

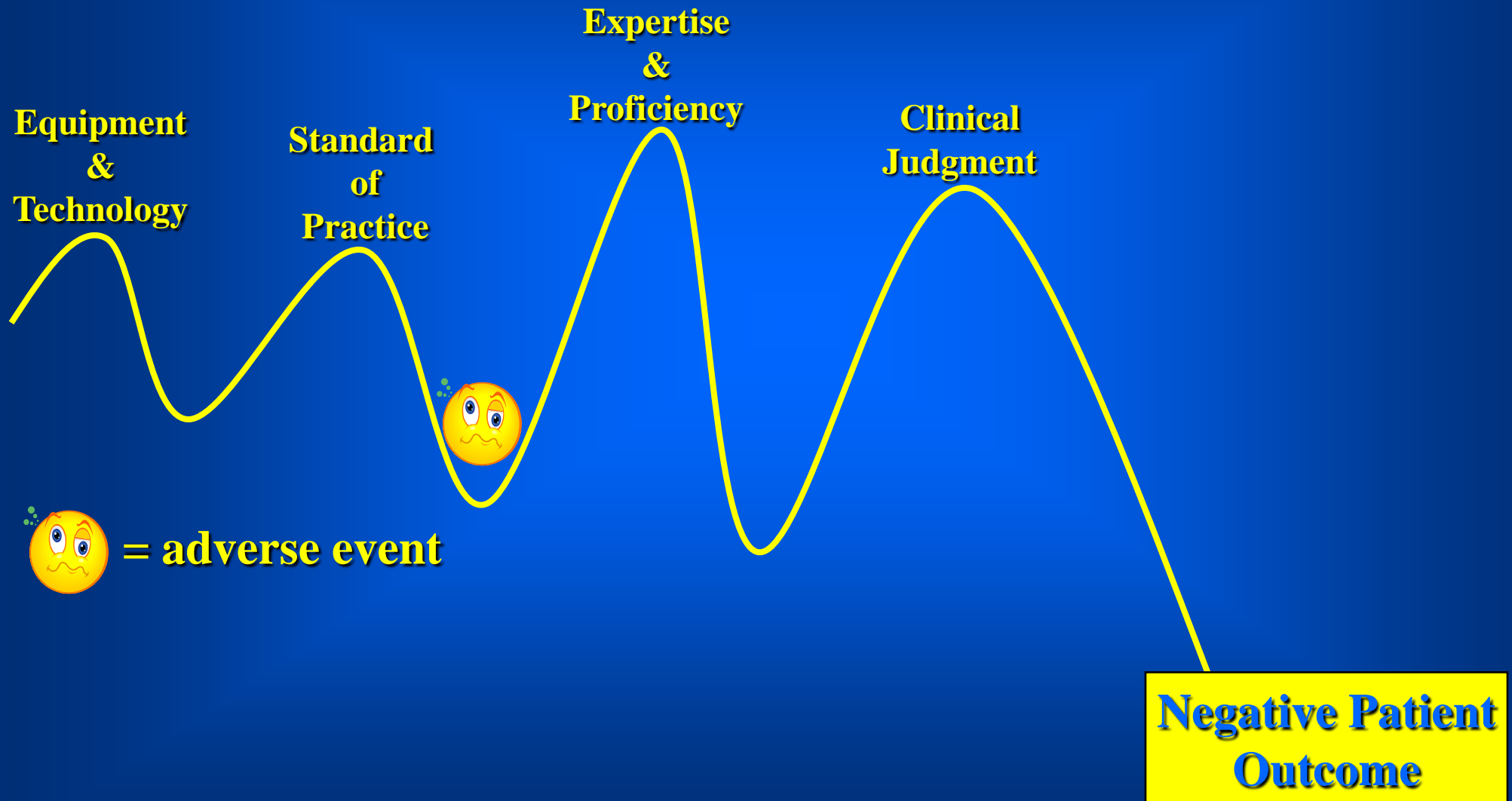
# **Are Sleepy Providers Keeping Patients Asleep?** *Time for a wake-up call?*



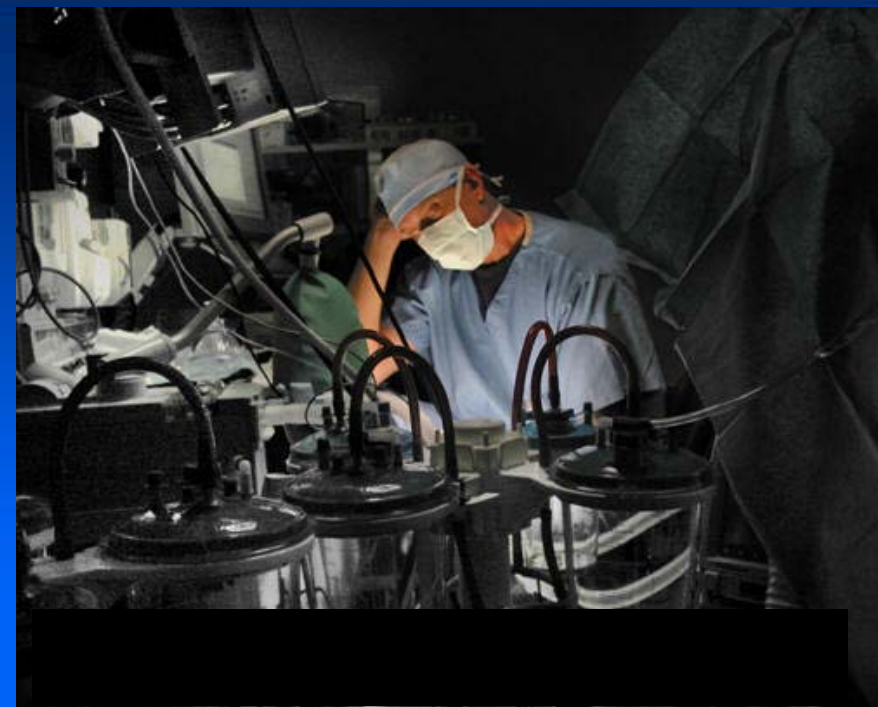
## **The National Sleep Study of Nurse Anesthetists**

C Biddle CRNA, PhD  
Virginia Commonwealth University

# Roller-ball model of patient safety



# The effect of *fatigue* on the roller-ball model



Equipment  
&  
Technology

Standard  
of  
Practice

Expertise  
&  
Proficiency

Clinical  
Judgment



**Negative Patient  
Outcome**



= adverse event

# Putting a 'Face' on Patient Safety





**In Denver, an 8-year-old boy died during routine ear surgery when his anesthesia provider fell asleep and failed to monitor the boy's status. The provider fell asleep during surgeries numerous times before but was never adequately disciplined.**



**In May 2009 XXX was convicted of manslaughter in the death of a toddler, sentenced to 8 years in prison. YYY was 3 when she died during strabismus surgery after XXX induced general anesthesia and intentionally disabled all alarm monitors. The Judge stated, "The defendant effectively went to sleep during the surgery without concern."**

## Doctors, nurses fighting fatigue

TORY SHEPHERD | The Advertiser | September 09, 2009 12:01am |  43 comments

A<sup>+</sup> A<sup>-</sup>   St

**MOONLIGHTING** doctors are so exhausted from excessive workloads they are risking patients' lives, experts say.


Sleep expert Professor Drew Dawson says doctors and nurses often work extra shifts and their fatigue is not being monitored or managed adequately.

Australian Medical Association state president Dr Andrew Lavender agreed there was an ongoing concern about doctors potentially compromising patients' safety.

Healthcare workers can work long hours in the workplace and can switch between jobs for the money, or because workf

## Doctor Falls Asleep During Surgery

### Board Revokes License

 Email  Print

 Recommend

POSTED: 5:44 am EDT July 26, 2007  
UPDATED: 9:49 am EDT July 26, 2007

SHARE    ...

**BOSTON** -- A former ( ) : who fell asleep in the operating room must prove he's clean before practicing medicine again.

( ) admitted to falling asleep during surgery in December 2005 after taking a prescribed medication. ( ) admitted that he "was under a great deal of personal stress," the state said in its complaint against him.

He also said he inhaled Isoflurane, an anesthetic, during his lunch break in January 2006 because he was having a panic attack and "felt he was going to die."

