Trends in Medication Prescribing for Pediatric Sleep Difficulties in US Outpatient Settings

Sasko D. Stojanovski, PharmD[1,3]; Rafia S. Rasu, PhD[2]; Rajesh Balkrishnan, PhD[1,4]; Milap C. Nahata, PharmD, MS[1,3,5]

[1]Division of Pharmacy Practice and Administration, The Ohio State University College of Pharmacy, Columbus, OH; [2]Division of Pharmacy Practice, University of Missouri Kansas City School of Pharmacy, Kansas City, MO; [3]Children's Hospital and Research Institute, Columbus, OH; [4]College of Public Health, The Ohio State University, Columbus, OH; [5]College of Medicine, The Ohio State University, Columbus, OH

Objectives: This study examined trends in physician-prescribing of medications for children with sleep difficulties in outpatient settings in the US. Additionally, we explored the incidence of physician prescribing patterns of medications with high abuse potential for children with sleep difficulties.

Methods: A cross-sectional study was conducted on patients aged ≤17 years with sleep difficulties from 1993–2004 using data from the National Ambulatory Medical Care Survey (NAMCS). Office visits were considered related to sleep difficulties if relevant ICD-9 codes were recorded and if sleep difficulties were reported as the reason for the visits. Medications were retrieved using the NAMCS drug codes, and all analyses were weighted to determine national estimates.

Results: During 1993 to 2004, approximately 18.6 million visits occurred for sleep related difficulty in children. The highest percentage of visits were by school-aged children (6 to 12 years). Pediatricians saw 35% of patients, psychiatrists saw 24%, and general/family practice physicians saw 13% of the patients. Eighty-one percent of visits among children with sleep difficulties resulted in a prescription for a medication. Many of these medications prescribed lack FDA approved labeling to assure their effectiveness and safety in this population.

Conclusion: The findings of this study suggest that physicians frequently prescribed medications for sleep difficulties in children in US outpatient settings. Of particular concern is prescribing of many unapproved medications for this population.

Keywords: Pediatrics, insomnia, sleep initiation difficulties and maintenance disorders, ambulatory care, drug therapy.

Citation: Stojanovski SD; Rasu RS; Balkrishnan R; Nahata MC. Trends in medication prescribing for pediatric sleep difficulties in us outpatient settings. *SLEEP* 2007;30(8):1013-1017.

INTRODUCTION

IN PRIMARY CARE PRACTICE, SLEEP DIFFICULTIES AMONG ADULTS ARE COMMONLY DOCUMENTED, AND THE ESTIMATED ANNUAL DIRECT COST WAS $14 BILLION for insomnia in 1995.[1,2] In addition, 10% to 25% of infants, children, and adolescents manifest sleep disorders at various stages of development.[3,4] Insomnia in adults is defined as difficulty initiating or maintaining sleep, waking up too early, or nonrestorative sleep. However, in pediatric insomnia the interpretation of the problem depends on its impact on the child or caregiver.[5] Depending on developmental status and age, a normal sleep requirement is 14 to 15 hours for an infant, 12 to 14 hours for a toddler (1 to 5 years), 9 to 11 hours for school-aged children (6 to 12 years), and 9 to 9.25 hours for an adolescent.[6] Sleep difficulties in school-aged children may present as sleepwalking, nightmares, sleep talking, restless sleep, and bedtime refusal; adolescent sleep loss is secondary to late and erratic schedules (e.g., homework or social activities).[7,8] Furthermore, many children with difficulty sleeping may have an increased risk of developing anxiety and depression in late childhood and early adolescence and even during adulthood.[9, 10] Behavioral problems among children with attention deficit hyperactivity disorder (ADHD) should be assessed for sleep disturbances manifest as periodic leg movements, bedtime struggles, and frequent awakening during the night compared to non-ADHD children.[11] Many medications prescribed or taken over-the-counter can affect sleep as well. The consumption of caffeinated beverages or soft drink by seventh, eighth, and ninth graders resulted in disturbed sleep.[12]

In the United States approximately 75% of prescription drugs are not labeled for use in infants and children.[13] It should be noted there is no medication labeled for use in pediatric patients for the treatment of insomnia in this country. However, by necessity, pediatric patients frequently receive off-label or unlicensed medications for the treatment of various illnesses. This study examined trends in physician prescribing of medications for children with sleep difficulties in outpatient settings in the US. In addition, this study explored the physician prescribing patterns of medications with high abuse potential for children with sleep difficulties.

