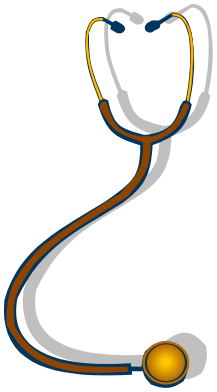
The Impact of Sleep and Fatigue on Resident Learning and Patient Safety



Rachel Givelber, MD

We begin with a case…

- 18 yo woman sent to ER by PCP for 2 days of flu like symptoms
- PMHx: Psych problems
- Social Hx: seems like a “partier”
- PE: T 103.5, agitated, no photophobia or nuchal rigidity, R TM erythematous
- WBC 18K, blood cultures sent, ABX started, admitted to floor

- Urgent page while you are at a code. Initial patient is agitated, crying in pain, thrashing around, required soft restraints. Nurse is desperate for orders.

What do you do?

A. Redraw cultures, tylenol
B. Dilaudid for pain, Haloperidol prn
C. Broaden antibiotics

- Increasing agitation, fever to 107.0, suffers respiratory and cardiac arrest and cannot be successfully resuscitated

Duty Hour Rules: Historical Factors

- Medical Student and Resident Groups
- Legislative Action
  - New York: Bell Commission concluded that trainee fatigue as well as insufficient supervision contributed to the death of Libby Zion (1989)
  - Petitions to OSHA in 2001
  - Bills in Congress
- “To Err is Human” National Academy of Sciences Institute of Medicine report (2000) estimates 98,000 patients die annually from preventable medical errors.

In the Days of the Giants…

- Long hours
- Frequent call
- Less supervision
- More continuity
- Fewer hand offs

- Longer and less acute hospitalizations

ACGME Duty Hour Requirements

- Beginning in 2003 (modified in 2011) all activities related to the residency program
  - No more than 80 hours/wk, averaged over 4 weeks
  - In-house call no more than 1 in 3 nights
    - No longer than 24 hours
    - May stay an additional 4 hours to participate in didactic activities, transfer care, conduct outpatient clinics and maintain continuity of medical and surgical care
  - At least 10 hours between daily duty periods and 14 hours after call
  - One day (24 continuous hours) off in 7 days, averaged over 4 weeks
  - Interns can work only 16 hours in a row

ACGME Duty Hour Requirements

- Rules derive from a compromise between face validity and service/training needs, rather than strong research
- Evidence was lacking on outcomes of interest
  - Improving safety for patients
  - Not compromising training/education of residents
    - Limited number of patients
    - Less opportunity to observe evolution of disease
  - Improving QOL for residents
- LACK of evidence ≠ INEFFECTIVENESS

What is FATIGUE?

- Tiredness, reduced motivation, need to expend increased effort to perform a task effectively and without error
  - Accumulates with increasing work duration and intensity
  - Affected by quantity and quality of sleep
  - Affected by time of day that work occurs (relative to circadian time)

Signs and Symptoms of Fatigue

- Mild/Early
  - Slowed cognition
  - Distractibility
  - Reduced motivation
  - Irritability
- Late/Severe
  - Lapses of attention
  - Sleep starts
  - Automatic behaviors
  - Intrusive sleep

45 yo M with h/o COPD presents with increased DOE and wheezing for 3 days. He has a cough productive of greeeeeeeeeeeeeeeeeeeeee eeeeeeeeeeeeeeeeeeeeeee

Sleep Deprivation Consequences

Behavioral/Mood

- Sleepiness
- Lapses
- Accidents
- Decreased Work Productivity
- Irritability
- Fatigue
- Depression
- Loss of Energy
- Lack of Motivation

Physiologic

- Hypoxemia
- Insulin Resistance
  - Craving “Junk Food”
  - Weight Gain?
- Elevated Sympathetic Activity
- Blunted Arousal Response (hypoxemia, $C0_2$, EEG)

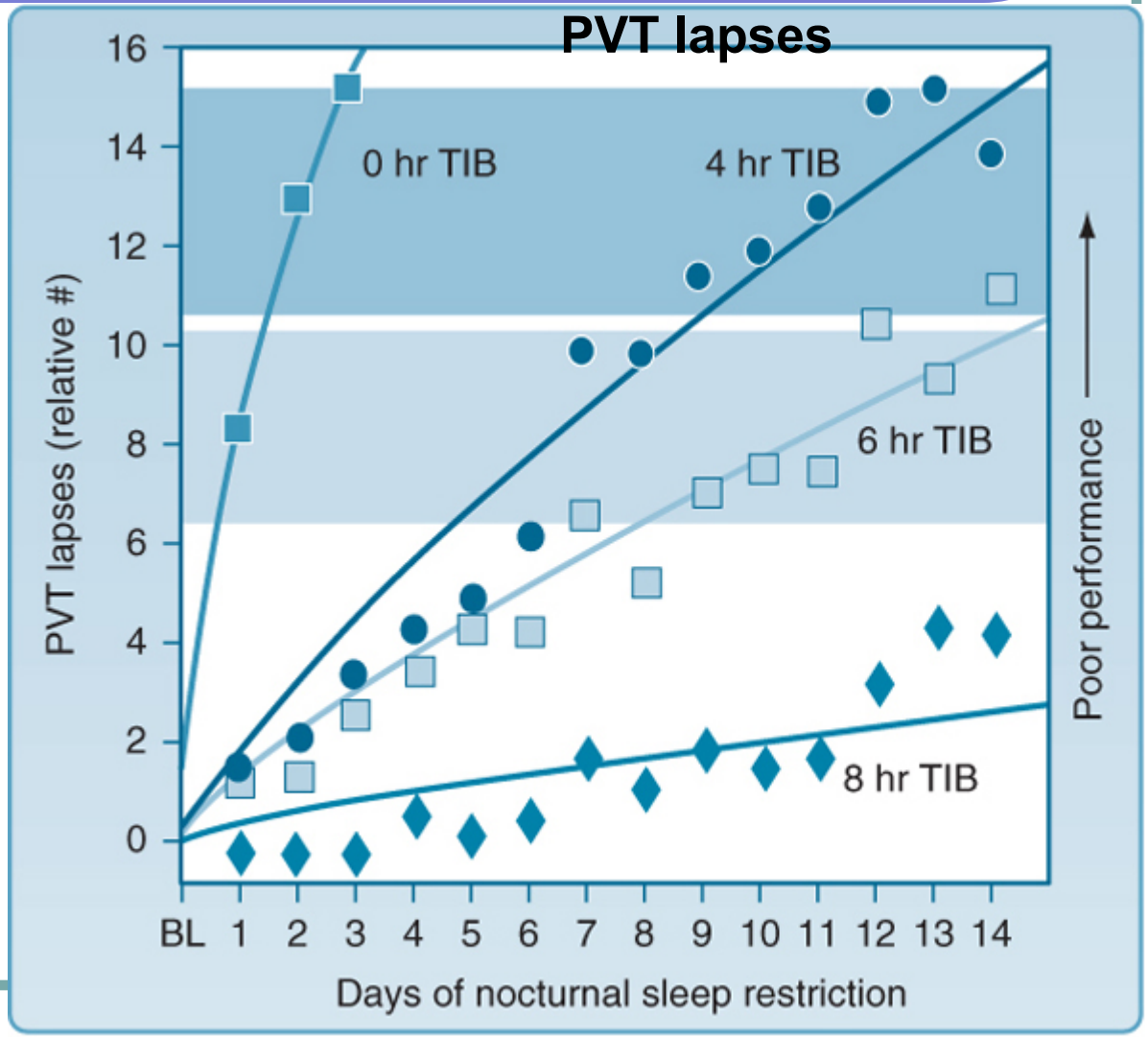
Cognitive Domains Affected by Sleepiness

- Attention
- Working memory
- Mood
- Executive Functioning – Problem solving and Decision Making

- Fatigued individuals have poor insight into their impairment

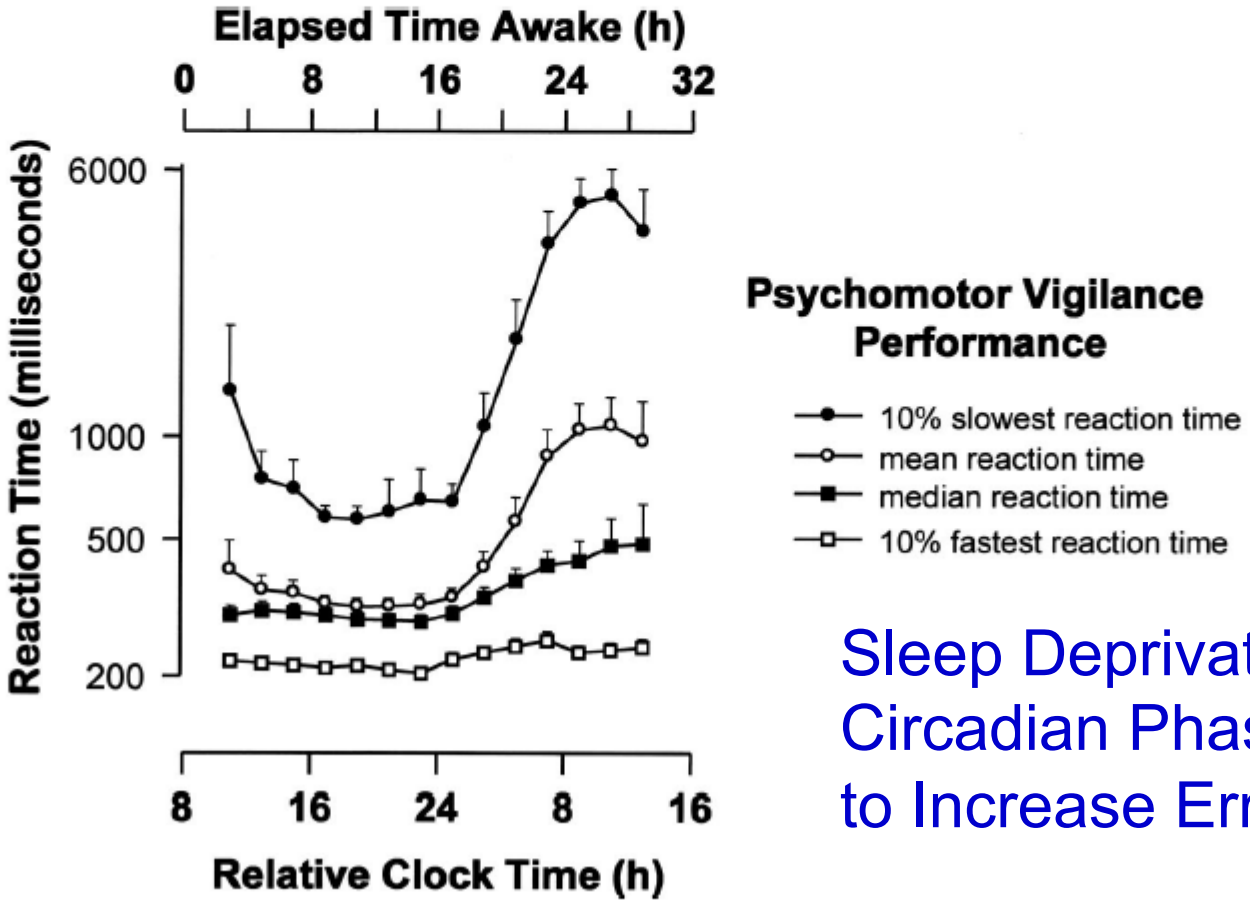
Acute and Chronic Sleep Restriction: Effect on Vigilance