# Why do we sleep?

**Restorative:** Body rejuvenates  
Growth hormone released  
Melatonin released  
Immune system boosted  
Memory organization



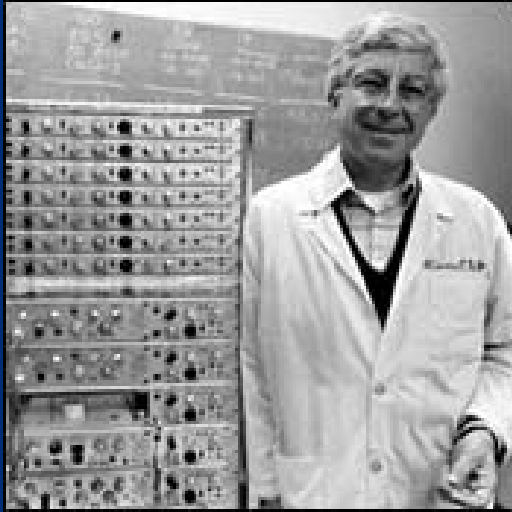
**Sleep is absolutely vital to biology & psychology**

**Deprivation → significant global impairment**

**Deprivation → immune system effects**



# Dr. W.C. Dement: "*Father of Modern Sleep Research*"



50+ years of work

Co-discoverer REM sleep

EEG study sleep

Pioneered Dx/Rx sleep disorders

When asked, *why do we sleep?*

**“As far as I know the only solid reason we need to sleep is because we get sleepy.”**



---

**“Drowsiness is a red flag!!”**

# Sleep-related fatigue

**Global cognitive dysfunction**

**Impaired vigilance**

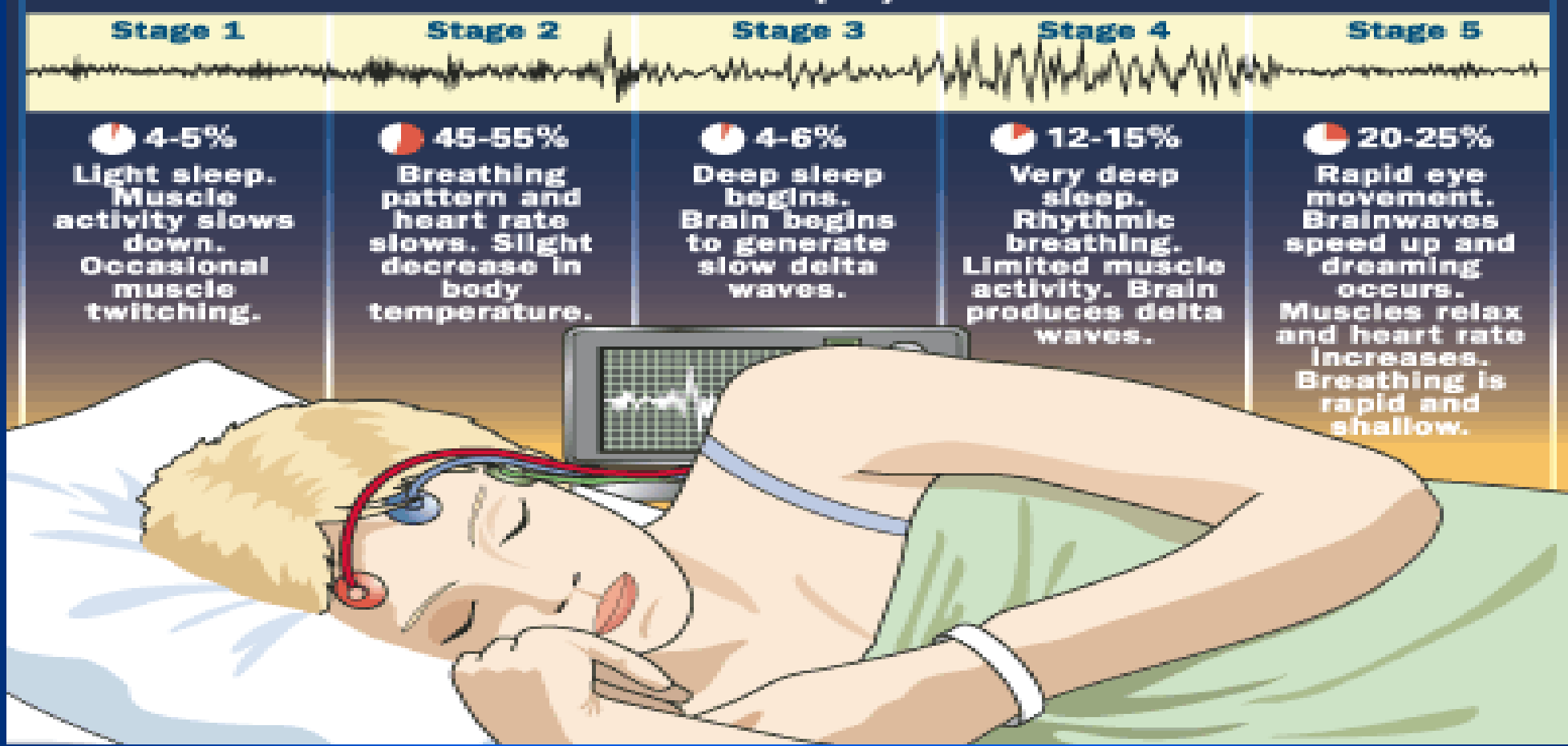
**Decay in problem solving ability**

**Decrement in memory retrieval**

**Eroded motivation**



# 100% Sleep Cycle



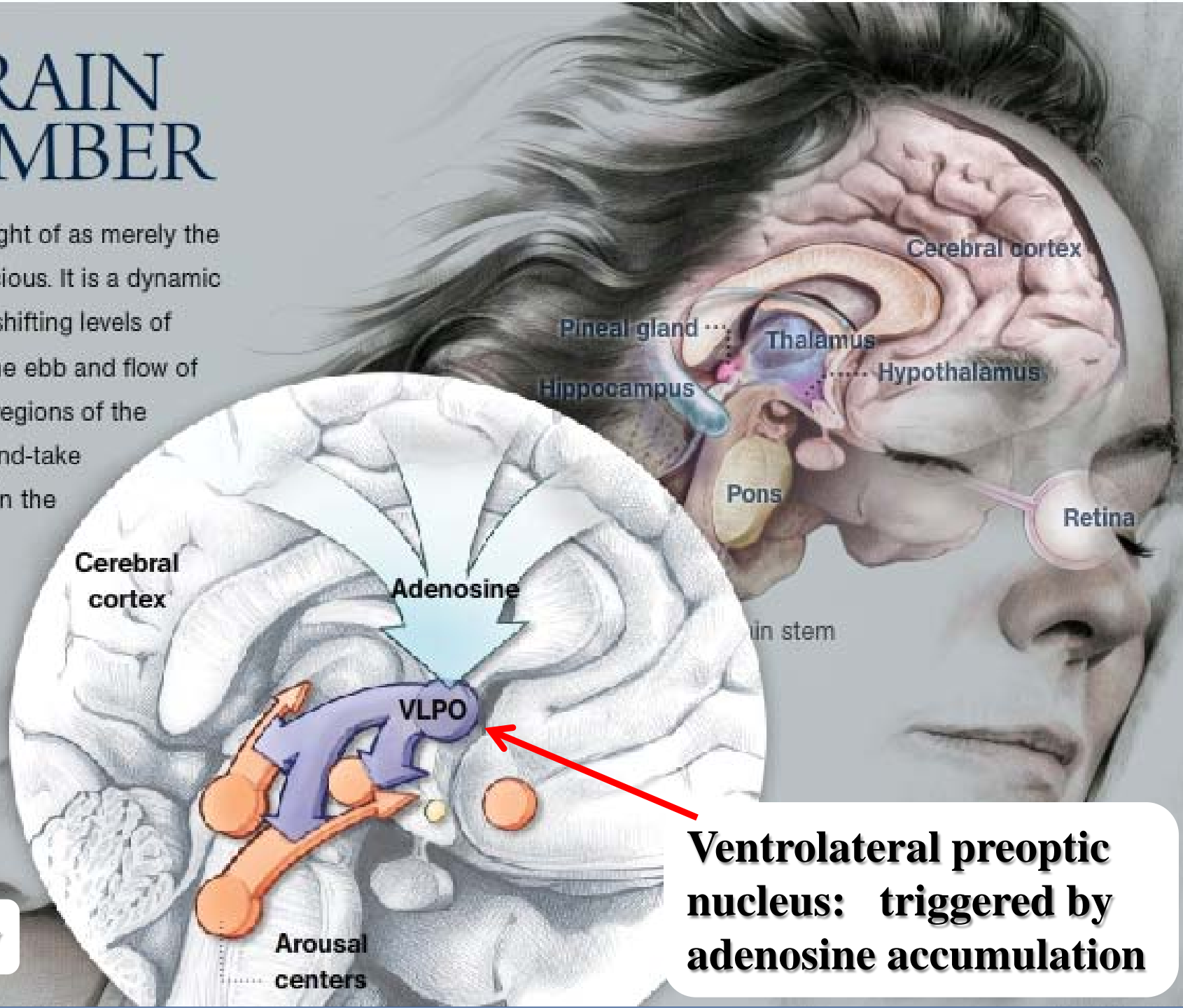
**We miss it, if we don't have it**

**No matter how hard we try to resist it, it conquers us in the end**

# THE BRAIN IN SLUMBER

Sleep is no longer thought of as merely the time we spend unconscious. It is a dynamic state characterized by shifting levels of electrical activity and the ebb and flow of chemicals into various regions of the brain. Key to this give-and-take are two tiny structures in the hypothalamus deep in the brain. The neural dance they engage in determines when we fall asleep, and when we wake again to face the day.

