Pediatric Insomnia: Behavioral and Pharmacologic Treatments

KYLE P. JOHNSON, MD
ASSOCIATE PROFESSOR, OHSU
DEPARTMENTS OF PSYCHIATRY AND PEDIATRICS
DIPLOMATE, AMERICAN BOARD OF SLEEP MEDICINE
Disclosures

- No financial support from industry
- No research grants presently
Disclaimer

- There are no FDA approved medicines for pediatric insomnia
- All medicines discussed in this talk would be “off-label” if used to treat pediatric insomnia
Pediatric Insomnia: Consensus Definition

- Difficulty initiating and/or maintaining sleep that is viewed as a problem by the child or caregiver
- Significance of the sleep problem characterized by:
  - Severity, chronicity, frequency, and associated impairment in daytime function in child or family
- Due to primary sleep disorder or in association with other sleep/medical/neuropsychiatric disorder

Insomnia Disorder per DSM-5

A. A predominant complaint of dissatisfaction with sleep quantity or quality, associated with one (or more) of the following symptoms:

1. Difficulty initiating sleep. (In children, this may manifest as difficulty initiating sleep without caregiver intervention.)

2. Difficulty maintaining sleep, characterized by frequent awakenings or problems returning to sleep after awakenings. (In children, this may manifest as difficulty returning to sleep without caregiver intervention.)

3. Early-morning awakening with inability to return to sleep
Insomnia Disorder per DSM-5

- B. The sleep disturbance causes clinically significant distress or impairment in social, occupational, educational, academic, behavioral, or other important areas of functioning
- C. The sleep difficulty occurs at least 3 nights per week
- D. The sleep difficulty is present for at least 3 months
- E. The sleep difficulty occurs despite adequate opportunities for sleep
Insomnia Disorder per DSM-5

- F. The insomnia is not better explained by and does not occur exclusively during the course of another sleep-wake disorder
- G. The insomnia is not attributable to the physiological effects of a substance
- H. Coexisting mental disorders and medical conditions do not adequately explain the predominant complaint of insomnia
Insomnia Disorder per DSM-5

- Specify if:
  - With non-sleep disorder mental comorbidity, including substance use disorder
  - With other medical comorbidity
  - With other sleep disorder

- Specify if:
  - Episodic: Symptoms last at least 1 month but less than 3 mos
  - Persistent: Symptoms last 3 months or longer
  - Recurrent: Two (or more) episodes within space of 1 year
Insomnia Disorder per DSM-5

• Note:
  ○ Acute and short-term insomnia (i.e., symptoms lasting less than 3 months but otherwise meeting all criteria with regard to frequency, intensity, distress, and/or impairment) should be coded as an other specified insomnia disorder
Prevalence Rates

- **Infants and Toddlers (> 6 months of age)**
  - 25-50% of infants and toddlers in cross-sectional studies are reported to have night wakings
  - 10-15% experience bedtime resistance

- **Preschool age children**
  - 15-30% experience difficulties falling asleep and night wakings

Prevalence Rates

- **Elementary school age children**
  - Overall prevalence of any parent-reported sleep problem is 25-40%
    - 15% bedtime resistance
    - 11% sleep-related anxiety

- **Adolescents**
  - Lifetime prevalence of insomnia in 13- to 16-year-old adolescents approaches 11%
  - Up to 35% of adolescents experience insomnia at least several times a month
  - Increased prevalence in girls postpuberty

Types of Pediatric Insomnia

- Behavioral insomnia of childhood
- Insomnia associated with a sleep disorder
  - Delayed Sleep Phase Syndrome
  - Restless Legs Syndrome
- Insomnia associated with a psychiatric disorder, neurodevelopmental disorders, and chronic medical disorders
- Psychophysiological Insomnia
- Primary Insomnia
Behavioral Insomnia of Childhood

- Sleep-onset association disorder
- Limit-setting sleep disorder
- Combined type
Video

How to Do Bad Sleep
with
Robert De Niro

Created by Daniel Cooper
Behavioral Interventions for Insomnia

- Parental and patient education
  - Awakenings during the night are normal
  - New sleep-onset associations can be taught
- Set bedtime and waketime
- Consider sleep restriction to help with sleep efficiency

The Opponent Process Model of Sleep
Behavioral Interventions for Insomnia

- **Stimulus Control**
  - Bed for sleep only
  - Use of “relaxing place” in bedroom or nearby room that is not the bed
    - Used prior to lights out at bedtime
    - Used for prolonged middle of the night awakenings with lights remaining off
Evening use of light-emitting eReaders negatively affects sleep, circadian timing, and next-morning alertness