- Fatigue related to sleep loss is cumulative.
- 1 week of 6 h / night sleep ≈ 1 night of complete sleep deprivation



Van Dongen, Sleep 2003

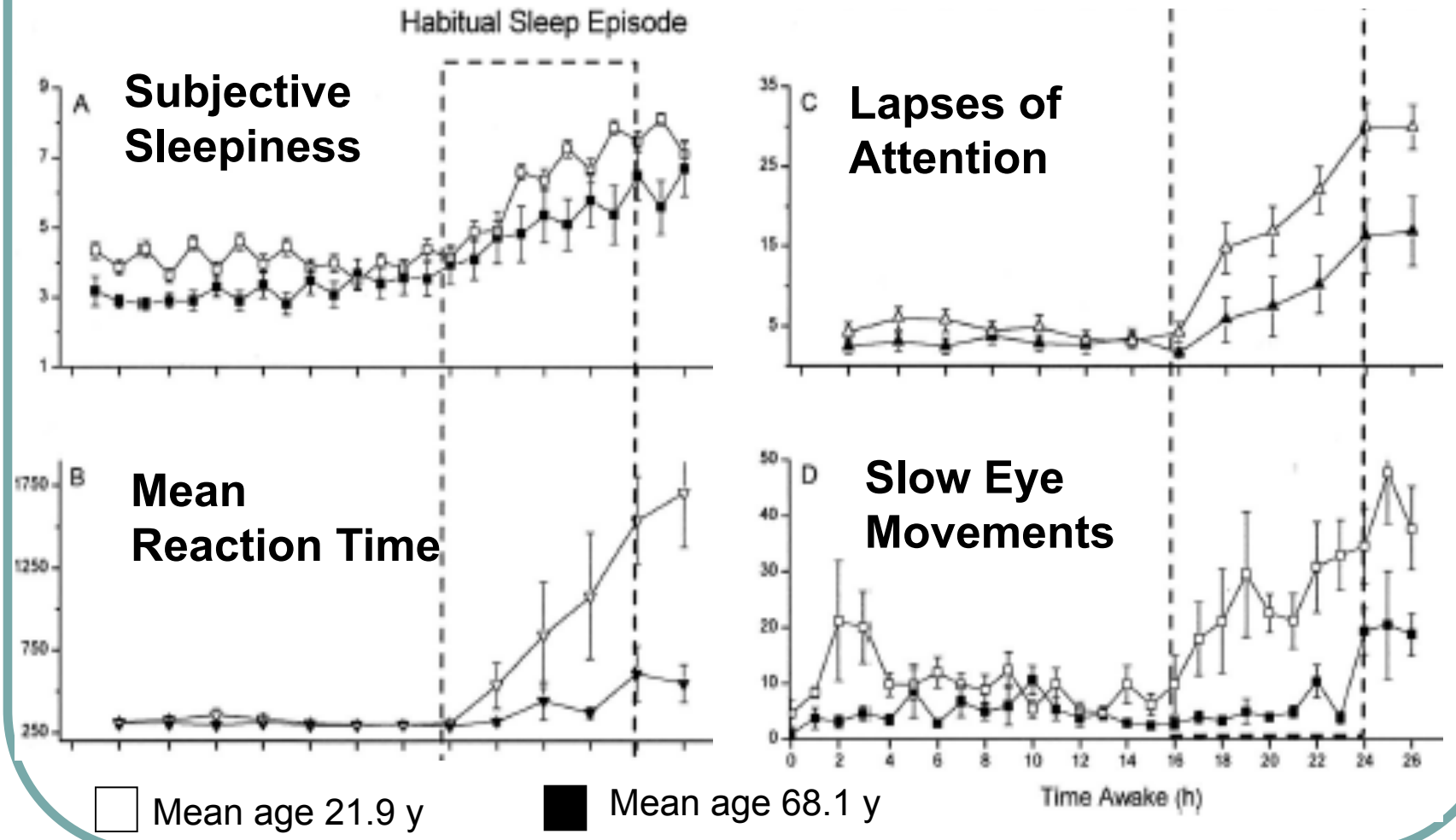
Cognitive Performance Declines after 16 Hours of Continuous Wakefulness



Sleep Deprivation and Circadian Phase Combine to Increase Errors

Cajochen et al, Am J Physiol 1999

Younger Adults More Vulnerable to Acute Sleep Loss than Older Adults



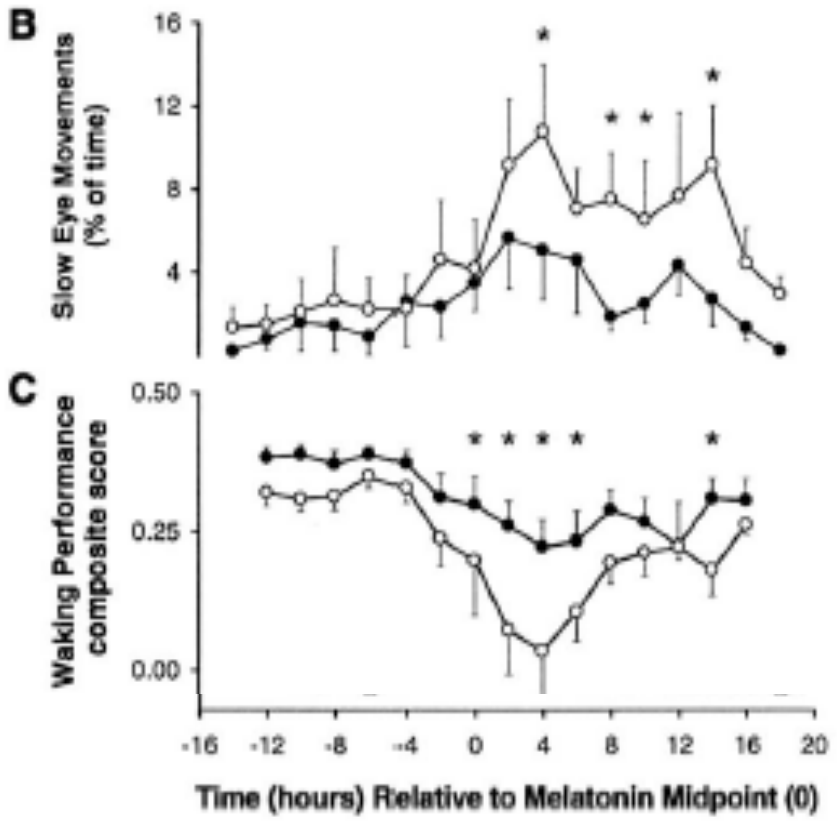
Duffy et al, J Am Geriat Soc 1999

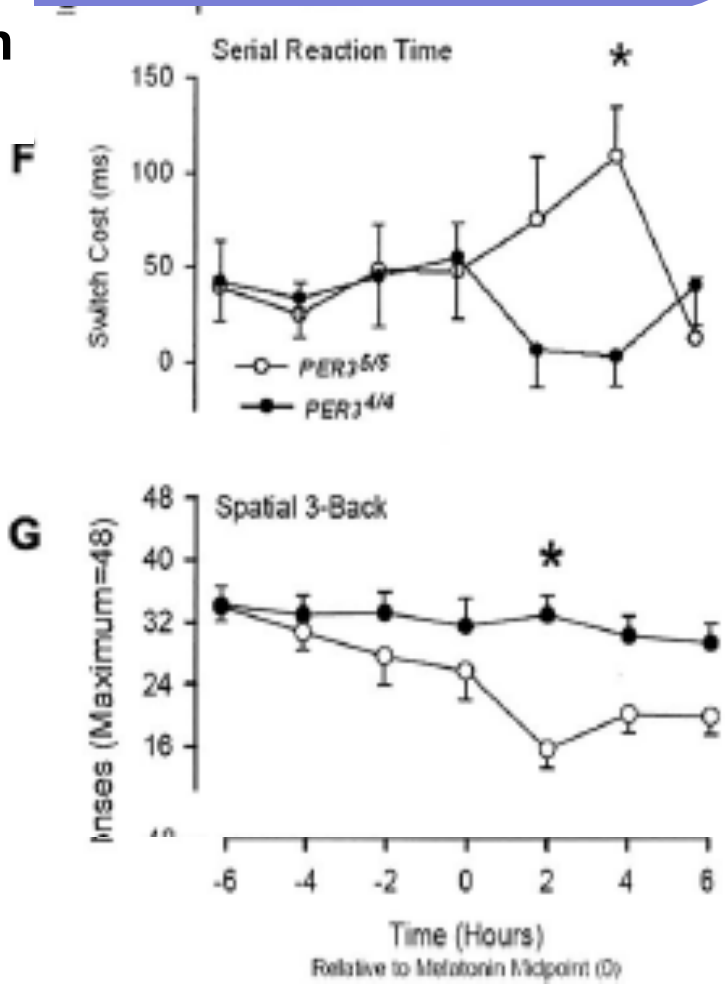
Inter-Individual Differences in Vulnerability to Sleep Loss

- 25% of study participants account for 67% of attentional failures
- Different individuals are susceptible to working memory impairment than are susceptible to reaction time slowing
- Relative differences in susceptibility persist whether sleep satiated or sleep restricted
- Performance after 16 – 18 hours of wakefulness also shows significant variability