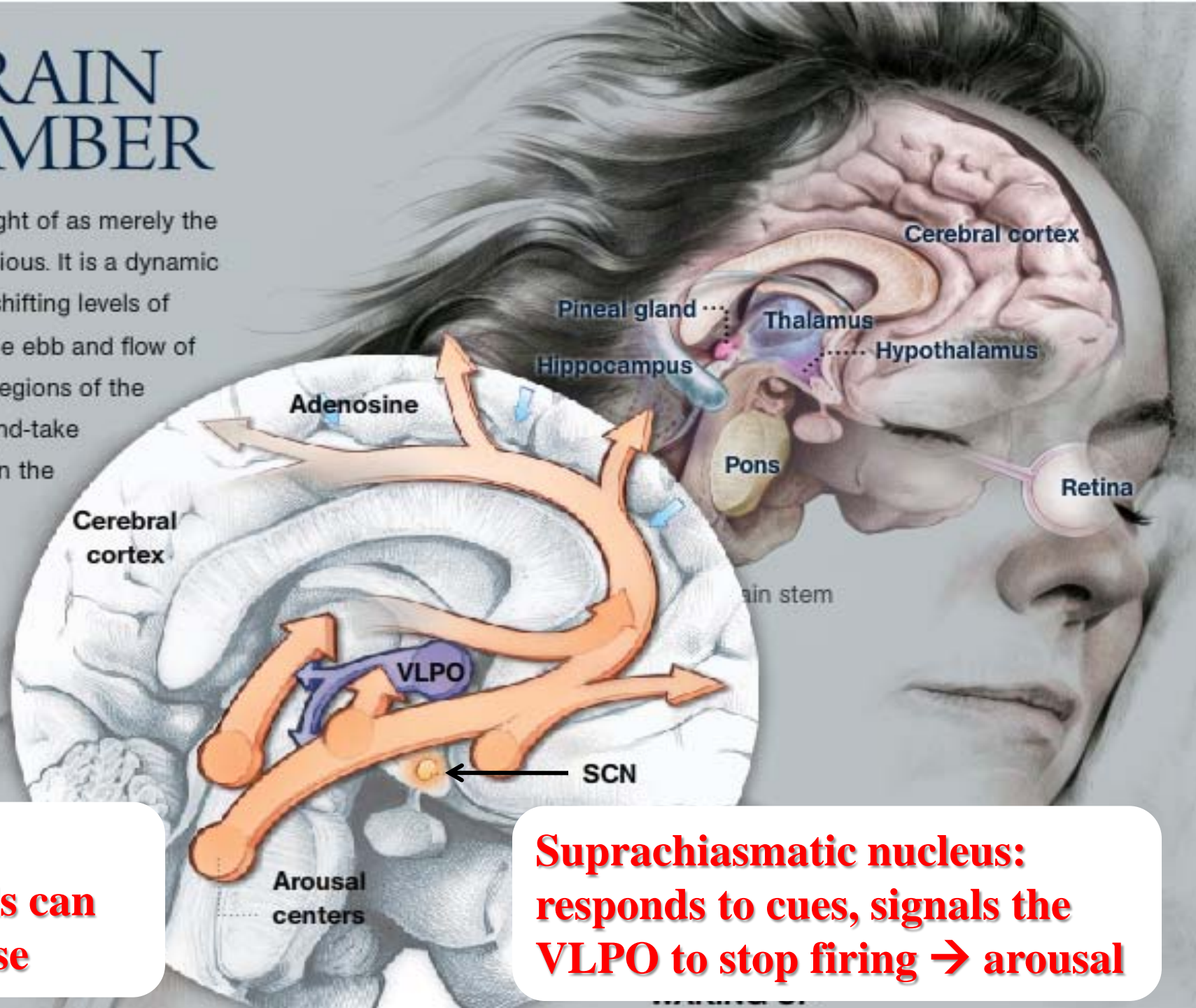
**Getting sleepy**



**Ventrolateral preoptic nucleus: triggered by adenosine accumulation**

# THE BRAIN IN SLUMBER

Sleep is no longer thought of as merely the time we spend unconscious. It is a dynamic state characterized by shifting levels of electrical activity and the ebb and flow of chemicals into various regions of the brain. Key to this give-and-take are two tiny structures in the hypothalamus deep in the brain. The neural dance they engage in determines when we fall asleep, and when we wake again to face the day.



**Waking up:**  
multiple signals can  
initiate response

**Suprachiasmatic nucleus:**  
responds to cues, signals the  
VLPO to stop firing → arousal

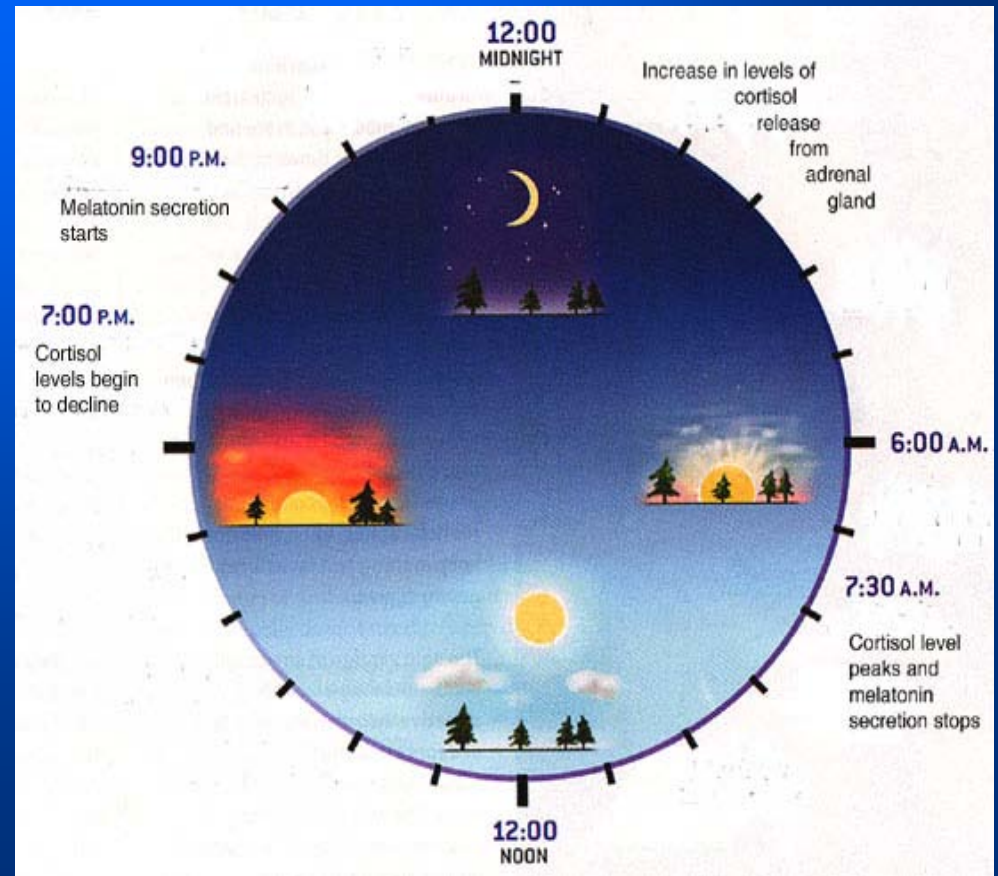
# The circadian “clock”

- Suprachiasmatic nucleus (hypothalamus)

**Dysfunction**



- Shift work
- Call responsibilities
- Trans-time zone travel
- Insomnia
- Drugs & alcohol



# Chemical modulators of wakefulness & sleep

- Acetylcholine
- Adenosine
- Dopamine
- Orexin A & B
- GABA
- Melatonin
- Norepinephrine
- Histamine
- Pituitary hormones
- Serotonin
- Glutamate
- Nitric oxide
- Cortisol