METHODS

This was a cross-sectional study utilizing National Ambulatory Medical Care Survey (NAMCS) data from 1993-2004 to examine the trends in physicians prescribing medications for children with sleep difficulties. The basic sampling unit was the physician-patient office visit. The was a national probability sample survey conducted by the Division of Health Care Statistics, National Center for Health Statistics (NCHS), and the Centers for Disease Control and Prevention (CDC). Only office visits of non-federally employed physicians who are primarily engaged in direct patient care (except anesthesiology, pathology, and radiology) were sampled. Each physician was randomly selected for a for a one-week reporting period during a year. Data collection was done through

Disclosure Statement
This was not an industry supported study. Drs. Stojanovski, Rasu, Nahata, and Balkrishnan have indicated no financial conflicts of interest.

Submitted for publication July, 2006
Accepted for publication March, 2007
Address correspondence to: Milap C. Nahata, PharmD, MS, Professor and Division Chair, Ohio State University College of Pharmacy, 500 W. 12th Avenue, Columbus, OH 43210; Tel: (614) 292-2472; Fax: (614) 292-1335; E-mail: nahata.1@osu.edu

Table 1—List of ICD-9 Codes for Sleep Difficulties

ICD-9 code	Diagnoses
307.47	Other dysfunctions of sleep stages or arousal from sleep
307.42	Persistent disorder of initiating or maintaining sleep
307.41	Transient disorder of initiating or maintaining sleep
307.40	Nonorganic sleep disorder, unspecified
307.48	Repetitive intrusions of sleep
292.85	Drug induced insomnia
307.3	Stereotypic movement disorder
307.46	Sleep arousal disorders
327.23	Obstructive sleep apnea
333.99	Restless legs syndrome
780.5	Sleep disturbances
780.50	Sleep disturbance, unspecified
780.52	Insomnia
780.56-	Dysfunctions associated with sleep stages or arousal from sleep
780.55	Disruptions of 24-hour sleep-wake cycle
780.59	Other sleep disturbances

the physician or physician staff in NAMCS. NAMCS utilizes a multistage sampling procedure. All statistics provided in the NAMCS are office visit level data and must be analyzed using a multistage estimation procedure in order to produce generalizable results that are reflective of the entire population of the United States. The publicly available online documents provide further details on the NAMCS sampling and weighting methods, as well as processing and estimation/quality control procedures.[14]

Patients aged ≥17 years with sleep difficulties treated in US outpatient settings were included in the study sample. Statistical sampling weights were assigned for each observation in this dataset to obtain nationally representative cross-sectional estimates. From 1993 to 2004, the NAMCS contained approximately 18.6 million weighted observations for the entire United States population over the 12-year period. Office visits were considered to be insomnia/sleep difficulty visits if any ICD-9 diagnosis codes for sleep difficulties (Table 1) were reported in the NAMCS dataset for the patient visit record. Office visits were also selected as insomnia/sleep difficulty related if sleep difficulties were reported in the "reason of visit" field and sleep medications (Table 2) were prescribed during visits. The NAMCS reports provided a maximum of 6 medications related to each patient visit, and a 5-digit medication code was assigned for each medication (Table 2). Visits were considered result in a medication prescription if assigned medication codes were mentioned in the patient record form. Patients were considered to be having diet and nutritional counseling, mental therapy and stress management therapy if these recommendations were made in patient record forms during their visits.

Statistical Analyses

All analyses were weighted using NAMCS sampling weights. Univariate and bivariate analyses were conducted using STATA® statistical software version 9.0. The unit of analysis was the individual patient visit. Many categorical variables were created from the independent variables identified in the NAMCS dataset for ease of analysis and interpretation. Bivariate analyses between variables were conducted using weighted two-way contingency table analysis. An alpha level of 0.05 was used as the level of significance. Variables significant in the bivariate analysis were included in multivariate analysis. Data trends were graphically plotted and further analyzed using weighted logistic regression analyses.