Anne-Marie Chang, Daniel Aschoff, Jeanne F. Duffy, and Charles A. Czeisler

in the past 50 y, there has been a decline in average sleep duration and quality, with adverse consequences on general health. A representative survey of 1,508 American adults recently revealed that 90% of Americans use some types of electronics at least a few nights per week within 1 h before bedtime. Mounting evidence from countries around the world shows the negative impact of such technology use on sleep. This negative impact on sleep may be due to the short-wavelength-enriched light emitted by these electronic devices, given that artificial-light exposure has been shown experimentally to produce alerting effects, suppress melatonin, and phase-shift the biological clock. A few reports have shown that these devices suppress melatonin levels, but little is known about the effects on circadian phase or the following sleep episode. Exposing a substantial gap in our knowledge of how this increasingly popular technology affects sleep. Here we compare the biological effects of reading an electronic book on a light-emitting device (eBook) with reading a printed book in the hours before bedtime. Participants reading an eBook took longer to fall asleep and had reduced evening sleepiness, reduced melatonin secretion, later timing of their circadian clock, and reduced next-morning alertness than when reading a printed book. These results demonstrate that evening exposure to an e-book phase-delays the circadian clock, acutely suppresses melatonin, and has important implications for understanding the impact of such technologies on sleep, performance, and health.

Significance

The use of light-emitting electronic devices for reading, communication, and entertainment has greatly increased recently. We found that the use of these devices before bedtime prolongs the time it takes to fall asleep, delays the circadian clock, suppresses levels of the sleep-promoting hormone melatonin, reduces the amount and delays the timing of REM sleep, and reduces alertness the following morning. Use of light-emitting devices immediately before bedtime also increases alertness at that time, which may lead users to delay bedtime at home. Overall, we found that the use of portable light-emitting devices immediately before bedtime has biological effects that may perpetuate sleep deficiency and disrupt circadian rhythms, both of which can have adverse impacts on performance, health, and safety.
eReaders vs. Print Book

- Lux
  - Print book = .91 lux
  - eBook = 31.73 lux

- Melatonin suppressed more with eBook vs Print Book

- Delay in circadian phase with eBook vs Print Book

Bright Light Therapy

- Useful in treating adolescents with delayed sleep phase syndrome
- Give in the morning soon after waking
Light Boxes

- Designed to be safe and effective but not approved or regulated by FDA
- Choose light box with little UV light
- Typically, light boxes use white light, some now give off blue light with shorter wavelength
Light Boxes

- Intensity: at least 2,000 lux but 10,000 lux optimal

- Wavelength: around 509 nM (White Light)
Other Behavioral Interventions

The Good Nite Lite

Product Description
The objective of the "Good Nite Lite" is to educate children to stay in bed until it is morning. Children between the ages of 3 and 5 years of age are just starting to grasp the concept of day and night and how it relates to regularly scheduled rest. The Good Nite Lite can assist children with better differentiating the concept of nighttime and daytime and reinforce the benefits of appropriate sleep patterns. The Good Nite Lite device itself is an innovative combination of a traditional night light and a built-in timer that changes the visual display characteristics to reinforce a regular sleep pattern.

Measures 6" in diameter

Having a bright light, even a regular nightlight, on in a child's room inhibits teaching them that when it is dark it is time for sleep and when it is light, it is time to get up.

NIGHT

At the preset time, the Good Night Light will brighten and display a cheerful "Sun" caricature letting the child know that it is time to wake up and permissible to get out of bed and start the day activities.

MORNING

www.goodnitelite.com
Bedtime Pass

- Best for addressing bedtime struggles
- Use in 3- to 10-year-old children who have verbal abilities
- Tied to rewards
Visual schedules clarify bedtime routines

- Time for bed
  - Put on pajamas
  - Use the bathroom
  - Wash hands
  - Brush teeth
  - Get a drink
  - Read a book
  - Get in bed and go to sleep

Tailor visual support based on child’s language level

Courtesy of Beth Malow
Books for Parents

**Sleeping Through the Night**

How Infants, Toddlers, and Their Parents Can Get a Good Night’s Sleep

Jodi A. Mindell, Ph.D.