*Many of us have abnormal expression of these modulators*



# National Sleep Foundation

Waking America to the Importance of Sleep®

## **March 3, 2009    National Sleep Survey Research Report**

**1/3 report falling asleep or severely sleepy at work**

**Average sleep / night = 6 hours, 40 minutes**

**Average wake up time: 5:35 am**

**Average bedtime: 10:53 pm**





**At age 70 you have spent ~ 25 years sleeping!!**



**14 months old**



**35 years old**



**70 years old**

**Although many of us are shortchanging ourselves!**

**No epidemiological studies describe the sleep-related behaviors of anesthesia providers**



# Examples of formal work hour rules



**Aviation**



**Long-haul trucking**

**Rail/road/ocean travel industries**

**Nuclear power**

**Healthcare education**





Federal Motor Carrier Safety Administration



# Interstate Passenger Carrying Driver's Guide to Hours of Service

## Interstate Passenger Carrying Driver's Guide to Hours of Service

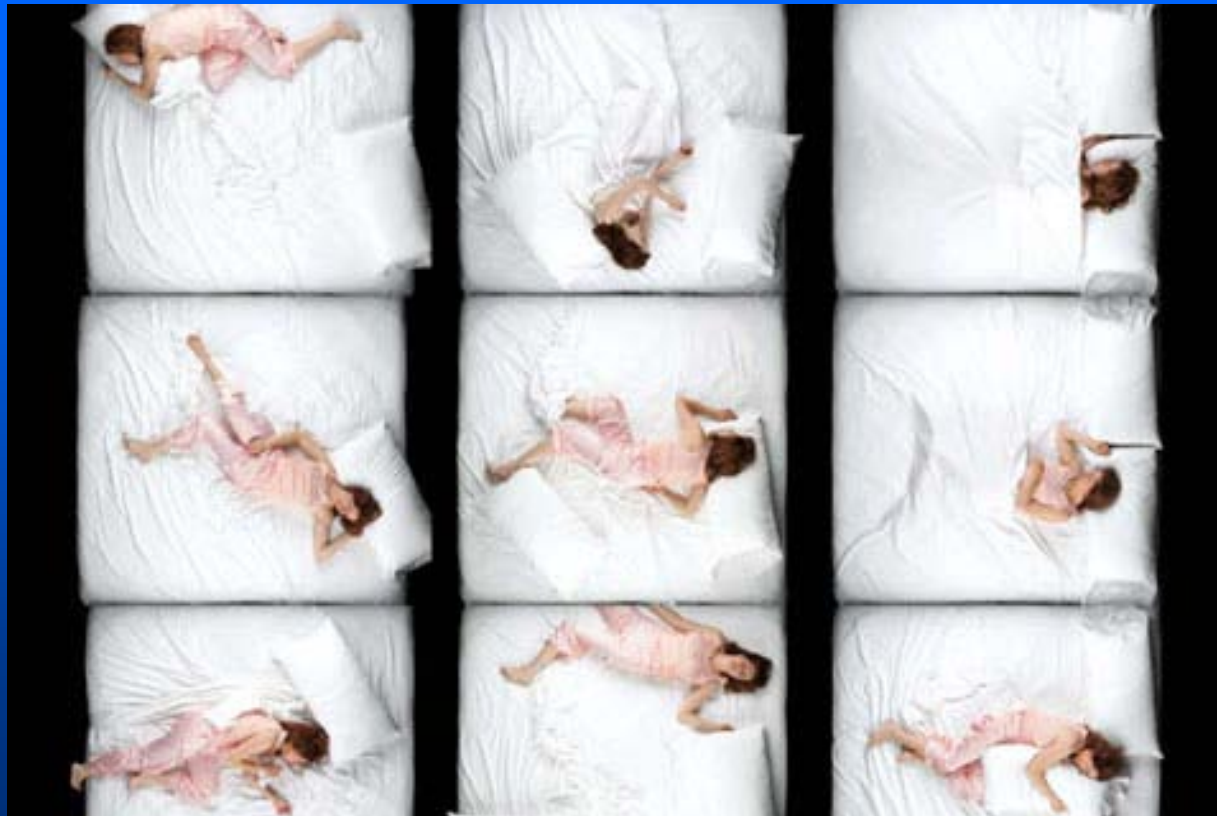
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## Comparison of IOM Committee Adjustments with Current ACGME Duty-Hour Limits.

Variable	2003 ACGME Duty-Hour Limits	IOM Recommendation
Maximum hr of work per wk	80 hr, averaged over 4 wk	No change
Maximum shift length	30 hr (admitting patients up to 24 hr, then 6 additional hr for transitional and educational activities)	30 hr (admitting patients for up to 16 hr, plus 5-hr protected sleep period between 10 p.m. and 8 a.m., with the remaining hours for transitional and educational activities) 16 hr with no protected sleep period
Maximum in-hospital on-call frequency	Every third night, on average	Every third night, no averaging
Minimum time off between scheduled shifts	10 hr after shift	10 hr after day shift 12 hr after night shift 14 hr after any extended duty period of 30 hr, not returning until 6 a.m. of next day
Maximum frequency of in-hospital night shifts	Not addressed	48 hr off after 3 or 4 nights of consecutive duty
Mandatory time off	4 days per mo 1 day (24 hr) per wk, averaged over 4 wk	5 days per mo 1 day (24 hr) per wk, no averaging One 48-hr period per month
Moonlighting	Internal moonlighting counted against 80-hr weekly limit	Internal and external moonlighting counted against 80-hr weekly limit All other duty-hour limits apply to moonlighting in combination with scheduled work
Limit on hours for exceptions	88 hr for select programs with a sound educational rationale	No change
Emergency room limits	12-hr shift limit, at least an equivalent period of time off between shifts; 60-hr workweek with additional 12 hr for education	No change

# The National Study of Sleep-related Behaviors of Nurse Anesthetists: Personal and Professional Implications

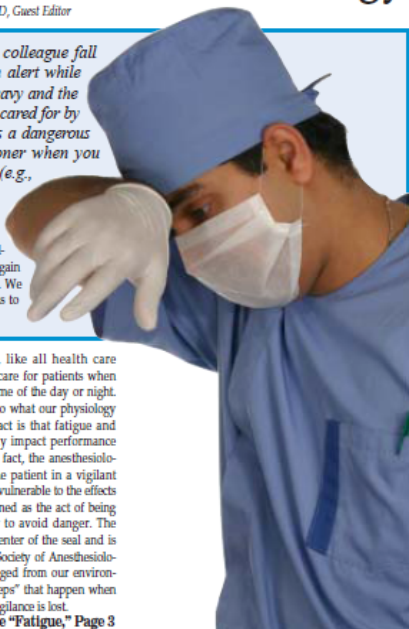


## Fatigue & the Practice of Anesthesiology

by Steve Howard, MD, Guest Editor

**Everyone has seen it.** For example, watching a colleague fall asleep at a meeting or watching an intern struggle to remain alert while holding a surgical retractor. Everyone has felt it. Eyelids get heavy and the environment starts to "grey out." Ask yourself if you desire to be cared for by health care workers who look and feel this way. This clearly is a dangerous situation for our patients. It is also unsafe for the practitioner when you consider the possibility of harm due to occupational injury (e.g., needles/ticks) and the increased risk of driving while sleepy.

This edition of the APSF Newsletter will focus on fatigue and the anesthesia care provider. There is renewed interest in this topic, and we have gathered a cadre of individuals who will present important new information on this topic. Anesthesiology has been very forward-looking regarding many aspects of safety, and there is again an opportunity to be at the "cutting edge" in dealing with this pervasive problem. We hope that the material in this issue will encourage others in our field to join with us to change the manner in which we practice and care for patients.



### Fatigue and Safety

Fatigue has played a causal or contributory role in some famous accidents.<sup>1</sup> In 1986, the Presidential Commission found that faulty decision-making by sleep-deprived managers contributed to the untoward launch of the space shuttle Challenger. The nuclear accidents at Three Mile Island and Chernobyl both occurred during the early morning hours when our bodies are craving sleep. The grounding of the Exxon Valdez was a monumental environmental catastrophe. The National Transportation Safety Board found that the probable cause of this accident was the fatigue of the person sailing the ship. The National Highway Traffic Safety Administrations estimates that over 100,000 people are killed or injured each year in crashes attributed to drivers who fell asleep at the wheel or were impaired by severe drowsiness. These examples and many others reveal that fatigue is a problem that extends beyond health care and is deeply embedded within our society.

Studies have shown a correlation between the performance effects of sleep deprivation and ethanol intoxication.<sup>2</sup> At 24 hours of continuous wakefulness, psychomotor function was equivalent to a blood alcohol concentration of 0.1%. This is at or above the legal limit for driving in most states. Think of the professional and personal liability of coming to work intoxicated!

Anesthesia providers, like all health care providers, are required to care for patients when they present for care—anytime of the day or night. This is often in opposition to what our physiology demands. An irrefutable fact is that fatigue and sleep deprivation negatively impact performance and mood (see Table 1). In fact, the anesthesiologist's role of monitoring the patient in a vigilant manner may be particularly vulnerable to the effects of fatigue.<sup>3</sup> Vigilance is defined as the act of being alertly watchful, especially to avoid danger. The word "vigilance" is at the center of the seal and is the motto of the American Society of Anesthesiologists. If we become disengaged from our environment (such as the "microsleeps" that happen when we are sleep-deprived), all vigilance is lost.

See "Fatigue," Page 3

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# The study's origins

- Personal experiences
- Conversations with providers
- Reports from other domains
- Simulation studies
- Radio, TV, newspaper reports
- Sense of professional responsibility

# Methodology

- IRB approved
- 10% of active AANA members surveyed– 7 regions
- Instrument reliability and validity established
- Random mailing      Anonymous, postage paid return
- Closed & open ended questions
- Quantitative & qualitative analysis



# Quantitative Findings

(42% return rate, 61% female)



- 80% go to bed after 10pm each night
- 72% awake before 5:30am
- 25% awaken  $\geq 3x/\text{night}$   $\rightarrow$  fragmented sleep
- 59% premature awakening  $\rightarrow$  can't regain sleep
- 56% daytime napping; 16% naps  $\geq 60$  minutes
- 47% routinely have difficulty falling asleep at night

# Quantitative Findings



- **24% use of sleep medications to generate sleep**
- **18.4% report restless legs syndrome**
- **16.5% frequently have nightmares → arousal from sleep**
- **56.2% have issues with snoring during sleep**
- **68% report excessively tiredness during the work day**

**A – Alcohol**  
**Advil PM**  
**Aleve**  
**Ambien & Ambien CR**  
**Aspirin**  
**Ativan**  
**“Antihistamines”**  
**B – Benadryl**  
**BIPAP**  
**C- CPAP**  
**Calms Forte**  
**Clonazepam**  
**Cough syrup**  
**D – Dramamine**  
**E- Excedrin,**  
**Excedrin pm**  
**Ext Strength Tylenol**  
**Extrovent pm**  
**Ear plugs**  
**Elavil**  
**H – Halcion**  
**Herbal OTC**  
**I – Ibuprofen**

**K – Klonopin**  
**L – Lunasom**  
**Lunesta**  
**Lyrica**  
**M – Marijuana**  
**Melatonin**  
**Mirapex**  
**Motrin**  
**Morphine**  
**N – Nyquil, Nytol**  
**Nitetime cough syrup**  
**R – Requip / Rozerem**  
**Rapid sleep pm**  
**Reading**  
**Restoril**  
**S- Sominex**  
**Simple sleep**  
**Seroquel**  
**Sonata**  
**St John’s Wart**  
**Sominex**  
**Sudafed**

**T-Tylenol pm**  
**Trazadone**  
**Tempzepam**  
**Triazolam**  
**Tryptophan**  
**Tramadol**  
**U - Unisom**  
**V - Valarian**  
**Vistaril**  
**Valium**  
**X - Xanax**  
**Z – Zanaflex**  
**Zaleplon**  
**Zolpidem**

**Reported sleep aides  
used by respondents**



# NyQuil.

The nighttime  
sniffling, sneezing,  
coughing, aching, get-  
you-so-sloshed-you-  
think-your-cat-is-  
Elvis medicine.