Genetic Polymorphisms May Account for Differences after Sleep Loss

↑ Vulnerability to Sleep Deprivation
In $PER3^{5/5}$ vs. $PER3^{4/4}$

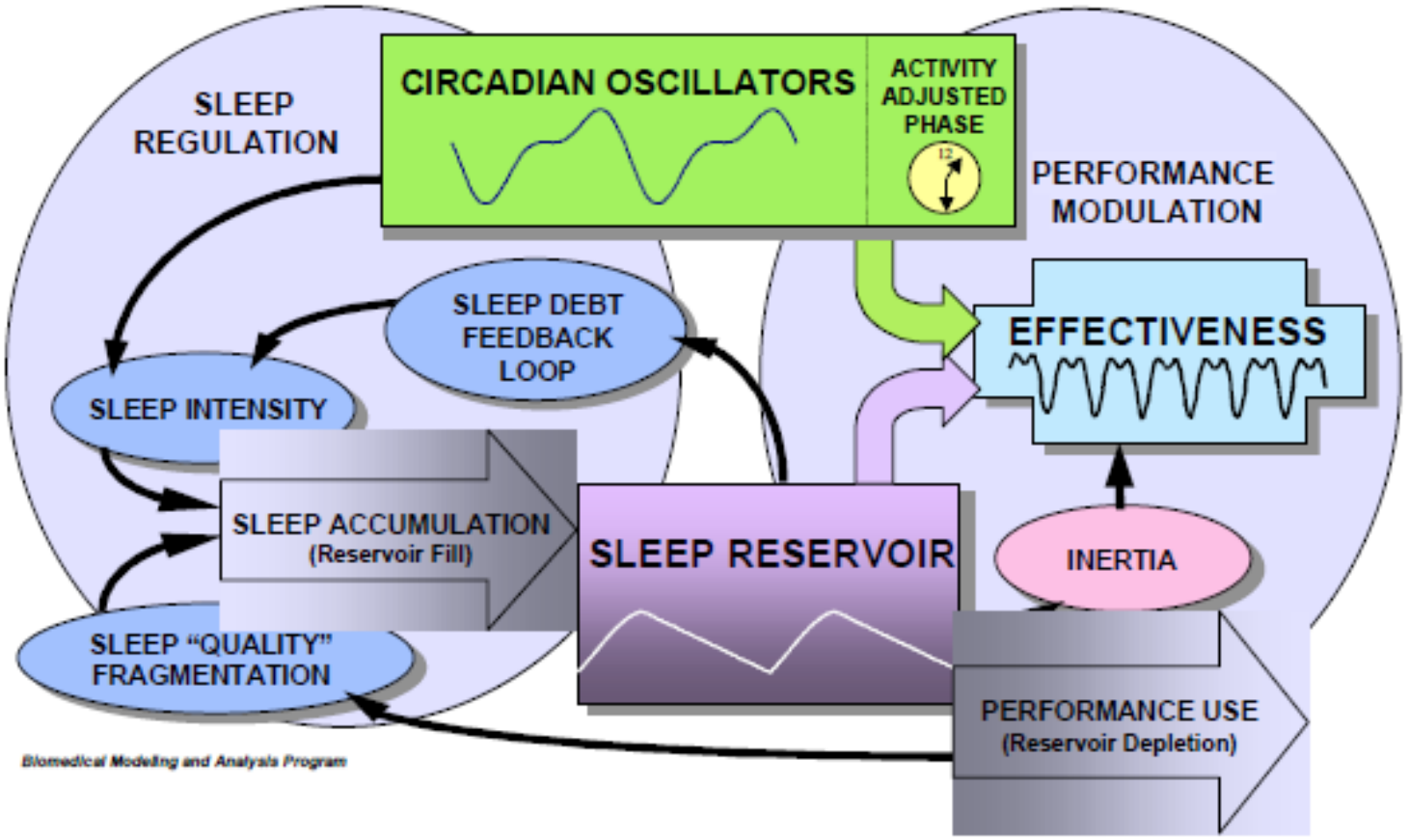




Haplotype of Adenosine A2A may be protective

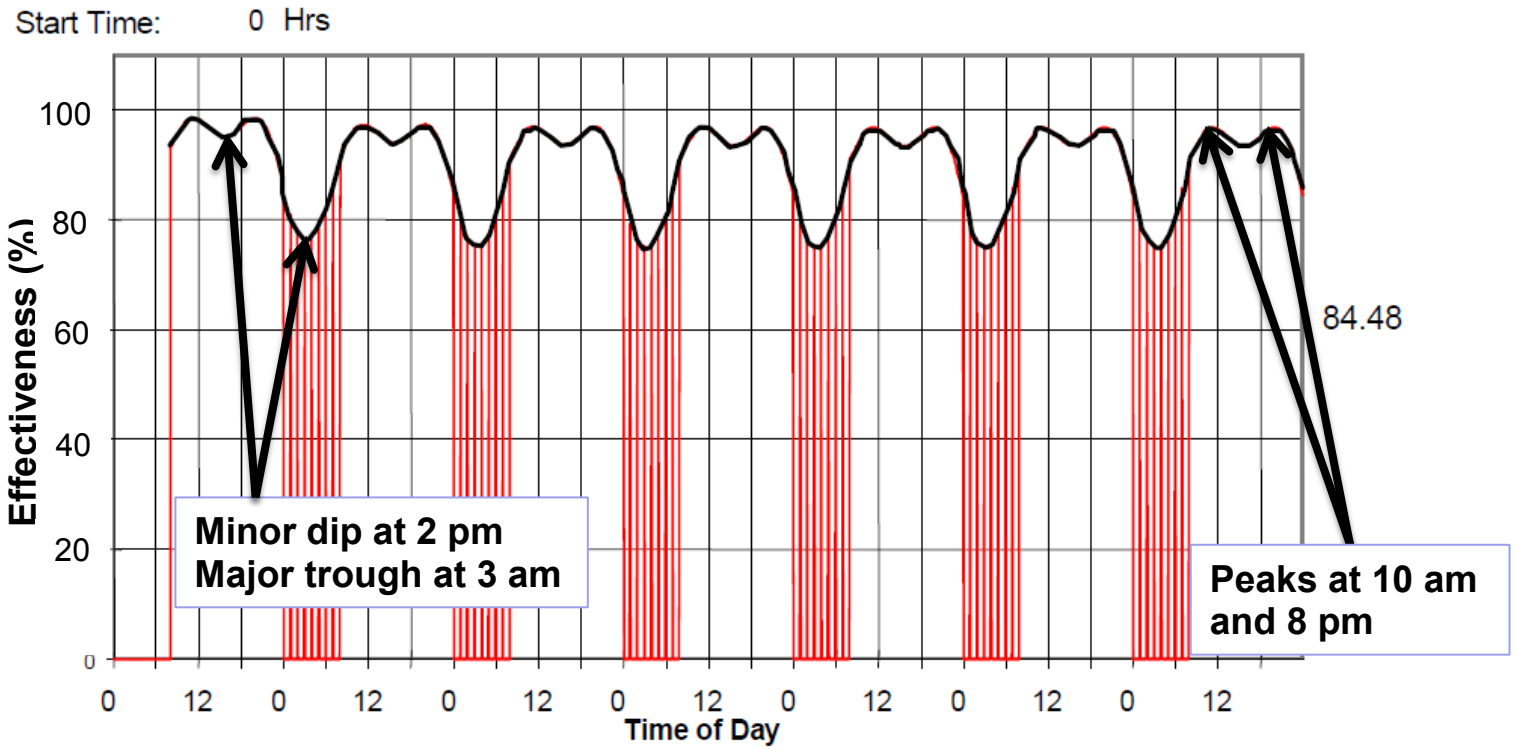
Viola et al, Curr Biol 2007
Groeger et al, Sleep 2008

Sleep, Activity, Fatigue and Task Effectiveness Model



The Fatigue Avoidance Scheduling Tool, Hursh et al, SAE International 2004

Expected Performance based on SAFTE



Assumes average person needs 8 h sleep / 24 h.

This pattern closely mimics actual performance as assessed experimentally, in timing of traffic accidents, and in dips in industrial productivity.

Myth of Acclimitization

- You can’t habituate or train yourself to need less sleep
  - You can sleep more efficiently (limited)
  - At 6 hours/night some people will not accumulate further sleep deficit

Surgeon Fatigue

- Orthopedic Residency
- Heavy workload rotations
  - Night float, trauma
  - 14-days of data collection
- Assessed with actigraphy and activity diary
  - Sleep Activity Fatigue and Task Effectiveness Model
  - Fatigue Avoidance Scheduling Tool

Surgeon Fatigue; McCormick, Arch Surg 2012

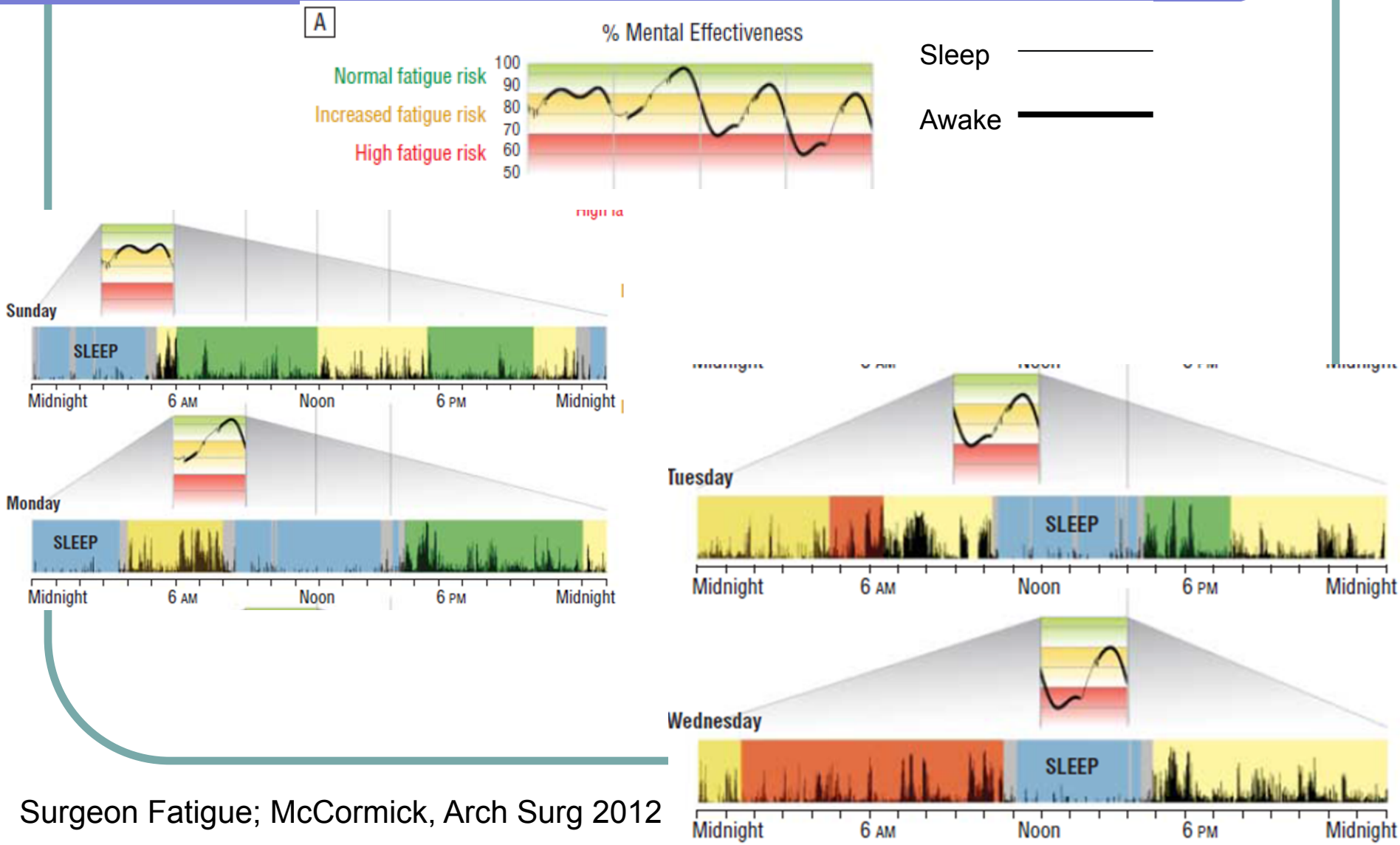
Surgeon Fatigue

Table. Calculation of the Dependent Variable Based on Actigraphy Watch Monitoring and Sleep, Activity, Fatigue, and Task Effectiveness Modeling

Variable	Group Mean (SD)	Individual Mean Range
Amount of daily sleep, h	5.3 (0.8)	3-7
Time awake at <80% mental effectiveness, %	48 (24)	20-88
Time awake at <70% mental effectiveness, %	27 (21)	0-74
Predicted risk of medical error, %	22 (10)	7-49