2005 HarperCollins
ISBN: 0-06074256-9

**Take Charge of Your Child’s Sleep**

The Sleep Doctors

Judy A. Owens, MD, and Jodi A. Mindell, PhD

2005 Marlowe & Company
Pediatric Insomnia

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

Sasko D. Stojanovski, PharmD1,3; Rafia S. Rasu, PhD2; Rajesh Balkrishnan, PhD1,4; Milap C. Nahata, PharmD, MS1,3,5

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

Antihistamines – 33%      Alpha-2 Agonists – 26%      Benzodiazepines - 15%

Antidepressants – 6%      Non-benzodiazepines – 1%
Original Article

Use of pharmacotherapy for insomnia in child psychiatry practice: A national survey

Judith A. Owens a,*, Carol L. Rosen b, Jodi A. Mindell c, Hal L. Kirchner b

a Brown Medical School, Rhode Island Hospital, 593 Eddy St., Potter Bldg., Suite 200 Providence, RI 02903, USA
b Department of Pediatrics, Case University School of Medicine, Cleveland, OH, USA
c Saint Joseph’s University, Children’s Hospital of Philadelphia, Philadelphia, PA, USA

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Abstract

Objective: To examine clinical practice patterns regarding non-prescription and prescription medication use for insomnia by child and adolescent psychiatrists.

Methods: Survey mailed to 6018 members of the American Academy of Child and Adolescent Psychiatry.

Results: The final sample (N = 1273) reported that insomnia was a major problem in almost a third of their school-aged and adolescent patients and endorsed using medication to treat the insomnia in at least a quarter of these patients. Overall, 96% of respondents recommended at least one of the listed prescription medications in a typical month, and 88% recommended an over-the-counter medication. Alpha agonists were the most commonly prescribed insomnia medication for ADHD (81%), significantly higher than in MR/DD (67%), mood (40%), or anxiety disorders (31%). Trazodone was the most commonly prescribed insomnia medication for children with mood (78%) and anxiety disorders (72%). Antidepressants as a class were also commonly used for children in these diagnostic groups. Atypical antipsychotics, anticonvulsants, and short-acting hypnotics were also more likely to be used in children with mood disorders. Melatonin was recommended by more than one-third of respondents. Mitigation of the effects of sleep disruption on daytime functioning was endorsed as an important rationale for the use of sleep medication; concerns about side effects and the lack of empirical support regarding efficacy were cited as significant barriers to their use.

Conclusions: Insomnia is a significant clinical problem in children treated by child psychiatrists for a variety of behavioral, neurodevelopmental, and psychiatric conditions. Management with a broad array of psychotropic medications is common and indicates a highly variable clinical approach to insomnia in this pediatric population.

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1273 practicing members of AACAP (26% response rate)

Fig. 1. Percent of patients identified with insomnia as a major problem symptom. Respondents were asked to estimate the total percentage of patients with insomnia in a typical 1-month period in each age group. If they could not estimate by age group, then they were instructed to enter an estimate in the “any age” category.

Fig. 2. Percent of patients treated with medication specifically to address the insomnia symptoms. Respondents were asked to estimate the total percentage of patients treated with medication specifically for insomnia in a typical 1-month period in each age group. If they could not estimate by age group, then they were instructed to enter an estimate in the “any age” category.

Owens JA, et al. Sleep Medicine 2010, 11;692-700
Fig. 3. Percentage of psychiatrists endorsing a frequency category for recommending medication for insomnia. Based on the number of psychiatrists who report seeing the condition. MR/DD = mental retardation and developmental delay; ASD = autism spectrum disorders (autism, pervasive developmental delay, Asperger’s); ADHD = attention deficit hyperactivity disorder (all subtypes); ODD/CD = oppositional defiant disorder, conduct disorder.

Fig. 4. Percentage of psychiatrists endorsing a frequency category for these psychiatric disorders. Based on the number of psychiatrists who report seeing these disorders. PTSD = post-traumatic stress disorder. Depression includes major depression, dysthymia, and seasonal affective disorder.
Table 3
Percentage of psychiatrists recommending various over-the-counter medication type for insomnia by clinical group. MR/DD = mental retardation, developmental delay. ADHD = attention deficit hyperactivity disorder.

<table>
<thead>
<tr>
<th>Medication</th>
<th>Total</th>
<th>MR/DD and autism</th>
<th>ADHD</th>
<th>Anxiety</th>
<th>Mood</th>
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</thead>
<tbody>
<tr>
<td>Antihistamines</td>
<td>80.5</td>
<td>69</td>
<td>66</td>
<td>68</td>
<td>63</td>
</tr>
<tr>
<td>Melatonin</td>
<td>50.5</td>
<td>39</td>
<td>36</td>
<td>37</td>
<td>37</td>
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<tr>
<td>Herbals</td>
<td>22.2</td>
<td>13</td>
<td>14</td>
<td>19</td>
<td>17</td>
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<tr>
<td>Pain reliever combo</td>
<td>11.6</td>
<td>7</td>
<td>7</td>
<td>8</td>
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</tbody>
</table>

Table 4
Percentage of psychiatrists prescribing medication specifically for insomnia by clinical group. ADHD = attention deficit hyperactivity disorder, MR/DD = mental retardation/developmental delay. SSRIs = selective serotonin reuptake inhibitors.