RESULTS

Between 1993 and 2004, based on the NAMCS estimates approximately 18.6 million visits (weighted population size) were made to office based physicians for sleep related difficulty in children 17 years of age or less. Descriptive statistics are mentioned in table 3. Fifty-six percent of these visits were by male children and mean age was 8.8 (SD 5.18) years. Infants (<1 year), toddlers (1 to 3 years), preschool children (4 to 5 years), school aged chil-

Table 2—Medications used for sleep difficulties and their NAMCS medication codes

Medications	Type	NAMCS Medication Codes
Clonidine (Catapres™)	Alpha-2 agonist	06985, 05895, 89019
Guanfacine (Tenex™)	Alpha-2 agonist	30777, 97089
Hydroxyzine (Atarax™)	Antihistamine	02875, 10803, 15100, 15105, 34270, 91029, 93415
Zolpidem (Ambien™)	Nonbenzodiazepine	57048, 93347, 94035
Zaleplon (Sonata™)	Nonbenzodiazepine	00039, 02107, 70115
Trazodone (Desyrel™)	Antidepressant	31997, 40520, 55903
Lorazepam (Ativan™)	Benzodiazepine	02900, 17888, 53145
Temazepam (Restoril™)	Benzodiazepine	26453, 30756, 55668
Flurazepam (Dalmane™)	Benzodiazepine	08390, 12810, 52350
Quazepam (Doral™)	Benzodiazepine	10257, 55028, 92022, 92148
Triazolam (Halcion™)	Benzodiazepine	13999, 55928, 93419, 96068
Estazolam (Prosom™)	Benzodiazepine	52068, 92080, 92123
Diazepam (Valium™)	Benzodiazepine	09370, 33555, 33558, 33574, 51695
Chlordiazepoxide (Librium™)	Benzodiazepine	17450, 51055
Clonazepam (Klonopin™)	Benzodiazepine	06980, 06990, 51270, 60790
Oxazepam (Serax™)	Benzodiazepine	22242, 27855, 54085
Halazepam (Paxipam™)	Benzodiazepine	23006, 52503
Prazepam (Centrax™)	Benzodiazepine	06095, 24804, 54760
Clorazepate Dipotassium (Tranxene™)	Benzodiazepine	03125, 06993, 31945, 51280

Table 3—Descriptive statistics for the study population (weighted population size= 18,640,820 cross sectional patient visits during 1993-2004)

Variables	Created analytical variables	Estimated Proportions
Demographic Characteristics		
Age		
	Mean age	8.8 (SE 0.27)
	Age less than 1 yr[b,c]	7%
	Age 1-3 yr[c,d]	15%
	Age 4-5 yr[c,d]	10%
	Age 6-12 yr[b,c]	36%
	Age 13-17 yr[b,c]	32%
Sex	Male[c,d]	56%
Physician/Practice Characteristics		
Physician specialty		
	Pediatrician[c,d]	35%
	Psychiatrists[b,c]	24%
	General/Family Practice[c]	13%
	Neurologists[b,c]	4%
	Other specialties[b,c,d]	23%
Region		
	Northeast	15%
	Midwest	19%
	South[b]	44%
	West	23%
Therapy Related Characteristics		
Medication therapy		81%
	Antihistamines	33%
	Alpha 2 agonist	26%
	Benzodiazepines	15%
	Antidepressants	6%
	Nonbenzodiazepines	1%
Behavioral therapy		22%
	Psychotherapy[a]	12%
	Mental /Stress management therapy[a]	17%
Diet and nutrition counseling		7%
Both Behavioral and Medication Therapy		19%

[a] Population size=16,916,314. [b] significantly correlated with having medication therapy at $P \leq 0.05$ level of significance [c] significantly correlated with having behavioral therapy at $P \leq 0.05$ level of significance, [d]significantly correlated with diet and nutrition counseling at $P \leq 0.05$ level of significance. All analyses weighted using NAMCS cross-sectional weights.

dren (6 to 12 years), and adolescents (13 to 17 years) accounted for 7%, 15%, 10%, 36%, and 32% of the visits, respectively. Approximately 35% of physicians identified were pediatricians, followed by psychiatrists (24%), general/family practice physicians (13%), neurologists (4%), and other specialists (23%). The majority of patients seen were located in the South (44%), followed by West (23%), Midwest (19%), and Northeast (15%).