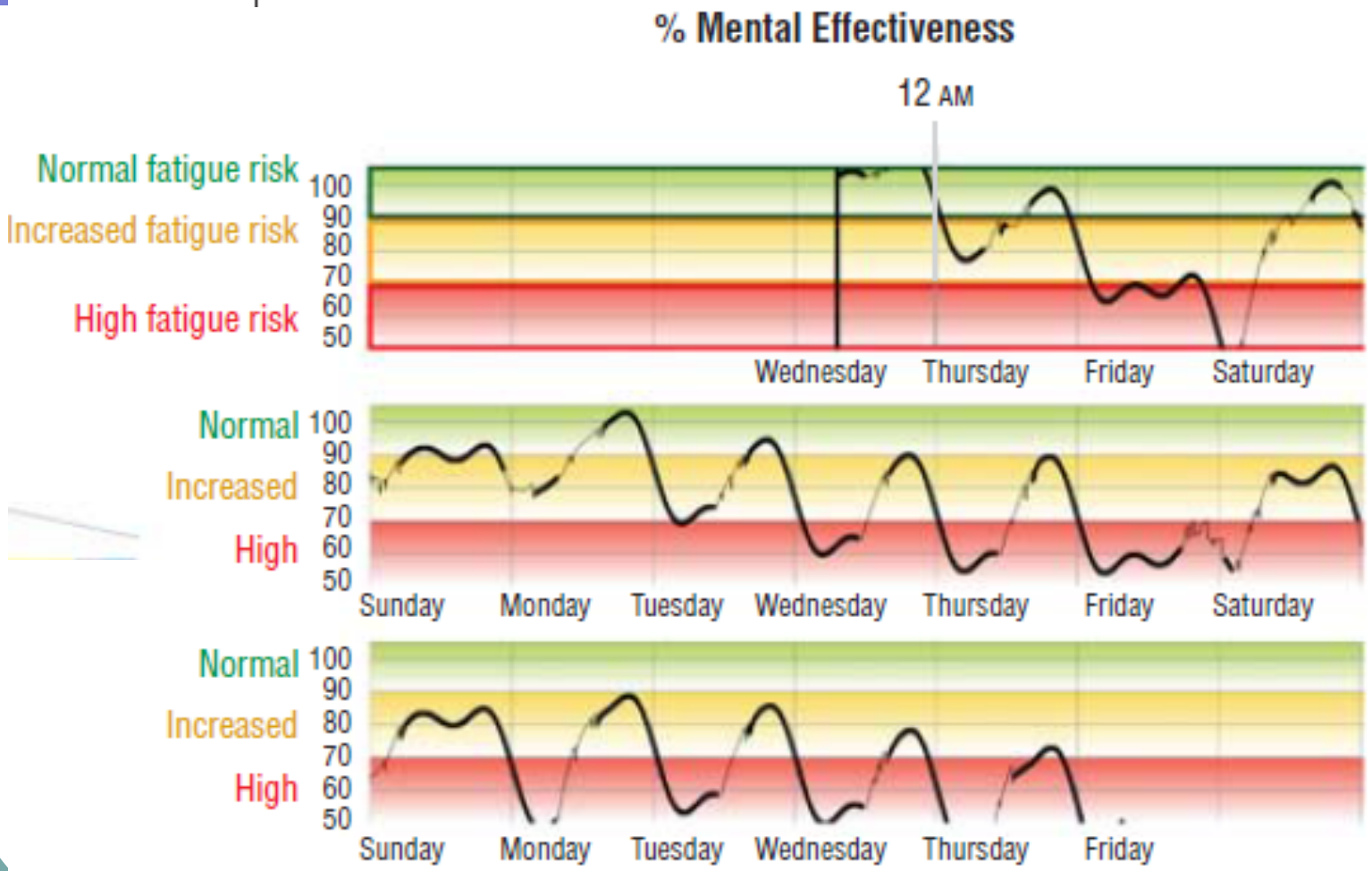
Surgeon Fatigue; McCormick, Arch Surg 2012

Transition to NF Associated with Severe Performance Decrement



Surgeon Fatigue; McCormick, Arch Surg 2012

Hard to Adjust to Night Schedule



Surgeon Fatigue; McCormick, Arch Surg 2012

Cumulative Effect of Sleep Deprivation on Resident Performance

- Crossover study
  - 34 pediatric residents, tested ~ 3 pm
  - Post call on “heavy call” rotation vs. “light call” rotation
  - HC given placebo drinks, LC given EtOH to achieve BAC 0.05

	7 days before testing		**24-h before testing**	
	Light Call (30)	Heavy Call (31)	Light Call (30)	Heavy Call (32)
Total Sleep Time (H)	6:38 (0:10)	5.32 (0:09)	6:07 (0:16)	3:02 (0:16)

Performance After Night Call and Alcohol Ingestion; Arnedt, JAMA 2005

Post Call Performance = BAC 0.05

- Heavy call worse performance
  - Reaction time 7 – 10% slower
  - Continuous Performance Test – 40 – 70% more errors of commission
  - Driving stimulation
    - Lane variability 13-27% higher
    - Speed variability 30% higher
    - More “off roads”
- Performed worse / no better than when intoxicated

Performance After Night Call and Alcohol Ingestion; Arnedt, JAMA 2005

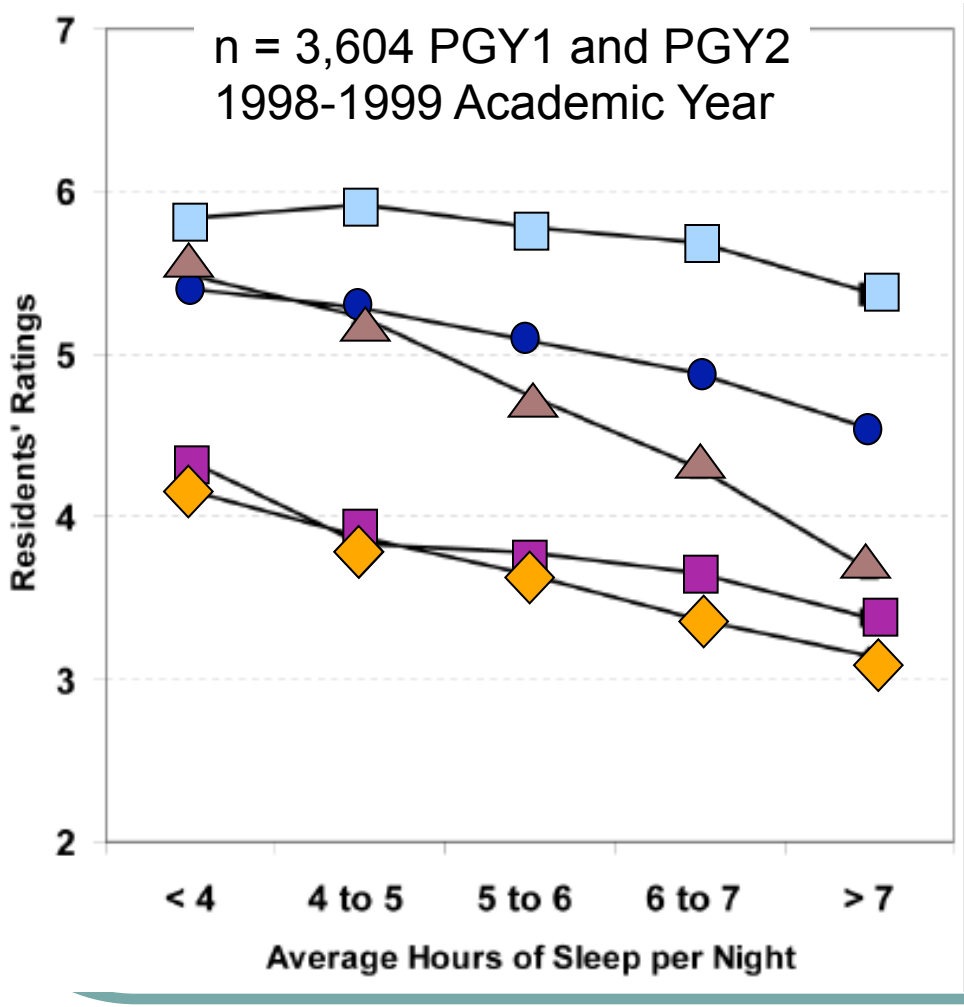
Possible Consequences of Sleep Deprivation in Residents

- Car accidents, needle sticks
- Missed educational opportunities
- Impairment in Physical Health
  - Increased alcohol use (hypnotic)
  - Stimulant medication abuse
  - Weight gain
  - DM
  - Hormone-sensitive malignancies
- Mental Health: depression, burn out

Possible Consequences of Sleep Deprivation in Residents

- Residents perform poorly in patient care scenarios or actual patient care (but the errors may be caught)
- Patients suffer – Mortality or Morbidity

Residents Self-Reported Effects of Sleep Deprivation

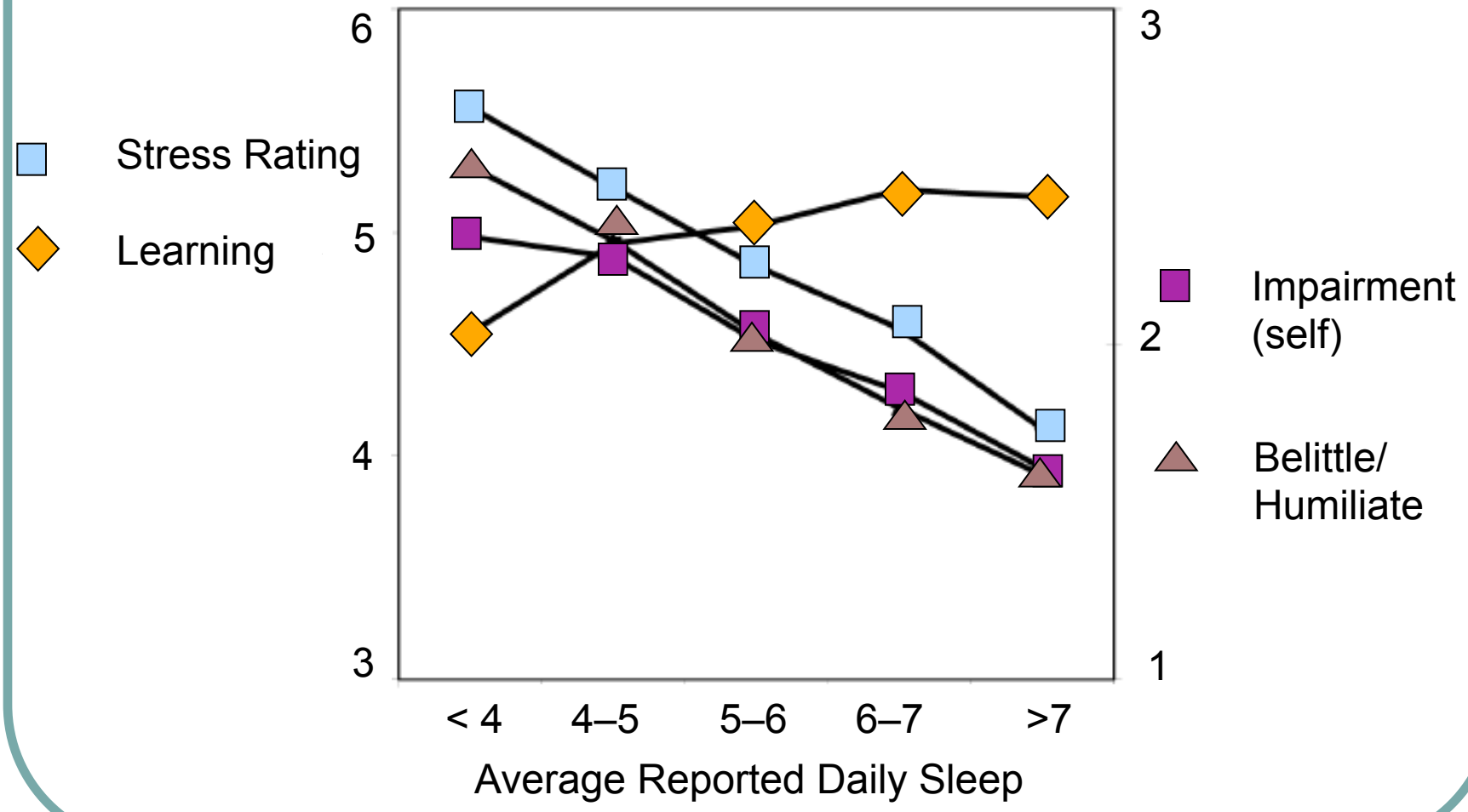


- Moodier, short tempered
- Impaired capacity to care for pts
- Work hours too long
- More conflicts with staff
- Misjudgments in pt care