<table>
<thead>
<tr>
<th>Medication</th>
<th>Total</th>
<th>ADHD</th>
<th>MR/DD and autism</th>
<th>Anxiety disorders</th>
<th>Mood disorders</th>
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</thead>
<tbody>
<tr>
<td>Alpha agonist</td>
<td>87.0</td>
<td>80.5</td>
<td>67.3</td>
<td>40.0</td>
<td>30.8</td>
</tr>
<tr>
<td>Trazodone</td>
<td>85.8</td>
<td>60.1</td>
<td>66.5</td>
<td>72.3</td>
<td>77.6</td>
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<tr>
<td>Sedating antidepressants</td>
<td>83.2</td>
<td>71.0</td>
<td>75.6</td>
<td>82.3</td>
<td>85.2</td>
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<tr>
<td>Atypical antipsychotics</td>
<td>68.9</td>
<td>34.2</td>
<td>52.3</td>
<td>33.4</td>
<td>52.3</td>
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<td>SSRIs</td>
<td>66.6</td>
<td>30.8</td>
<td>39.7</td>
<td>56.7</td>
<td>57.3</td>
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<tr>
<td>Benzodiazepines</td>
<td>54.5</td>
<td>12.0</td>
<td>21.6</td>
<td>47.2</td>
<td>36.0</td>
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<tr>
<td>Short-acting hypnotics</td>
<td>50.2</td>
<td>17.6</td>
<td>20.9</td>
<td>40.5</td>
<td>41.8</td>
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<tr>
<td>Antihistamines</td>
<td>49.5</td>
<td>33.2</td>
<td>37.7</td>
<td>42.1</td>
<td>33.1</td>
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<tr>
<td>Anticonvulsants</td>
<td>49.1</td>
<td>15.9</td>
<td>30.5</td>
<td>15.3</td>
<td>42.6</td>
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<td>Tricyclics</td>
<td>48.3</td>
<td>30.1</td>
<td>25.5</td>
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<td>Pharmacologic Options</td>
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<td><strong>Over the Counter</strong></td>
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<tr>
<td>• Melatonin</td>
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<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>• Antihistamines</td>
<td></td>
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<td></td>
<td></td>
</tr>
<tr>
<td>• Herbal</td>
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<tr>
<td><strong>Prescribed Medications</strong></td>
<td></td>
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<td></td>
<td></td>
</tr>
<tr>
<td>• Benzodiazepines</td>
<td></td>
<td></td>
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<td></td>
<td></td>
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<tr>
<td>• Non-Benzodiazepine, Benzodiazepine Receptor Agonists</td>
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<td></td>
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<td></td>
<td></td>
</tr>
<tr>
<td>• Sedating antidepressants</td>
<td></td>
<td></td>
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<td></td>
<td></td>
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<tr>
<td>• Alpha-2 agonists</td>
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</tbody>
</table>
Evidence Base for Melatonin

- Several studies (including RCT’s) in typically developing children with sleep–onset insomnia, ADHD, and ASD demonstrate efficacy.
- Appears to be safe.
- Studies in ADHD and ASD have not demonstrated improvements in core symptoms/behaviors.

Garstang 2006; Van der Heijden, 2007; Anderson, 2008; Wasdell, 2008; Hoebert, 2009; Wright, 2011.
Melatonin Recommendations

- If certain treating delayed sleep phase syndrome, can give ~ 300 mcg 5-6 hours before present sleep onset time

- In treating sleep-onset insomnia, recommend higher doses given 30 minutes before lights out
Melatonin Dosing Recommendations

- Children less than 40 kg, start with 1-1.5 mg and increase weekly by 1-1.5 mg increments to max of 6 mg
- Children weighing > 40 kg, start with 1-3 mg and increase by 1-1.5 mg increments until max of 9 mg although unlikely to see improvements > 6 mg
Melatonin Recommendations

- Melatonin stable in strawberry yogurt, jam, OJ, milk
- Tend to recommend melatonin sold in larger pharmacies
  - Natrol, Twin Labs, Rexall, etc.
  - Can find “pharmaceutical grade”
- Liquid and controlled release formulations available
Pharmacology of Pediatric Insomnia