Among 18,640,820 weighted patient visits for insomnia/sleep difficulties, physicians prescribed various nonpharmacological and pharmacological treatment regimens. Diet and nutritional counseling were recommended for 7% of patients, and 22% were prescribed behavioral therapy including psychotherapy (12%) and mental health and stress management therapy (17%). However, medications were prescribed in 81% of patients: antihistamines were prescribed to 33% of patients, followed by alpha-2 agonists (26%), benzodiazepines (15%), antidepressants (6%), and non-benzodiazepines (1%). Both behavioral and medication therapy were prescribed in 19% of patients.

Table 4—Logistic Regression Analysis of Physician and Patient Characteristics Associated with Medication Therapy (Weighted Population Size= 18,640,820 Cross Sectional Patient Visits During 1993-2004)[a]

Independent variable	Dependent variable, OR (95% CI)
Age 1-3 yr	3.33 (1.27-8.72)
Age 4-5 yr	5.26 (1.80-15.37)
Age 6-12 yr	5.89 (2.39-14.67)
Age 13-17 yr	5.53 (2.10-14.60)
Psychiatrist	3.60 (1.65-7.86)
Pediatrics	2.04 (0.94- 4.42)
Neurology	0.82 (0.36-1.83)
Other Specialties	1.14 (0.53-2.45)
Midwest	1.18 (0.55-2.52)
South	1.90 (0.93-2.52)
West	0.90 (0.42-1.89)

[a] For categorical independent variables with >2 categories (age, physician specialty, georgpraphical region), the reference (dropped) categories are: age less than one year old, general/family practice, Northeast. All analyses were weighted using NAMCS sampling weights. All variables that were significant in the univariate analyses were included in the multivariable models. Variables in bold are considered significant (P-value ≤0.05).

Table 4 describes the results of the weighted logistic regression analysis of physician and patient characteristics associated with medication therapy for the entire sample of 18 million weighted outpatient visits for pediatric sleep disorder. Within the whole population, patients aged 1-3 years, aged 4-5 years, aged 6-12 years and aged 13-17 years were 3.33 times (OR: 3.33, 95% CI: 1.27-8.72), 5.26 times (OR: 5.26, 95% CI: 1.80-15.37), 5.89 times (OR: 5.89, 95% CI: 2.39-14.70) and 5.53 times (OR: 5.5, 95% CI: 2.10-14.70) respectively, as likely to receive medication therapy as patients aged less than one year old. Patients seen by psychiatrist were 3.60 times (OR: 3.60, 95% CI: 1.65-7.86) as likely to be prescribed with medication therapy as patients seen by general/family practice physicians.

The results of the weighted logistic regression analysis of physician and patient characteristics associated with behavioral therapy during outpatient visits for pediatric sleep disorder appears in Table 5. Within the whole population, visits in which patients aged 1-3 years were 85% less likely (OR: 0.15, 95% CI: 0.03-0.90), to be associated with having behavioral therapy than patients aged less than one year. Patients seen by psychiatrists were 24.52 times (OR: 24.52, 95% CI: 8.11-74.19) as likely to be prescribed behavioral therapy as patients seen by general/family practice physicians. Behavioral therapy was prescribed for 22% of children. Age of the child was significantly related to prescribing behavioral therapy for patients with sleep difficulties ($P \leq 0.05$).

Table 6 displays the results of the weighted logistic regression analysis of physician and patient characteristics associated with diet and nutritional counseling for pediatric sleep disorder. Within the whole population, patients seen by other physician specialties were 78% less likely (OR: 0.22, 95% CI: 0.05-0.92) to be associated with having diet and nutritional counseling as compared to patients seen by general/family practice physicians.