**Analgesic / antipyretic:**

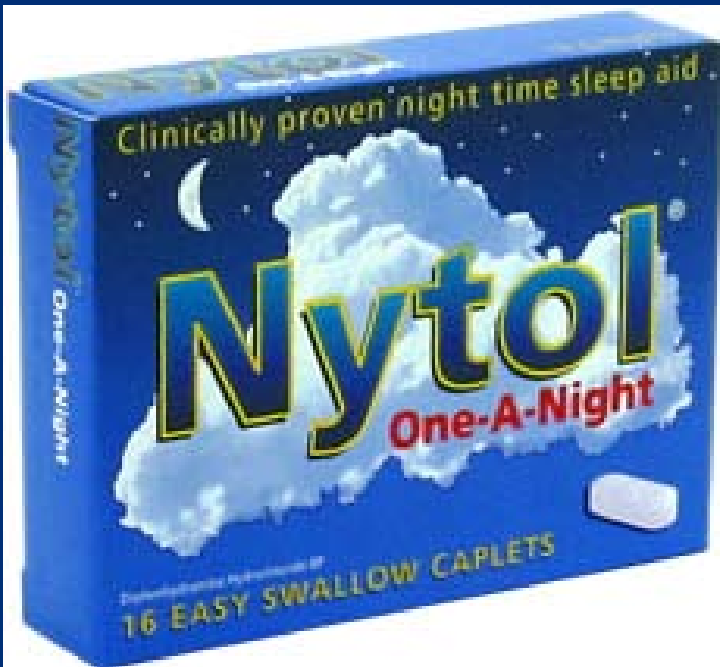
**Acetaminophen 500 mg / 15 mL**

**Cough suppressant:**

**Dextromethorphan 15 mg / 15 mL**

**Antihistamine / hypnotic:**

**Doxylamine 6.25 mg / 15 mL**

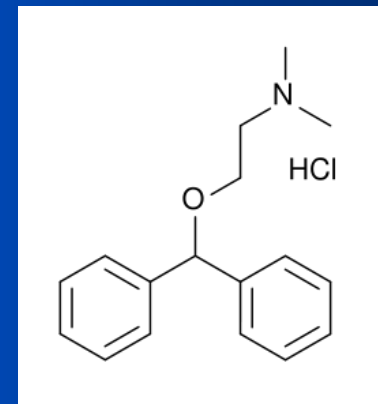


**Contains diphenhydramine**

**+ Regular strength 25 mg / tablet**

**+ Extra strength 50 mg / tablet**

*Sominex, Sleepinal, Twilite, Unisom, etc.*



- **Half-life 4-8 hours: hypnotic effect lasts ~ 6 hours**
- **Tolerance usually develops after a few days of use**
- **Significant and additive effects with alcohol, hypnotics, etc.**
- **Paradoxical effects in some, particularly the elderly**

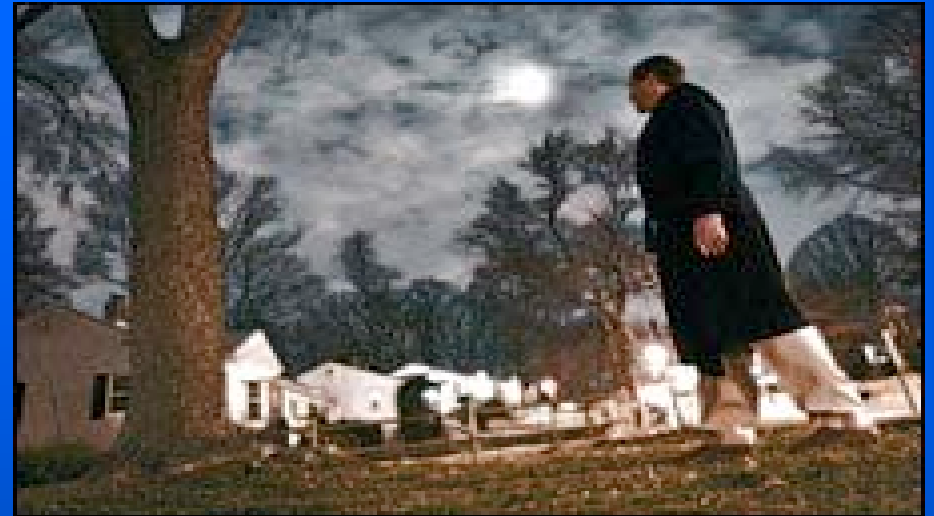


Rebound insomnia

Psychological addiction

Low efficacy if abnormal neurotransmitters

# 2007 & 2008 & 2009: FDA orders stronger warnings for sleep aides



- Ambien, Lunesta & 11 other common sleep aides
- Risk of bizarre and paradoxical behaviors
  - *Sleepwalking*    *Hallucination*    *Violent outbursts*
  - *Nocturnal binge eating*    *Abnormal sex drive*    *Driving while asleep*

**Sales for Ambien & Lunesta alone > \$5 billion (2008)**

# Quantitative Findings



- **0.4% use stimulants (besides caffeine) to maintain wakefulness during workday**
- **10.6% have sleep regularly disrupted due to child care issues**
- **10.3% see or are considering seeing a sleep specialist**
- **15.7% report having fallen asleep during an anesthetic**
- **48.8% have witnessed a colleague asleep during a surgical case**



**Adderall**

**Caffeine (coffee, soft drinks)**

**Caffeinated drinks (Red Bull, NOS, Stacker, 5-Hour Energy )<sup>TM</sup>**

**Caffeine tablets (Nodoz<sup>TM</sup>)**

**Herbal tea**

**Ephedra**

**Provigil (Cephalon, Equip)<sup>TM</sup>**

**CX717 (investigational drug similar to Provigil)**

**Primatine mist nasal spray**

**Ritalin**

**Vivarin<sup>TM</sup>**

**Vyvanse<sup>TM</sup>**

**Wakefulness promoters  
reportedly used by respondents**

# What's in that stuff?

Hershey's Chocolate Kiss

1mg

12 oz. Snapple Tea

32mg

12 oz. Coca-Cola Classic

34mg

12 oz. Dr. Pepper

41mg

12 oz. Mountain Dew

55mg

8.5 oz. Red Bull

80mg

8 oz. coffee

135mg (variable)

1 Vivarin™ caffeine pill

200mg

16 oz. Starbucks Coffee Grande

259mg

24 oz. BooKoo Energy drink

360mg

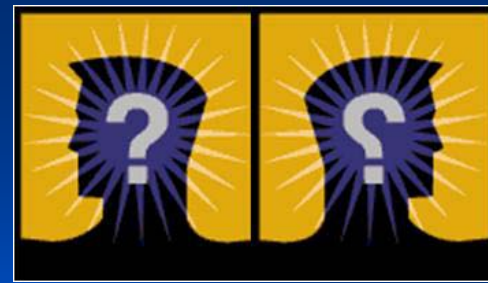


## *Issues provoking or exacerbating loss of sleep*

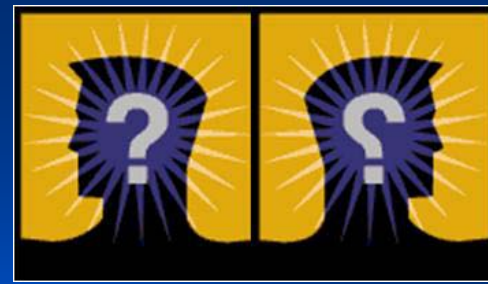


- Menopause, frequent need to urinate, aging worsens the problem
- Shift work, swing shifts, call back from home
- Anxiety over caseload, challenging cases, cases that went poorly
- Snoring bed partner
- Obstructive sleep apnea syndrome, restless leg syndrome
- Nightmares
- Domestic issues: child care, care of ill spouse/parent, lacks partner help
- Medical-legal, financial, relationship, workplace problems
- A vicious cycle of poor sleep, stress, worsening sleep

*Issues indicating concern for  
patient and personal safety*



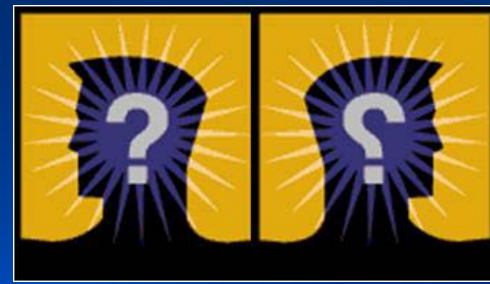
- **Personally falling asleep during anesthetic care**
- **Feeling “at risk” of falling asleep during anesthetic care**
- **Aware of colleagues engaging in sleep behaviors during anesthetic care**
- **Making errors of omission; making errors of commission**
- **Falling asleep while driving after a long shift**
- **Generalized cognitive impairment from sleep-fatigue**
- **Chronic sleep loss is deleterious to my health**
- **In denial about nature and extent of problem**