- **Age influences choices**
  - **Preschool age child**
    - Benzodiazepines (clonazepam or lorazepam)
    - Potentially trazodone in female patient
    - Potentially clonidine or guanfacine in child with history of trauma
  - **School age child**
    - Similar choices as above but also may consider mirtazapine
Pharmacology of Pediatric Insomnia

- Adolescent
  - Consider newer hypnotic agents used in adults
    - Zolpidem – immediate release form generic; must take just as patient gets in to bed; warn about risk of confusion, sleep walking.
    - Zolpidem CR – controlled release form is generic
    - Zaleplon
    - Eszopiclone
Pharmacology of Pediatric Insomnia

- **Concerns**
  - **Overdoses**
    - Particularly of clonidine or guanfacine
  - **Significant Side Effects**
    - Priapism with trazodone
    - Confusion or parasomnias with zolpidem
  - **Do not suggest prescribing antipsychotics for insomnia**
8 week, multicenter, DB PCT
- Zolpidem dosed at 0.25 mg/kg per day with maximum of 10 mg/day

Two groups of children with ADHD:
- 6-11 y/o’s and 12-17 y/o’s

Primary measure was latency to persistent sleep between weeks 3 and 6
Results:

- Mean change in latency to persistent sleep at week 4 did not differ between zolpidem and placebo groups.
- Zolpidem in older age group showed improved CGI scores at weeks 4 and 8.
- No next day residual effects or rebound in insomnia after discontinuation.
- 7.4% discontinued zolpidem:
  - dizziness, headaches, hallucinations.
Caffeine
75% drink at least one caffeinated beverage/day
31% two or more
- 26% 6-8th and 35% 9-12th graders consume 2+ cans/cups/day
- Sleep problems: later bedtime, increased sleep onset latency, difficulty staying asleep, shorter sleep duration, increase in weekday and weekend discrepancy
- Daytime sleepiness: napping, falling asleep in school/doing homework, feeling cranky, irritable; report depression, get lower grades
# Caffeine Content

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<thead>
<tr>
<th>Product</th>
<th>Caffeine (mg)</th>
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<tbody>
<tr>
<td>Pepsi One*</td>
<td>57</td>
</tr>
<tr>
<td>Mountain Dew*</td>
<td>55</td>
</tr>
<tr>
<td>Dr. Pepper*</td>
<td>43</td>
</tr>
<tr>
<td>Sunkist*</td>
<td>41</td>
</tr>
<tr>
<td>Arizona Green Tea</td>
<td>200</td>
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<tr>
<td>Snapple ice tea</td>
<td>42</td>
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<tr>
<td>Starbucks brewed Tall</td>
<td>260</td>
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<tr>
<td>Starbucks brewed Venti</td>
<td>415</td>
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<table>
<thead>
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<th>Product</th>
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<td>Hot chocolate</td>
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<td>Chocolate milk</td>
<td>9</td>
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<tr>
<td>Ben &amp; Jerry Heath Bar Crunch</td>
<td>84</td>
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<tr>
<td>Hagen Daz coffee ice cream</td>
<td>58</td>
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<tr>
<td>Dark chocolate bar</td>
<td>31</td>
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<tr>
<td>No-Doz</td>
<td>200</td>
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*FDA limits caffeine content sodas to 65 mg/12 oz
# Caffeine Content

<table>
<thead>
<tr>
<th>Product</th>
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<th>Product</th>
<th>Total (mg)</th>
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<td>Red Bull</td>
<td>80</td>
<td>Cocaine</td>
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<td>Monster</td>
<td>160</td>
<td>BooKoo</td>
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<td>Rockstar</td>
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<td>Fixx</td>
<td>500</td>
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<tr>
<td>SoBe No Fear</td>
<td>174</td>
<td>WiredX505</td>
<td>505</td>
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<tr>
<td>Blow</td>
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<td>Redline</td>
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<tr>
<td>Jolt</td>
<td>280</td>
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</tbody>
</table>
Caffeine: Effects on Sleep

- Survey of 7-9\textsuperscript{th} graders (2 week sleep diary and caffeine use):\textsuperscript{1}
  - Intake range 0-800mg/d; mean intake 53mg/d; 20% averaged >100mg/d; increased on weekends, in boys
  - Higher caffeine intake associated with decrease in sleep duration and increase in wake after sleep onset
- 1998 NICHD US survey > 15,000, grades 6-10\textsuperscript{2}
  - >1/2 moderate to high intake
  - High consumers almost 2x difficulty sleeping, am fatigue

\textsuperscript{1}Pollack et al, 2003, \textsuperscript{2}Orbeta et al, 2006
The End

johnsoky@ohsu.edu