Likert Scale:
1 strongly disagree
4 neither agree nor disagree
7 strongly agree

Baldwin, Sleep 2004

Self-Reported Sleep and Satisfaction with Work Environment



Baldwin, Sleep 2004

Self Reported Sleep and Adverse Outcomes

	Average Daily Hours of Sleep					
	< 4 (n=131)	4-5 (n=356)	5-6 (n=1560)	6-7 (n=808)	> 7 (n=380)	p-value
Medical Errors	45.0	34.6	26.7	22.4	20.9	<.0001
Adverse Pt Outcomes	10.7	5.7	4.8	3.8	3.8	.0003
Serious Conflict Nurse	15.5	10.7	9.5	6.6	5.5	<.0001
Sig Wt. Change	52.7	40.5	35.8	27.8	23.2	<.0001
Serious Accident/Injury	10.9	3.7	3.0	2.5	2.1	<.0001

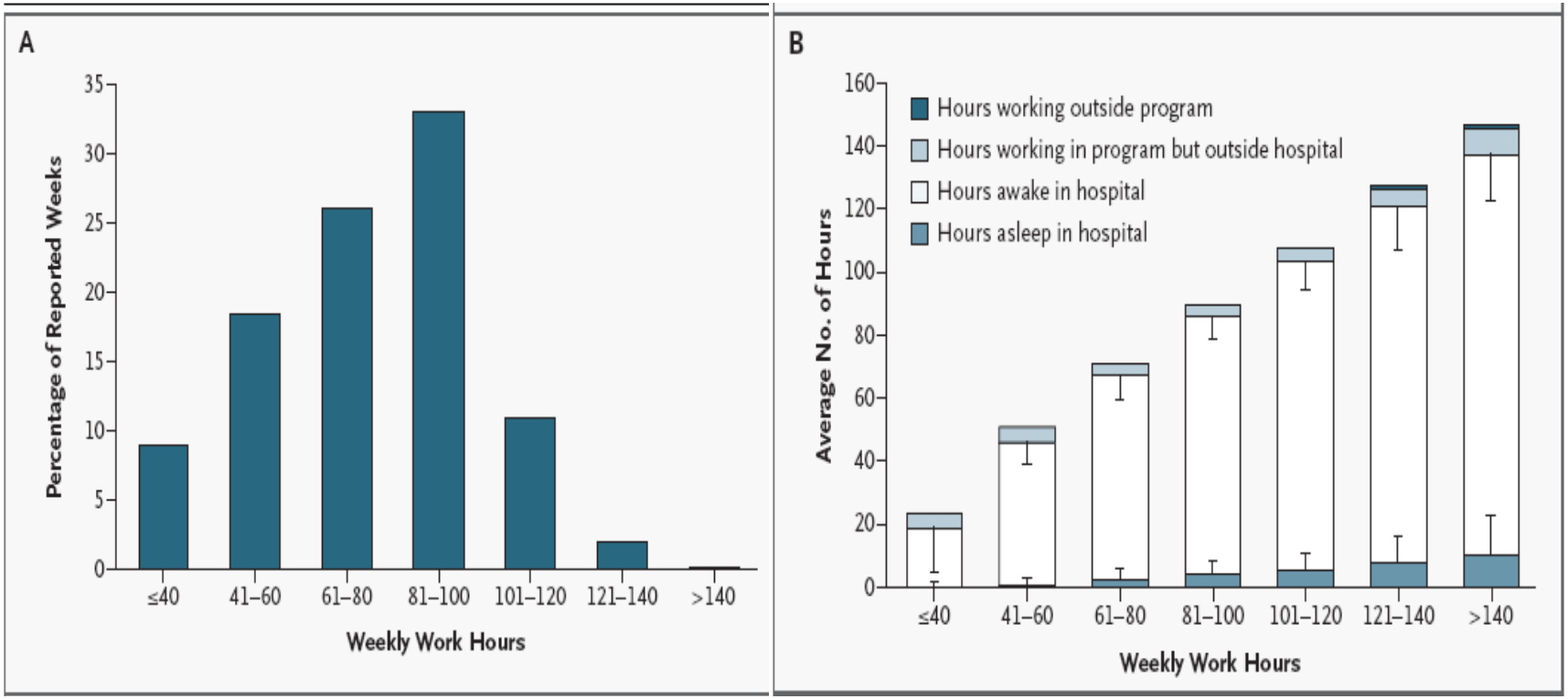
Baldwin, Sleep 2004

Impact of Extended Shifts

- 2737 Interns, 2002-2003 academic year
- Monthly web-based survey
  - Work hours, extended shifts = ≥ 24 h
  - Motor vehicle crash and “near misses”
    - Validated by police report, photo, written description
  - Involuntary sleep “incidents”
  - Subset validated hours with diary and direct observation, r = 0.98 for extended shifts
- Within person case-crossover analysis, and Poisson regression between # extended shifts and occurrence of crashes

Barger, NEJM 2005

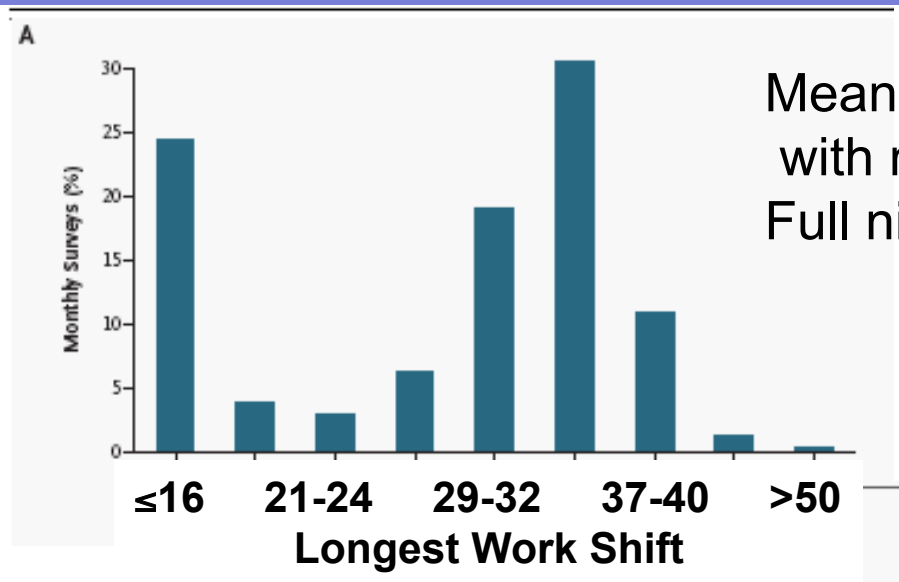
Prospective Risk of MVA in Interns: Work Hours



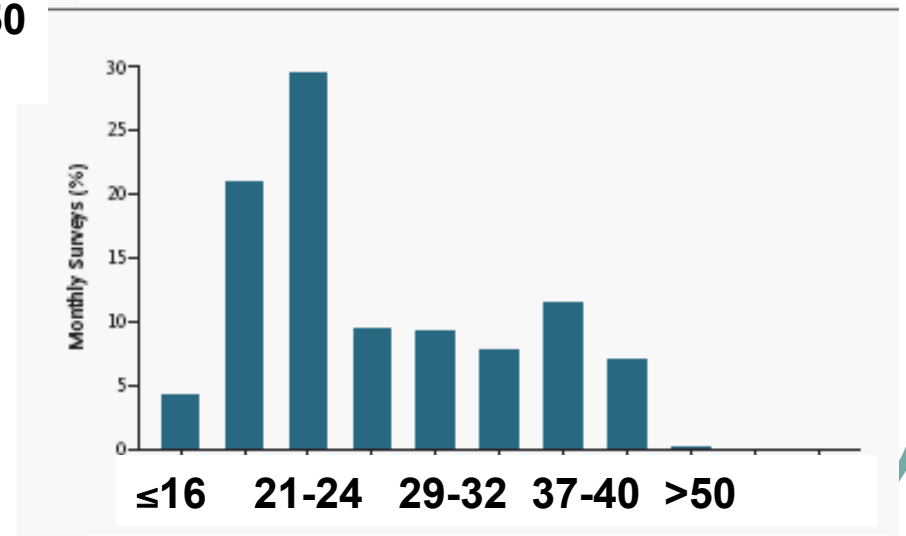
Mean work week 70.7 ± 26 hours, including 3.2 ± 4.2 hours of sleep.

Barger, NEJM 2005

Prospective Risk of MVA in Interns: Extended Shifts



Mean # of extended shifts 3.9 ± 3.4,
with mean duration 32.0 ± 3.7 h.
Full night float 7%, Some night float 7%



Barger, NEJM 2005

Prospective Risk of MVA in Interns

- 320 crashes in 17,003 person-months
  - 133 “consequential”
    - ER treatment, > $1000 damage, police report
  - 131 occurred on the commute home
- Risk after Extended Shift
  - Each extended shift/month increased monthly crash rate by 9.1%
  - Each extended shift/month increased risk of a commuting crash by 16.2%

Barger, NEJM 2005

Risk of Motor Vehicle Crashes and Near-Miss Incidents after Extended shifts

Variable	Extended Work Shifts (≥24 hr)	Nonextended Work Shifts (<24 hr)
Crashes		
No. reported	58	73
No. of commutes	54,121	180,289
Rate (per 1000 commutes)	1.07	0.40
Odds ratio (95% CI)	2.3 (1.6–3.3)	1.0
Near-miss incidents		
No. reported	1,971	1,156
No. of commutes	54,121	180,289
Rate (per 1000 commutes)	36.42	6.41
Odds ratio (95% CI)	5.9 (5.4–6.3)	1.0

Barger, NEJM 2005

Risk of Percutaneous Injuries

- Same web-based survey as the crash study (2002-2003 academic year)
  - 2,737 baseline and 17,003 monthly surveys
- Demographics
  - 53% women
  - mean age 28.0 (3.9)
  - 85% from US medical schools
  - 79% medical specialties, 11% surgical, 10% other/not specified

Ayas, N. T. et al. JAMA 2006;296:1055-1062.

Factors Reported by Interns to Have Contributed to Percutaneous Injuries

Contributing Factor	No. (%) Reporting
Lapse in concentration in you	286 (63.8)
Fatigue in you	139 (31.0)
Inadequate lighting	31 (6.9)
Patient movement	74 (16.5)
Leaving a sharp exposed	81 (18.1)
Passing a sharp to another	25 (5.6)
Recapping needle	23 (5.1)
Splashing fluid	0

*Based on 448 percutaneous injuries in which at least 1 contributing factor was reported. More than 1 factor could be associated with a single incident. Phrases are as stated in the survey.

Ayas, N. T. et al. JAMA 2006;296:1055-1062.

Percutaneous Injuries During Daytime Hours for Non-extended vs. Extended

	Non-Extended	Extended	
	Rate per 1000 Opportunities	Rate per 1000 Opportunities	**OR (95% CI)**
All Injuries	0.76 (0.54 – 0.98)	1.31 (0.88 – 1.75)	1.61 (1.46- 1.78)
Reported to OH	0.35 (0.2 – 0.49)	0.64 (0.34 – 0.94)	1.83 (1.48 – 2.28)
Injuries in ICU	0.46 (0.01-0.9)	0.80 (0.02 – 1.59)	1.87 (0.69 – 5.04)
OR, L&D	2.05 (1.25 – 2.85)	3.67 (2.14 – 5.21)	1.77 (1.49 – 2.09)
ICU, non-ICU, ED	0.21 (0.10 – 0.33)	0.45 (0.19 – 0.70)	2.17 (1.56 – 3.00)

Injuries between 6:30 am and 5:30 pm; extended work-shift length ≥ 32 h

Ayas, N. T. et al. JAMA 2006;296:1055-1062.

