A rejoinder to Hislop and Arber. Sociology of Health & Illness, 26(4), 453–459 discussion 460-453.
- Williams, S. J., Coveney, C. M., & Gabe, J. (2013). Medicalisation or customisation? Sleep, enterprise and enhancement in the 24/7 society. Social Science & Medicine, 79, 40–47.
- Williams, S. J., Seale, C., Boden, S., Lowe, P., & Steinberg, D. L. (2008). Waking up to sleepiness: Modafinil, the media and the pharmaceuticalisation of everyday/night life. Sociology of Health & Illness, 30(6), 839–855.
- Zarhin, D. (2015). Contesting medicalisation, doubting the diagnosis: Patients' ambivalence towards the diagnosis of obstructive sleep apnoea. Sociology of Health & Illness, 37(5), 715–730.