## *Suggestions for dealing with the problem of sleep-related fatigue*

- **Regulation needed — work hour restrictions like airline pilots**
- **Improved, scheduled breaks during work hours**
- **Sleep aides education needed: medications are a two-edged sword**
- **Start cases later in the day**
- **Provide nap-rooms at work**
- **Feel safe in admitting problem. Seek professional help if problem persists**

## *Miscellaneous criticisms/questions of the study's intent and design*



- **Worthless study---**sleep-related issues not a problem in clinical practice
- **Timely study, provokes needed discussion about workplace safety**
- **Use Ipod ear buds to listen to music to keep me alert. Is this bad?**
- **Does reading or listening to books on tape help or hurt?**
- **Does using the Internet during cases help or hurt?**
- **Thank you! Have seen patients & colleagues hurt by sleep issues**
- **Waste of time, we knew all this already**
- **You bring negative publicity to us! This will hurt us with physicians!**
- **Likely underestimating problem---**people reluctant to admit problems

# Sleep disturbances are common

- ~ 40% adults → acute/chronic issues each year
- *Under-reporting is very likely*
- Links to health, social and job dysfunction
  
- Metric of its pervasiveness
  - OTC & prescription advertising (TV, radio, magazine)
  - Widespread & growing use of sleep aides
  - Financial success of distributors
  - Surveys of worker fatigue



## Practice Guidelines for the Perioperative Management of Patients with Obstructive Sleep Apnea

A Report by the American Society of Anesthesiologists Task Force on Perioperative Management of Patients with Obstructive Sleep Apnea

**CME** This article has been selected for the Anesthesiology CME Program. After reading the article, go to <http://www.asahq.org/journal-cme> to take the test and apply for Category 1 credit. Complete instructions may be found in the CME section at the back of this issue.

**PRACTICE guidelines** are systematically developed recommendations that assist the practitioner and patient in making decisions about health care. These recommendations may be adopted, modified, or rejected according to clinical needs and constraints. Practice guidelines are not intended as standards or absolute requirements. The use of practice guidelines cannot guarantee any specific outcome. Practice guidelines are subject to revision as warranted by the evolution of medical knowledge, technology, and practice. They provide basic recommendations that are supported by analysis of the current liter-

ature and by a synthesis of expert opinion, open forum commentary, and clinical feasibility data.

### Methodology

**A. Definition of Obstructive Sleep Apnea**  
Obstructive sleep apnea (OSA) is a syndrome characterized by periodic, partial, or complete obstruction of the upper airway during sleep. This, in turn, causes repetitive arousal from sleep to restore airway patency, which may result in daytime hypersomnolence or other daytime manifestations of disrupted sleep such as aggressive or distractible behavior in children. The airway obstruction may also cause episodic sleep-associated oxygen desaturation, episodic hypercarbia, and cardiovascular dysfunction. It is estimated that the adult prevalence of sleep-disordered breathing, as measured in a sleep laboratory, is 9% in women and 24% in men, whereas the prevalence of overt OSA has been estimated to be 2% in women and 4% in men.<sup>1</sup> These figures are likely to increase as the population becomes older and more obese. In the perioperative period, both pediatric and adult patients with OSA, even if asymptomatic, present special challenges that must be systematically addressed to minimize the risk of perioperative morbidity or mortality. It is the opinion of the Task Force that the perioperative risk to patients increases in proportion to the severity of sleep apnea.

Because procedures differ among laboratories, it is not possible to use specific values of indices (such as the apnea-hypopnea index [AHI]) to define the severity of sleep apnea. Therefore, for the purposes of these Guidelines, patients will be stratified using the terms *mild*, *moderate*, and *severe* as defined by the laboratory where the sleep study was performed.

### B. Purpose of the Guidelines

The purpose of these Guidelines is to improve the perioperative care and reduce the risk of adverse outcomes in patients with OSA who receive sedation, analgesia, or anesthesia for diagnostic or therapeutic procedures under the care of an anesthesiologist. The Task Force recognizes that it is not possible to determine with 100% accuracy whether a given patient will develop perioperative complications related to OSA. Therefore, these Guidelines should be implemented with the goal of reducing the likelihood of adverse outcomes in patients who are judged to be at the

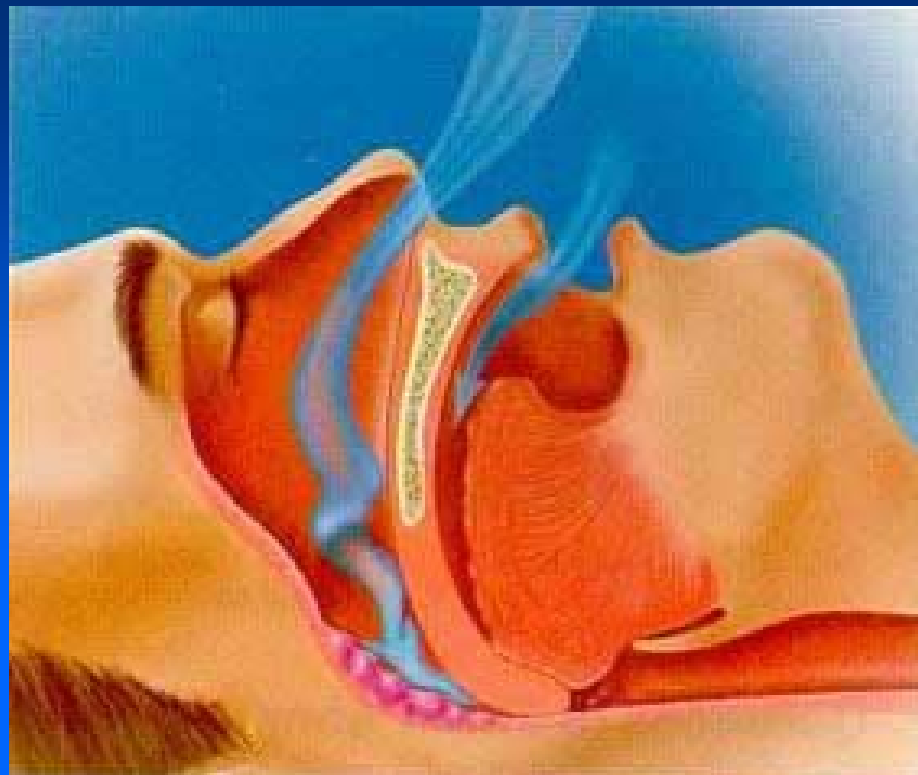
This article is featured in "This Month in Anesthesiology." Please see this issue of Anesthesiology, page 5A.

Additional material related to this article can be found on the Anesthesiology Web site. Go to <http://www.anesthesiology.org>, click on Enhancements Index, and then scroll down to find the appropriate article and link. Supplementary material can also be accessed on the Web by clicking on the "ArticlePlus" link either in the Table of Contents or in the HTML version of the article.

Developed by the American Society of Anesthesiologists Task Force on Perioperative Management of Obstructive Sleep Apnea: Jeffrey S. Gross, M.D., Olathe, Kansas; Kenneth L. Bachenberg, M.D., Holliston, Washington; Jonathan L. Benumof, M.D., San Diego, California; Robert A. Caplan, M.D., Seattle, Washington; Richard T. Coombs, Jr., D., Woodville, Washington; Charles J. Corle, M.D., Boston, Massachusetts; David G. Nickerson, Jr., D., Bellevue, Washington; Wreck Prackman, M.D., Chicago, Illinois; Debra S. Ward, M.D., Rochester, New York; Edward M. Warner, M.D., M.P.H., Seattle, Washington; Lawrence Yoken, M.D., Santa Fe, New Mexico; Song Yu, M.D., Farmington, Connecticut.

Submitted for publication November 1, 2005. Accepted for publication November 1, 2005. Supported by the American Society of Anesthesiologists under the direction of James F. Aron, M.D., Chair, Committee on Practice Management. Approved by the House of Delegates on October 25, 2005. A complete list of references used to develop these Guidelines is available by writing the American Society of Anesthesiologists. These Guidelines have been endorsed by the American Academy of Sleep Medicine and the American Academy of Otolaryngology-Head and Neck Surgery. They have received an "Affirmation of Value" from the American Academy of Pediatrics.

Address reprint requests to the American Society of Anesthesiologists, 520 North North West Highway, Park Ridge, Illinois 60062-2773. The Practice Guidelines article, as well as all published ASA Practice Parameters, may be accessed at no charge through the Journal Web site, [www.anesthesiology.org](http://www.anesthesiology.org).