Percutaneous Injuries During Daytime (7:30 am – 3:30 pm) vs. Nighttime (11:30 pm – 7:30 am)

	Daytime Rate per 1000 Opportunities	Nighttime* Rate per 1000 Opportunities	OR (95% CI)
All Injuries	0.70 (0.61 – 0.79)	1.48 (1.19 – 1.79)	2.04 (1.98 – 2.11)
Reported to OH	0.31 (0.25 – 0.38)	0.50 (0.33 – 0.68)	1.59 (1.46 – 1.73)
Injuries in ICU	0.42 (0.20 – 0.63)	1.42 (0.70 – 2.17)	3.11 (2.32 – 4.19)
Injuries in OR	1.73 (1.39 – 2.09)	0.83 (0.34 – 1.32)	0.49 (0.40 – 0.59)
ICU, non-ICU, ED	0.18 (0.13 – 0.22)	0.88 (0.65 – 1.12)	5.13 (4.77 – 5.54)
Injuries in L & D	0.66 (0.29 – 1.04)	3.05 (1.33 – 4.77	4.39 (3.17 – 6.07)

*** Night float months excluded, but inclusion did not change results**

Ayas, N. T. et al. JAMA 2006;296:1055-1062.

Self-Reported Medical Errors and Extended Duration Shifts: Resident Perception

	0 Shifts	**1 - 4**		**≥ 5**	
	+ve / Person-Mon	+ve / Person-Mon	OR 95% CI)	+ve / Person-Mon	OR 95% CI)
Sleep Deprivation	125 / 3,323	327 / 3,329	**3.5 (3.3 -3.7)**	1,153 / 7,355	**7.5 (7.2-7.8)**
Adv. Out.	7 / 3,232	38 / 3,329	**8.7 (3.4-22)**	118 / 7,355	**7.0 (4.3-11)**
Fatality	3 / 3,205	8 / 3,040	**3.2 (0.1-106)**	23 / 6,325	**4.1 (1.4-12)**
No Sleep Deprivation	213 / 3,326	264 / 3,329	1.05 (1-1.1)	670 / 7,345	1.4 (1.4-1.5)
Adv. Out.	33 / 3,326	45 / 3,329	1.1 (0.9-1.3)	99 / 7,345	1.05 (0.9-1.2)
Fatality	8 / 3,145	13 / 3,109	0.8 (.4-1.6)	21 / 6,773	1.3 (0.6-2.7)

Barger et al, PLOS Medicine 2006

Impact of Duty Hours on Learning

- Prospective single center surgical program
  - Data collected before ACGME requirements and 1 year after
  - Time cards to quantify day-to-day activities
  - Web-based survey – QOL, Maslach Burnout Inventroy
  - Interviews with PhD investigator
  - Quantitative Data

Hutter 2006, Annals of Surgery 243:864

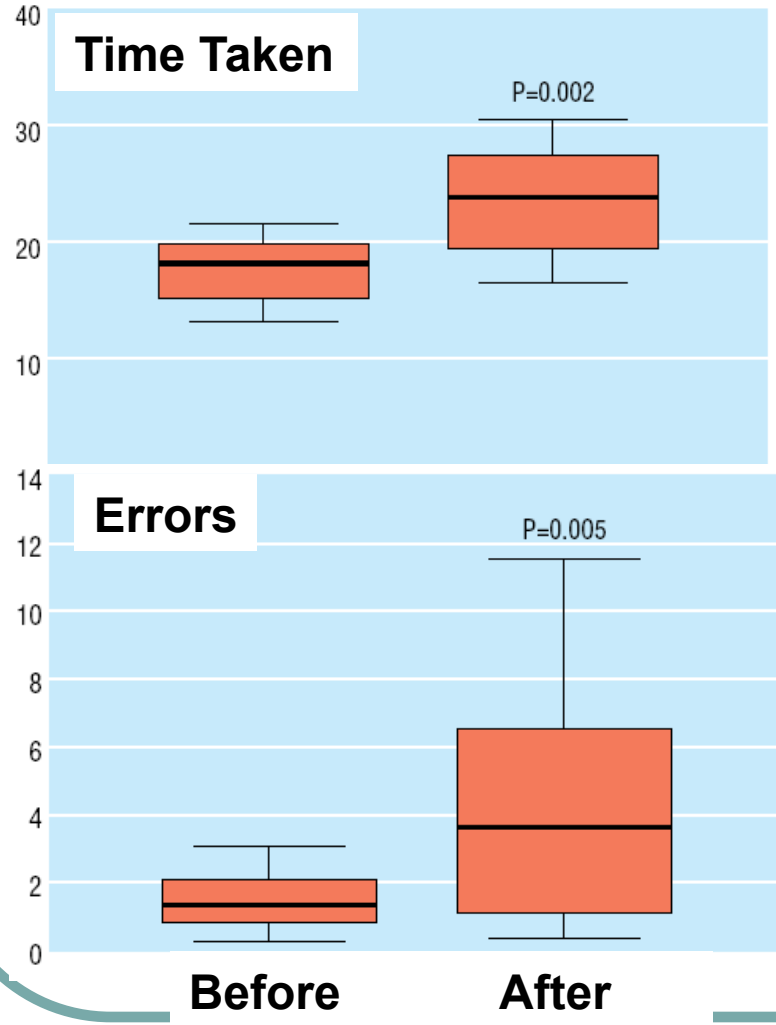
Impact of Duty Hours on Surgical Residents and Attendings

Resident Perceptions	Before	After	P value
Eat Lunch %	56	65	0.04
Time in Conf. (min)	13.3	21.3	0.00
Days in outpt. Office (%)	13	7	0.03
In OR before pt. asleep (#/d)	2.16	1.68	0.00
Emotional exhaustion	29.1 (high)	23.1 (med)	0.02

Attending Perceptions	Before	After	P value
Technical Skill	3.75	2.70	< 0.01
Clinical judgment	3.67	2.40	<0.01
Sense of responsibility	3.50	2.32	<0.01
Preparedness for cases	3.63	2.40	<0.01
Efficiency	3.57	2.51	<0.01

Hutter 2006, Annals of Surgery 243:864

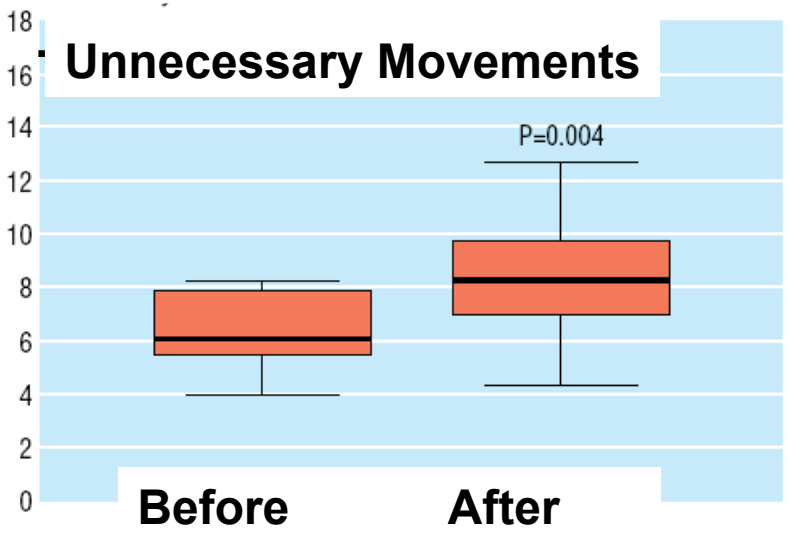
Laproscopic Performance after Night Shift



14 surgical trainees, mean PGY6

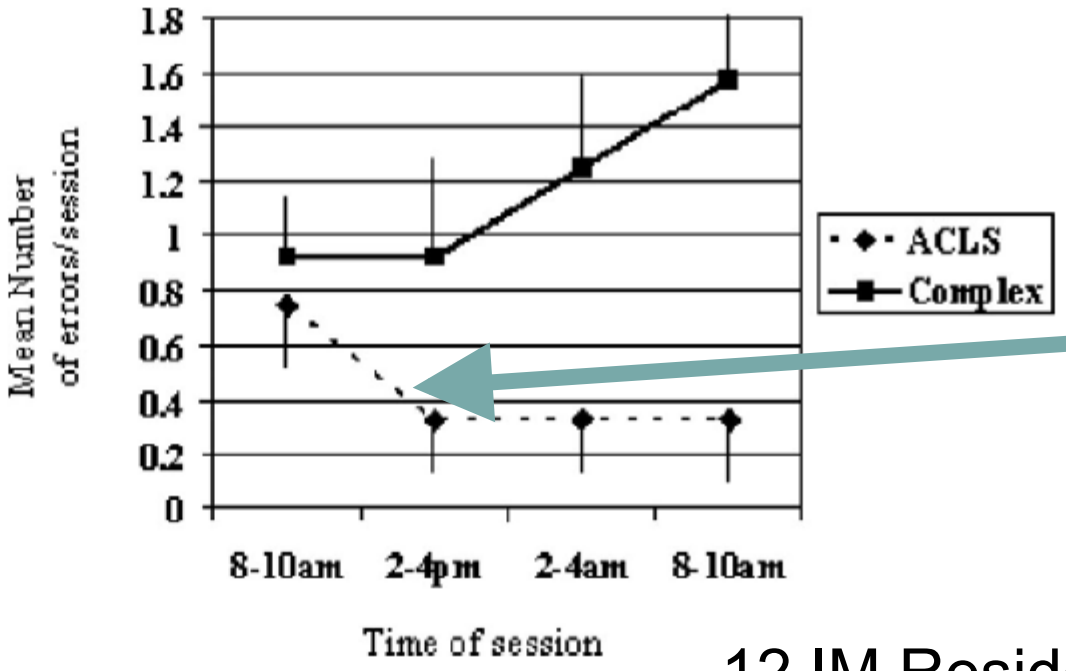
Shift 3:30 pm - 9 am, mean sleep on call 1.5 h. Tested at 9:30 am.