Table 5—Logistic Regression Analysis of Physician and Patient Characteristics Associated with Behavioral Therapy (Weighted Population Size= 18,640,820 Cross Sectional Patient Visits During 1993-2004)[a]

Independent variable	Dependent variable, OR (95% CI)
Age 1-3 yr	0.15 (0.03-0.90)
Age 4-5 yr	0.42 (0.09-1.88)
Age 6-12 yr	1.28 (0.32-5.24)
Age 13-17 yr	1.79 (0.43-7.5)
Male	1.68 (0.96-2.93)
Psychiatrist	24.52 (8.11-74.19)
Pediatrician	0.99 (0.30-3.67)
Neurology	0.64 (0.15- 2.68)
Other specialties	0.42 (0.09-1.88)

[a] For categorical independent variables with >2 categories (age, physician specialty), the reference (dropped) categories are: age less than one year old, general/family practice. All analyses were weighted using NAMCS sampling weights. All variables that were significant in the univariate analyses were included in the multivariable models. Variables in bold are considered significant (P-value ≤0.05).

Table 6—Logistic Regression Analysis of Physician and Patient Characteristics Associated with Diet and Nutritional Counseling (Weighted Population Size= 18,640,820 Cross Sectional Patient Visits During 1993-2004)[a]

Independent variable	Dependent variable, OR (95% CI)
Male	0.67 (0.31-1.44)
Psychiatrist	0.45 (0.13-1.55)
Pediatrician	1.48 (0.46-4.75)
Neurology	0.35 (0.08-1.51)
Other physician	0.22 (0.05-0.92)

[a] For categorical independent variable with >2 categories (physician specialty), the reference (dropped) categories is general/family practice. All analyses were weighted using NAMCS sampling weights. All variables that were significant in the univariate analyses were included in the multivariable models. Variables in bold are considered significant (P-value ≤0.05).

DISCUSSION

In the 12-year study period, 81% of patients with pediatric insomnia were prescribed a sleep medication: 33% received antihistamines, and another 26% were prescribed alpha-2 agonists. This rate of medication prescribing was higher than previously reported. In an abstract, over a 39-month review period from 1995 to 1998, 38,111 Medicaid recipients in Michigan were assessed to identify prescription medications (e.g., anxiolytics, sedatives, hypnotics, including clonidine and trazodone) used to treat sleep disorders among pediatric patients. The number of children prescribed at least one prescription over the study period by a physician was 4.42% (n=1686).[15] The difference could be attributed to numerous factors including sample size (38,111 vs. 18,640,820), age range (≤19 years vs. ≤17 years), and different time period (39 months vs. 12 years). Rasu et al found that 48% of the adult patients suffering from insomnia and sleep difficulties received a prescription for drug treatment.[16]

Among 18.6 million weighted patient visits for insomnia/sleep difficulties in this study, physicians prescribed various nonpharmacological and pharmacological treatment regimens. Physicians prescribed diet/nutritional counseling and behavioral therapy in 7% and 22% of patients, respectively. Consuming less caffeinated beverages and foods, enforcement of an appropriate and regular bedtime for the child's age, and restricting non-sleep activities in bed were treatment strategies recommended by pediatricians 25% to 85% of the time.[17]

In 1994 Mindell et al performed a series of studies to investigate the training of 156 pediatric residency programs. One of these studies[18] assessed 88 practicing pediatricians' basic knowledge of sleep and sleep disorders. In addition, the beliefs of 183 pediatricians on the effects of these problems on the family unit and actual prescribing habits were also examined. The authors concluded further education and training was required for physicians in sleep disorders in children and adolescents. The respondents felt the child's sleep disorder caused a significant increase of stress on the parents. The majority of physicians recommended behavioral intervention: establishment of a bedtime routine (95.1%), letting the child cry with frequent parental checks (84.6%), and naps (52.8%). Approximately 15% of pediatricians prescribed pharmacological treatment (e.g., chloral hydrate, diphenhydramine, hydroxyzine, promethazine); the remaining patients were provided only counseling because the drugs were either not proven to be effective or were contraindicated within the age groups of patients.[18]