Anesthesiology  
May 2006 1081-1093

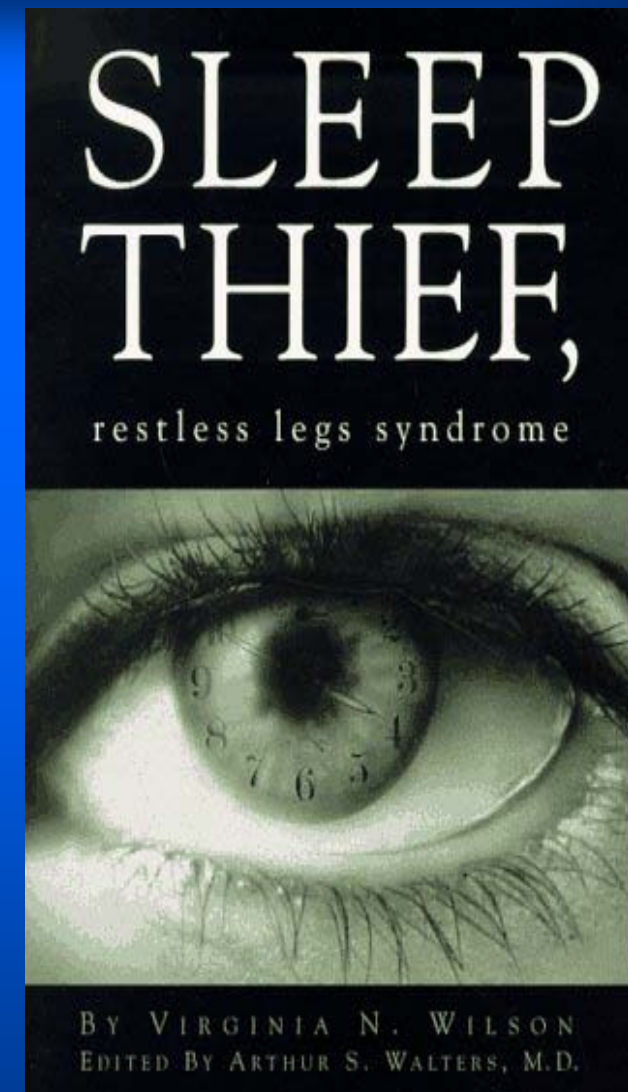


# Restless legs syndrome

## Periodic limb movement disorder

- 41 yo with nightly insomnia for 10 yrs
- “Uncomfortable sensations in my legs”
- “Uncontrollable urge to move my legs”
- Sensation only relieved by walking
- Maddening to bed partner
- Daytime life is distressing – exhaustion

- 5 - 20% of Americans
- Under-reporting is highly likely

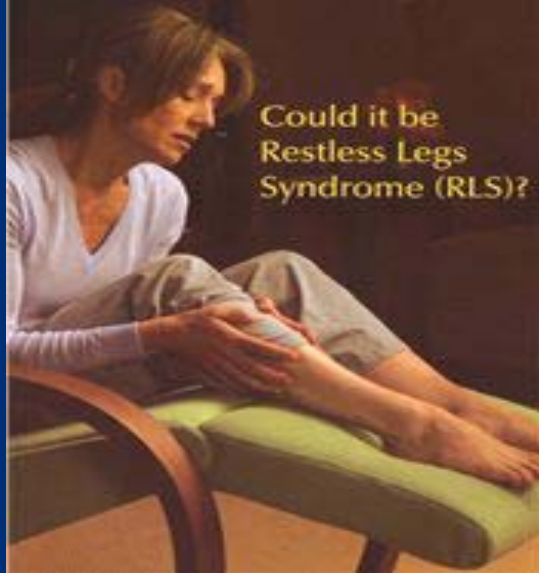


*JAMA* 2007;297:1865-6

*J Int Med* 2009;266:419-431

# Creepy, Crawly Legs?

Could it be  
Restless Legs  
Syndrome (RLS)?



- FDA approved drug for RLS
- Anti-parkinsonian agent
- Activates postsynaptic dopamine receptors

NEW! 2-WEEK Sample AIT

**Requip®**  
(ropinirole HCl tablets)  
*for treatment of moderate-to-severe  
primary restless legs syndrome*

2-WEEK Sample AIT

- 2 weeks worth of medication
- 2 weeks worth of medication
- 2 weeks worth of medication

Please read the accompanying Patient Information Leaflet to be informed about possible side effects.

[Visit Website](#)

Requip®  
ropinirole HCl

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Reduce the  
compelling  
urge to move  
your legs.

You may have a condition  
known as Restless Legs  
Syndrome.

[Learn More](#)

Do you think you might have Restless Leg Syndrome?

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[Restless Legs Syndrome Info for Healthcare Professionals](#)

**gsk** GlaxoSmithKline

**Together R**  
ORANGE  
Cap  
Consumer Savings



# Narcolepsy

1:2,000 Americans suffer

Inappropriate, sudden hypersomnia  
Low levels hypothalamic neuropeptides  
Autoimmune injury to secreting cells?

Rx: Behavior modification to Px injury  
Family & coworkers involved  
Ritalin  
Selective serotonin reuptake inhibitors  
Provigil

## Treatment of Narcolepsy and other Hypersomnias of Central Origin

An American Academy of Sleep Medicine Review

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**Objective:** The purpose of this paper is to summarize current knowledge about treatment of narcolepsy and other hypersomnias of central origin. **Methods:** The task force performed a systematic and comprehensive review of the relevant literature and graded the evidence using the Oxford grading system. This paper discusses the strengths and limitations of the available evidence regarding treatment of these conditions, and summarizes key information about safety of these medications. Our findings provide the foundation for development of evidence-based practice parameters on this topic by the Standards of Practice Committee of the American Academy of Sleep Medicine. **Results:** The majority of recent papers in this field provide information about use of modafinil or sodium oxybate for treatment of sleepiness associated with narcolepsy. Several large randomized, placebo-controlled studies indicate that modafinil and sodium oxybate are effective for treatment of hypersomnia due to narcolepsy. We identified no studies that report direct comparison of these newer medications versus traditional stimulants, or that indicate what proportion of patients treated initially with these medications require transition to traditional stimulants or to combination therapy to achieve adequate alertness. As with the traditional stimulants, modafinil and sodium oxybate provide, at best, only moderate improvement in alertness rather than full restoration of alertness in patients with narcolepsy. Several large randomized placebo-controlled stud-

ies demonstrate that sodium oxybate is effective for treatment of cataplexy associated with narcolepsy, and earlier studies provide limited data to support the effectiveness of fluoxetine and tricyclic antidepressants for treatment of cataplexy. Our findings indicate that very few reports provide information regarding treatment of special populations such as children, older adults, and pregnant or breastfeeding women. The available literature provides a modest amount of information about improvement in quality of life in association with treatment, patient preferences among the different medications, or patient compliance. **Conclusion:** Several recent studies provide evidence that modafinil and sodium oxybate are effective for treatment of hypersomnia due to narcolepsy. No studies were identified that report direct comparison of these newer medications with traditional stimulants. Despite significant advances in understanding the pathophysiology of narcolepsy, we do not have an ideal treatment to restore full and sustained alertness. Future investigations should be directed toward development of more effective and better tolerated therapies, and primary prevention. **Keywords:** Hypersomnia, narcolepsy, cataplexy, modafinil, sodium oxybate, stimulants  
**Citation:** Wise MS, Arand DL, Auger RR, Brooks SN, Watson NF. Treatment of Narcolepsy and other Hypersomnias of Central Origin. *SLEEP* 2007;30(12):1712-1727.

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### Disclosure Statement

This is not an industry supported study. Dr. Brooks has worked for Pacific Sleep Medicine a company that contracts to participate in industry sponsored clinical trials. The other authors have indicated no financial conflicts of interest.

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Treatment of Narcolepsy and other Hypersomnias—Wise et al

*Sleep* 2007

# Modafinil (Provigil)



- Wakefulness-promoting drug
- FDA approved: narcolepsy, OSAS, 'shift work syndrome'
- Inhibits dopamine and norepinephrine reuptake
- Activity at hypothalamus (orexin neurons)



**2004 Gold Medal Revoked  
1600 M Relay  
Calvin Harrison**





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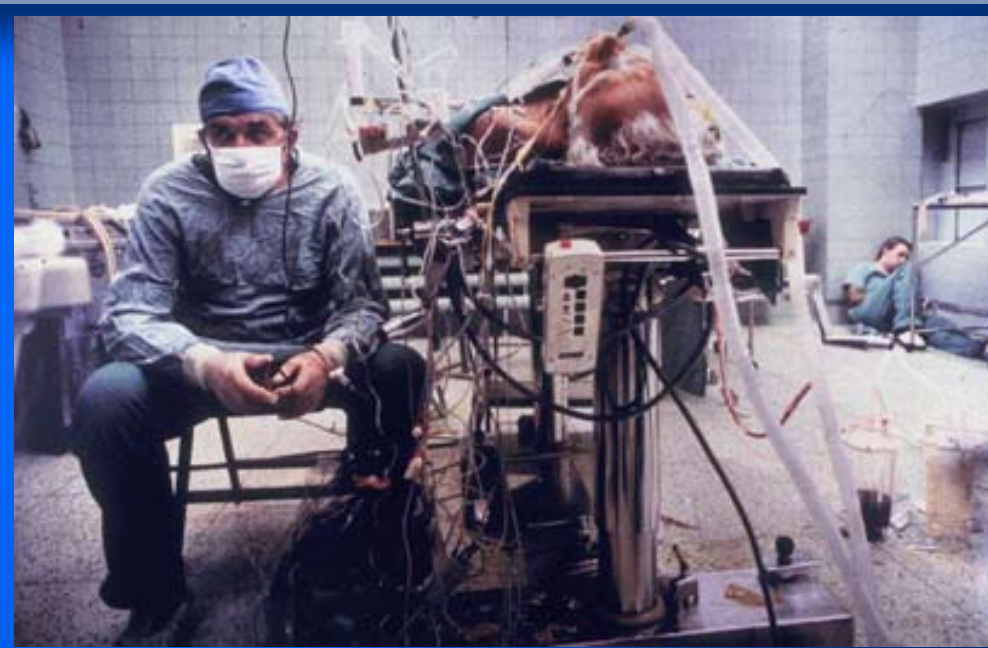
Arlington, Virginia