Previously performed 10 times on minimally invasive surgical trainer simulator



Grantcharov, BMJ 2001

Extended Shift Effect on ICU Simulation



Training Effect

12 IM Residents
ACLS scenarios repeated.
Complex patient scenarios were all different.

Sharp et al, CCM 2010

Impact on Education

- Resident survey before after duty hour rules in 76 programs at 2 large hospitals
  - 60% response rate
- “Reduced Hours” group - 13 programs
  - Mean weekly hours > 65 in 2003
  - Dropped by at least 5 hours/week in 2004

Jagsi, 2006; Acad Med 81:1059

Impact on Education

	Reduced Hours (N = 420)			Other Group (N = 1350)		
	2003	**2004**	**Change**	**2003**	**2004**	**Change**
% > 80h in last wk	43	16.9	-26.1	13.4	8.9	-4.6*
% > 30 shift	39.5	12.1	-27.4	11.5	4.8	-6.8*
Hours on duty	76.1	67.1	-9	61.5	60.9	-0.6*

Jagsi, 2006; Acad Med 81:1059

Impact on Education

- No change in “Reduced Hours” group in
  - Number of patients admitted
  - Number of procedures performed
  - Slight increase in number of patients cross-covered
- Most measures of educational quality and adequacy stable
  - Faculty teaching “good or excellent” declined from 98.5% to 96.2%
  - Opportunity to perform research increased from 53.8% to 67.6%

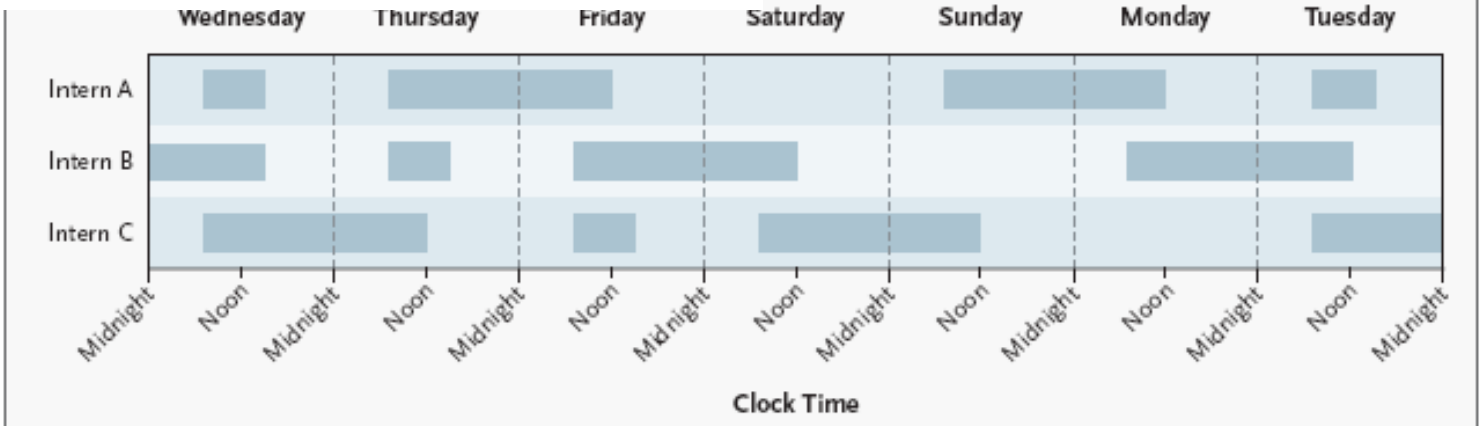
Jagsi, 2006; Acad Med 81:1059

Clinical Trial on Reducing Work Hours

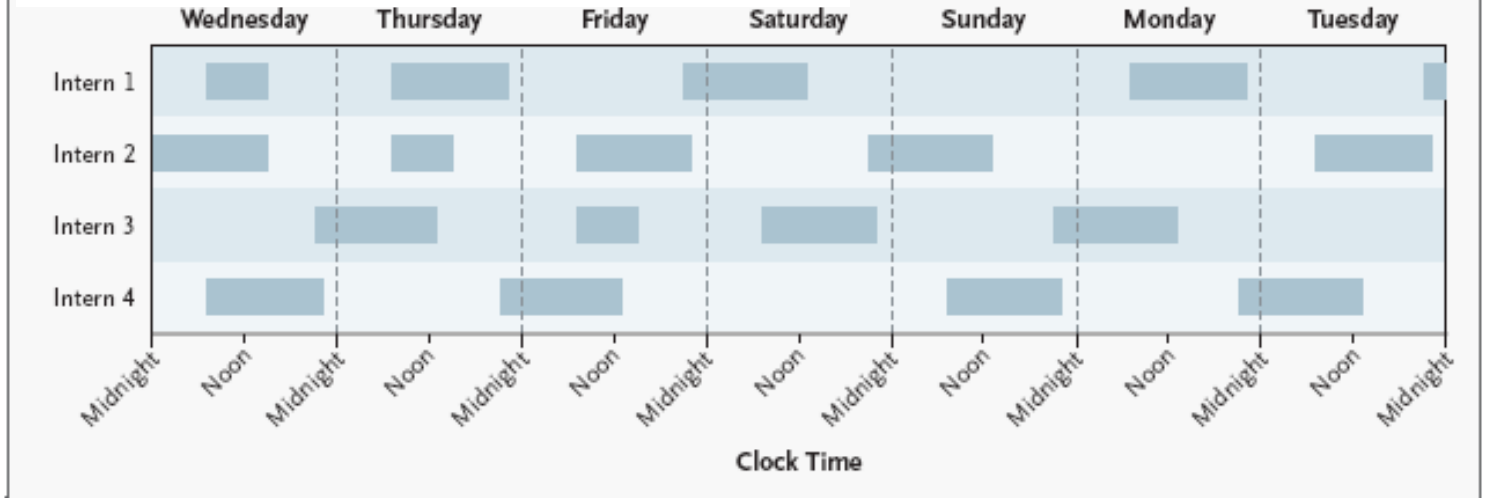
- Hypothesis: Eliminating extended work shifts would ↑ sleep and ↓ attentional failures
- 20 interns, mean age 28, within subject comparison during 3 week rotations in 10-bed ICUs
  - Traditional, q 3d call, max 30 h/shift
  - Intervention, max 16 h shift – required a 4th intern
  - Sign-out template
- Work hour log, direct observation by study staff
- Sleep log; continuous ambulatory PSG 3 days/week
- Medical errors identified by multidisciplinary approach
  - Independently rated by 2 physicians unaware of intern's schedule

Scheduled Work Hours

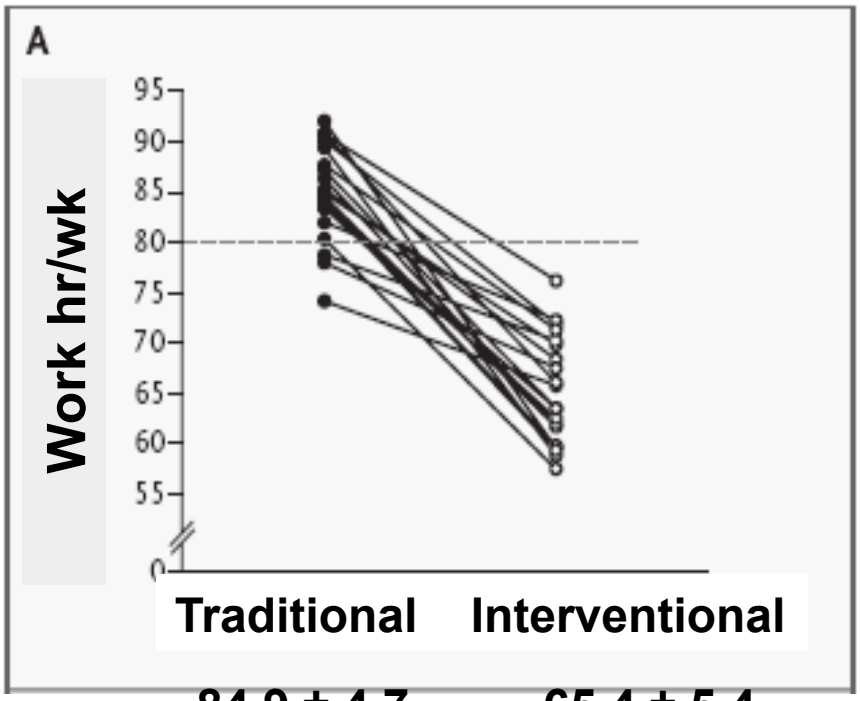
Traditional Schedule – 3 Interns



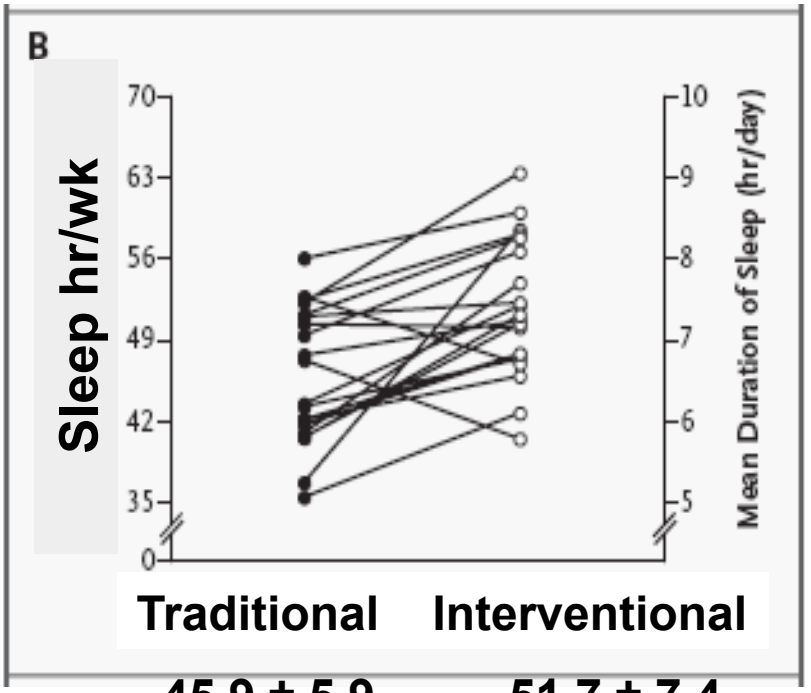
interventional Schedule – 4 Interns



Work and Sleep Hours: Traditional vs. Interventional



84.9 ± 4.7 **65.4 ± 5.4**

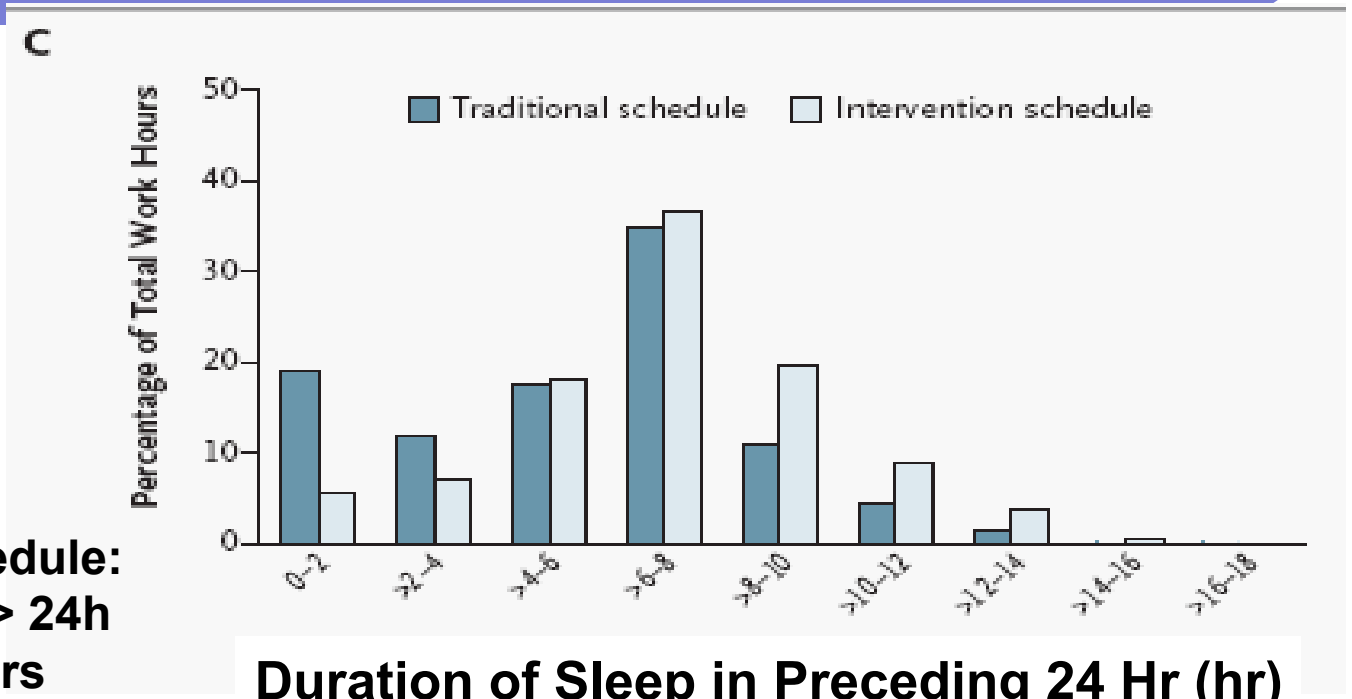


45.9 ± 5.9 **51.7 ± 7.4**

Sleep hours and work hours significantly correlated: r = -0.57, p < 0.001
Predicted loss of 19.2 min of sleep/week for each additional hour of work

Lockley 2004, NEJM 351: 1829

Shift Length and Prior Sleep



Traditional Schedule:

- **60% of shifts > 24h**
- **84% of work hrs during extended shifts**

Shift to q4 D call would improve total hours and ↓ percentage of extended shifts, but most of work would still occur in these shifts.