In 2001, Owens et al assessed 828 academic and community-based physicians on their knowledge and attitudes regarding sleep disorders in children and adolescents. A greater proportion of physicians practiced in the community (83.6%) and identified themselves as pediatricians (75%), followed by family medicine (18.2%). Respondents reported that they did not routinely ask about sleep problems during well-child visits for 16.5% of infants, 18.2% of toddlers, 19% of school-aged children, and 43.9% of adolescents. Patients suspected of obstructive sleep apnea were referred to an otolaryngologist 63.6% of the time. Children with night terrors were recommended a psychological exam in 43% and diphenhydramine at bedtime was recommended in 25%. Adolescents with insomnia secondary to poor sleep habits were recommended to restrict nonsleep activities in bed (64.8%), modify a sleep schedule (85.5%), or prescribed a hypnotic (11.4%). Physicians acknowledged sleep disorders in children had an impact on injuries and academic performance. Less than one-half of the physicians felt confident in screening for sleep problems, and only 25% felt confident treating sleep problems in children. The survey confirmed conclusions by Mindell et al that sleep disorders in pediatric populations are not being adequately addressed in outpatient settings, and additional education and training of physicians treating sleep disorders in children is needed to manage these medical conditions more effectively.[17,18]

Only 40% of parents with children having sleep problems addressed this concern with their pediatricians.[6] A 2-year retrospective medical records review was conducted at 2 general pediatric clinics on 86 children (mean age 6.6±3.1 years) to assess sleep disorders. Sleep related symptoms were documented in 16 of 103 medical notes for these 86 children, and 2.9% were prescribed treatment. Sleep disorders were underrecognized among pediatric patients either by the physician or caregiver.[19]

A survey accessed the use of psychotropic drugs for sleep disorders in 3,287 French adolescents among 4 age categories:

ages 12-13 years, 14-15, 16-17, and 18-20 years. The total percentage of patients receiving prescription drugs for sleep disorders increased (6.3%, 7.5%, 8.3%, and 12%) in relation to age ($P < 0.001$). Specific information such as name of the medication was not identified in the survey.[20]

A national survey of 671 of pediatric physicians from 6 US cities (Philadelphia, Atlanta, Cleveland, Dallas, Providence, and San Diego) was conducted over a 6-month period about the use of both nonprescription and prescription medications for various sleep disorders. The physicians recommended over-the-counter antihistamines and α-agonists for 67.9% and 30.6% of patients in the past 6 months, respectively. Antidepressants (e.g., trazodone) and benzodiazepines (e.g., clonazepam) were prescribed in approximately 16% and 12% of children with sleep difficulties, respectively.[21]

Although approximately 15% of pediatricians reported prescribing pharmacological treatment in 1994, a recent survey indicated the number of physicians prescribing either nonprescription or prescription medication was on the rise. Physicians recommended the use of over-the-counter products (e.g., antihistamines, combination products, melatonin, and herbal products) in 75% of their patients, and >50% have prescribed a sleep medication. However, retrospective survey relying on the recall of respondents to assess their prescribing habits over a 6-month period can potentially yield unreliable data.[22] Antihistamines were the most prescribed (33%) class of medication for this study population but its usage decreased significantly from 1999 to 2004.

The NAMCS database did not provide specific information whether the patient was prescribed or taking over-the-counter hypnotics, herbals, or melatonin. We were unable to assess whether each prescription was dispensed for the caregiver of the patient. Each patient in the database was limited to 6 drugs per patient visit and therefore a possibility exists for missing an observation. For this specific study we have considered medications prescribed for pediatric sleep difficulties presented in Table 2. NAMCS did not include information on the severity of symptoms or duration of pharmacotherapy received by patients.

In summary, our observations suggest that pediatric patients were prescribed a number of sleep medications. Many of these medications were frequently used to treat children with sleep difficulties in outpatient settings despite lack of FDA approved labeling to assure their effectiveness and safety in this population. Reasons for such prescribing and strategies to minimize prescribing of unapproved medications for sleep difficulties in this population need to be studied.

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