**We all have a major stake in understanding the impact of sleep on clinical performance and career sustainability**



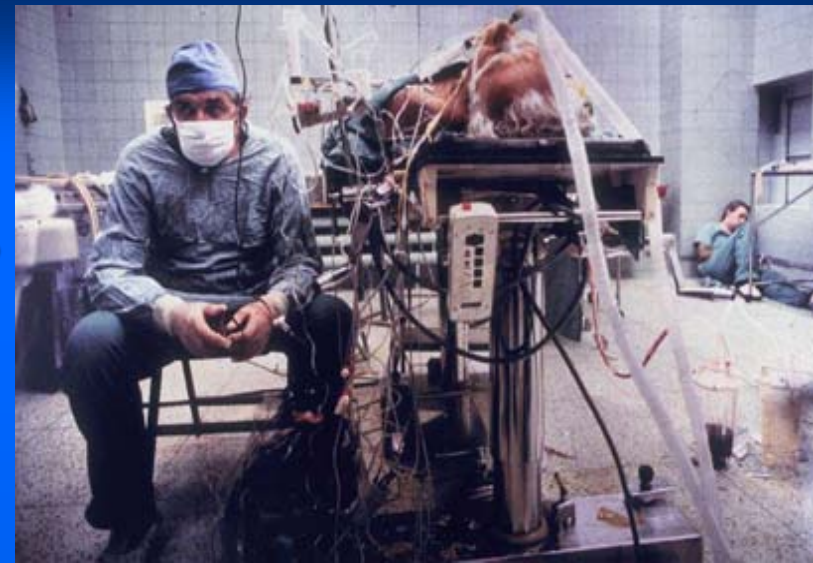
**Sleep deprivation impairs vigilance  
and neuro-cognitive function**

## The anesthesia provider.....



- **Renders care when the patient presents (day or night)**
- **Timing of task readiness & rest --- often asynchronous**
- **Fatigue & sleep deprivation negatively impact performance**
- **Each of us is genetically “hard wired” for sleep requirement**

# Many anesthesia providers.....



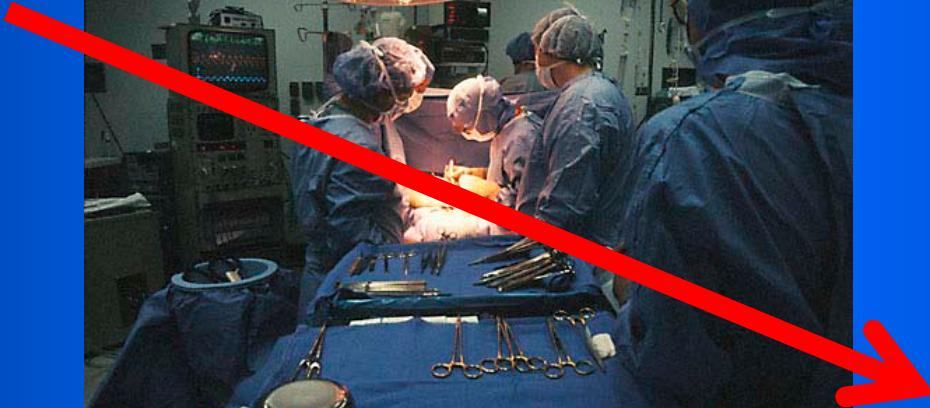
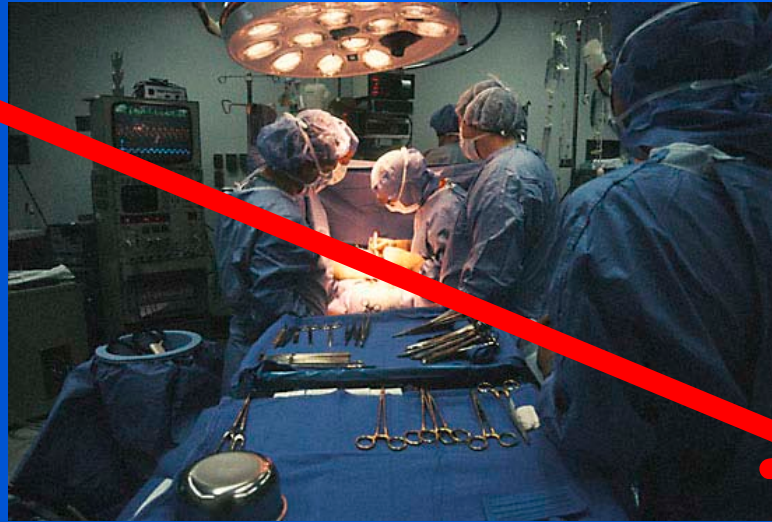
- Are chronically sleep deprived
- Commonly push the envelope further & further
- Are often unaware ( or in denial ) of degree of impairment

*Layering acute sleep deprivation on top of an existing sleep debt is a recipe for catastrophe\* ^*

\*Van Dongen. *Sleep* 2003;26:117

^Dement. Personal communication. 4/10







**How often have you been here???**

**Sleep debt, sitting still, repetitive task performance  
-- seriously degrade coping defenses --**

## The Human Condition



The combination of :

- Sleep deprivation
- Life stressors
- Prescription drugs / OCT drugs
- Overall physical health
- Overall mental health
- Alcohol use / ‘recreational’ drugs

*Have profound and variable effects upon each of us*

24 hours of continuous wakefulness = BA 0.1%\*^

\*Dawson. *Nature*. 1997;388:235

^Dement. Personal communication. 4/10

# Caveats

- Fatigue / sleepiness = major provider concerns
- Greater detrimental effects with age\*
- Sleepiness during patient care removes an essential layer of protection in a very dangerous environment
- Many providers fall asleep during care yet deny doing so\*^



\*Reilly. Age, rhythms of physical performance. *Occup Environ Med.* 1997; 54:812.

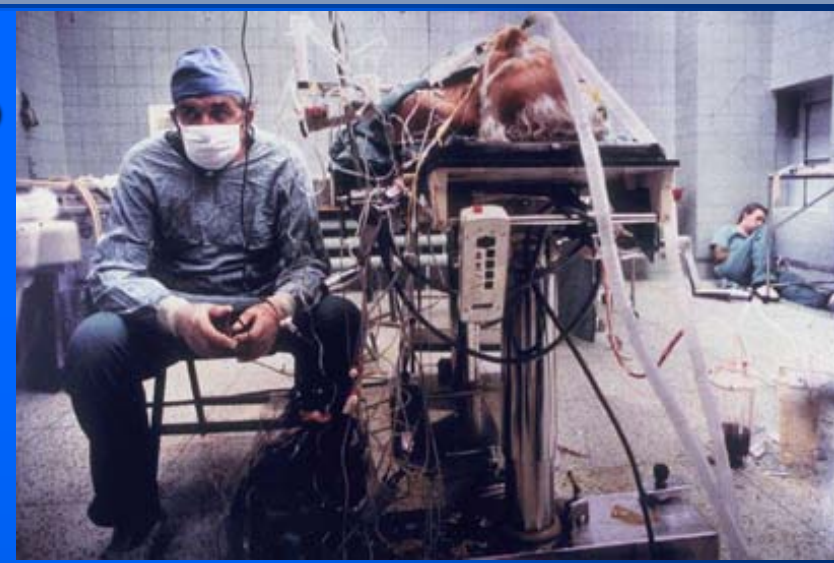
^Howard. Risks of excessive sleepiness in residents. *Acad Med.* 2002; 77: 1019.

# Should there be regulation?

- Bus drivers
- Airline pilots
- Truck drivers
- Cruise ship captains
- Train / subway operators

- **What about us?**

- Too often *The Sleepy are Keeping People Asleep*

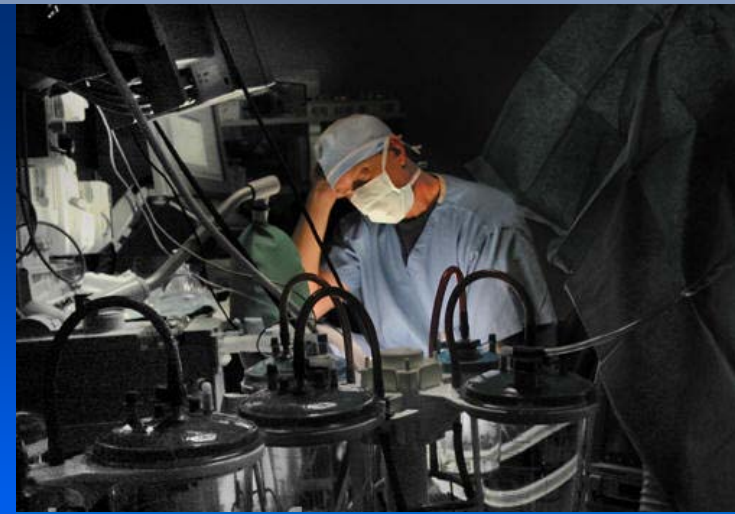


# Sleep-related fatigue

Major concern in any domain where workforce behavior has immediate or potential negative consequences for others

*Often the danger is self-evident. What we do with it is up to us.*





- You witness a provider who falls asleep while engaging in patient care....
- A surgeon or circulator tells you that a departmental member was sleeping during patient care....
- You are aware of a colleague who frequently self-medicates to remain alert at work....
- You are falling asleep during patient care and you have recently experienced 'near misses'....

*.....what would you do?*