Lockley 2004, NEJM 351: 1829

Incidence of Serious Medical Errors Made by Interns

Variable	Traditional Schedule	Intervention Schedule	P Value
	no. of errors (rate/1000 patient-days)		
Serious medical errors made by interns			
Serious medical errors	176 (136.0)	91 (100.1)	<0.001
Preventable adverse events	27 (20.9)	15 (16.5)	0.21
Intercepted serious errors	91 (70.3)	50 (55.0)	0.02
Nonintercepted serious errors	58 (44.8)	26 (28.6)	<0.001
Types of serious medical errors made by interns			
Medication	129 (99.7)	75 (82.5)	0.03
Procedural	11 (8.5)	6 (6.6)	0.34
Diagnostic	24 (18.6)	3 (3.3)	<0.001
Other	12 (9.3)	7 (7.7)	0.47

Landrigan 2004; NEJM 351:38

All Serious Medical Errors Unit-wide

Table 3. Incidence of Serious Medical Errors.

Variable	Traditional Schedule	Intervention Schedule	P Value
	no. of errors (rate/1000 patient-days)		
All serious medical errors, unit-wide			
Serious medical errors	250 (193.2)	144 (158.4)	<0.001
Preventable adverse events	50 (38.6)	35 (38.5)	0.91
Intercepted serious errors	123 (95.1)	63 (69.3)	<0.001
Nonintercepted serious errors	77 (59.5)	46 (50.6)	0.14
Types of serious medical errors, unit-wide			
Medication	175 (135.2)	105 (115.5)	0.03
Procedural	18 (13.9)	11 (12.1)	0.48
Diagnostic	28 (21.6)	10 (11.0)	<0.001
Other	29 (22.4)	18 (19.8)	0.45

Landrigan 2004; NEJM 351:38

Trial of Schedule Change to Reduce Attentional Failures and Medical Errors

- Interventional schedule did not
  - Reduce orders written by interns
  - Reduce procedures done by interns
  - Shift work to senior staff
- Sign-out was “suboptimal”
  - Drazen editorial commented that interns did not know patients well
- Interns and residents had different shifts
  - May have interfered with education/bonding
- Impossible to blind Medical Observers

Landrigan 2004; NEJM 351:38

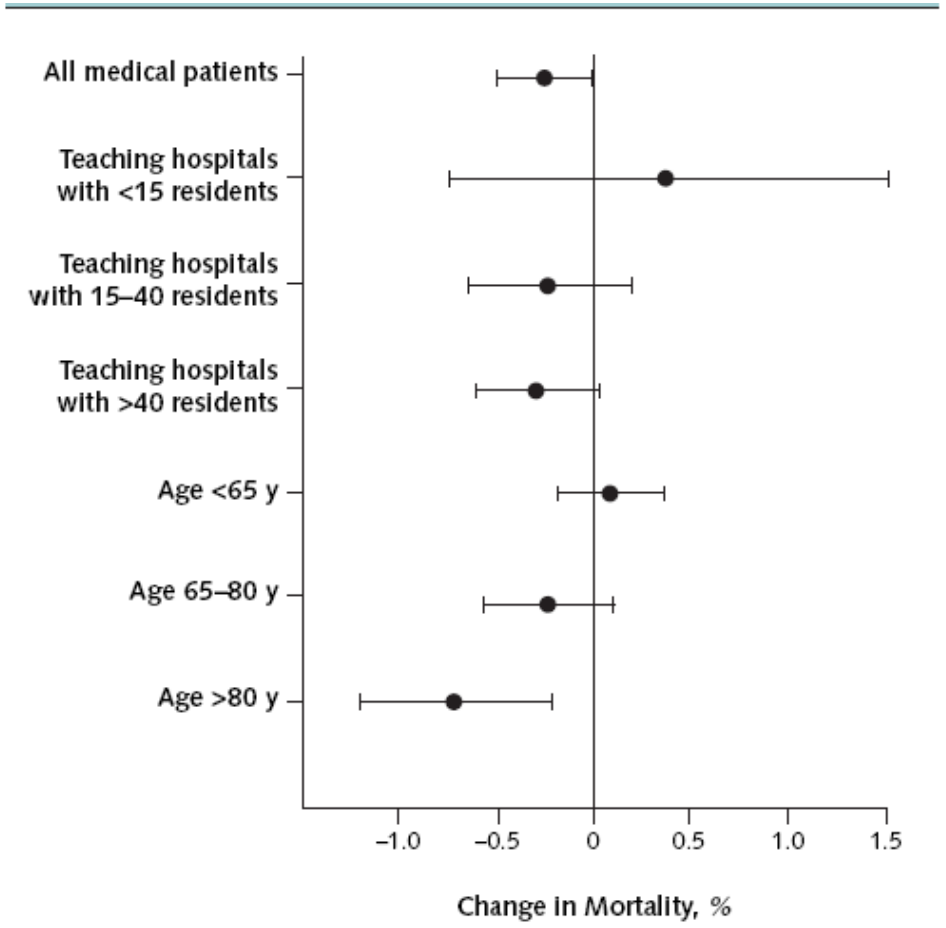
Impact of Duty Hours on Patient Mortality

- 551 US community hospitals
  - Classified as teaching or not based on residency program at the hospital
- 1,511,945 admissions for 20 medical and 15 surgical diagnoses
  - Compared Jan01-Jun03 with July03-Dec04
- “Difference-in-differences” approach between teaching and nonteaching hospitals

Shetty 2007; Annals Intern Med 147:73

Impact of Duty Hours on Patient Mortality: Medical Patients

- -0.25% absolute change in mortality
- -3.75% relative change in mortality

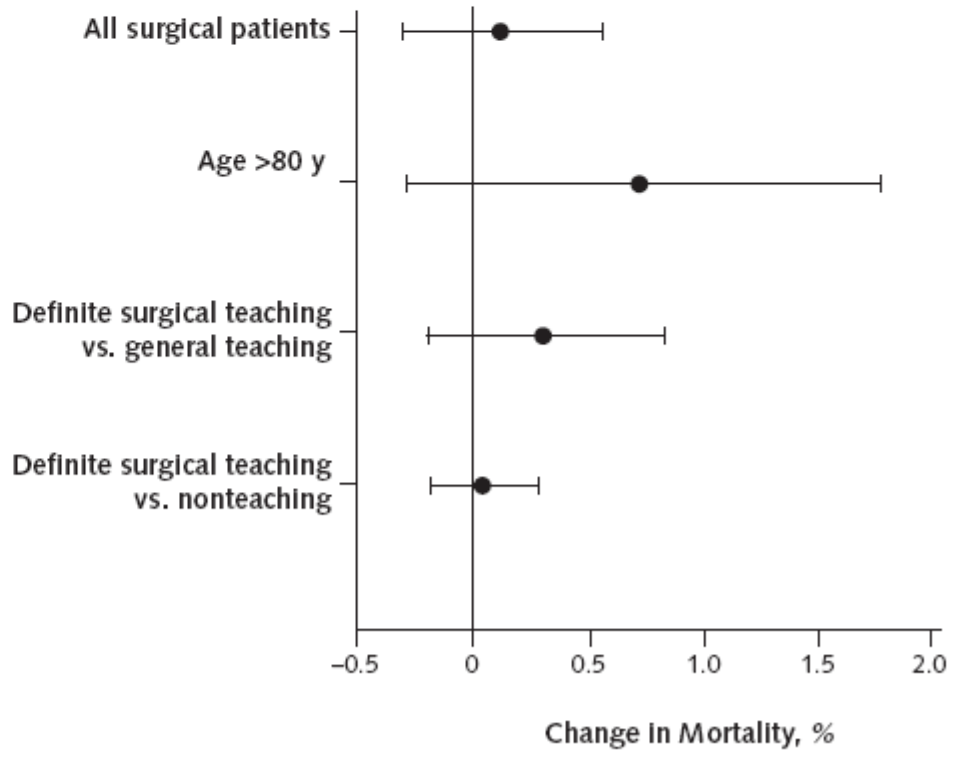


Shetty 2007; Annals Intern Med 147:73

Impact of Duty Hours on Patient Mortality: Surgical Patients

- 0.13% absolute change in mortality
- 3.77% relative change in mortality

Figure 2. **Changes in mortality among surgical patients.**



Shetty 2007; Annals Intern Med 147:73

Impact of Duty Hours on Patient Mortality: Limitations

- Patients classified on basis of hospital – no ability to determine if residents actually involved in care
  - Better outcomes due to hospitalists
  - Long term deleterious effects if residents get insufficient experience and skills
- Unclear why different results in medical and surgical patients
  - More limited ability to increase providers?
- In-hospital mortality only

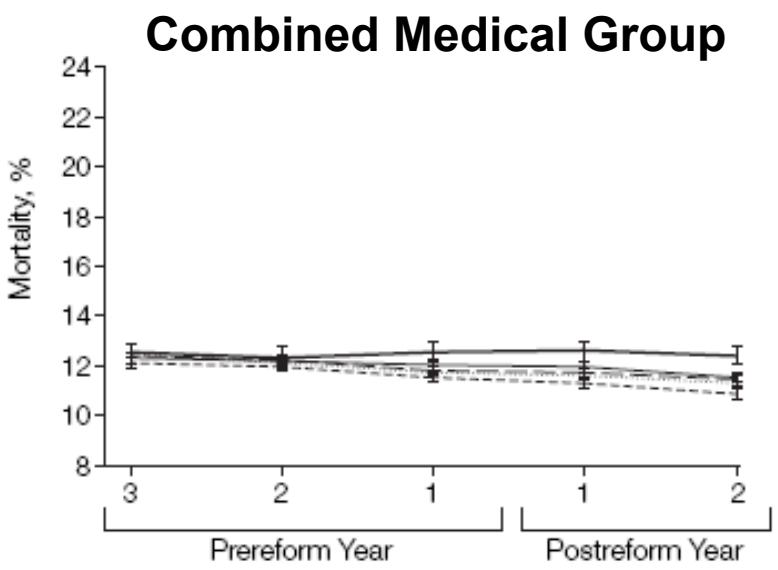
Shetty 2007; Annals Intern Med 147:73

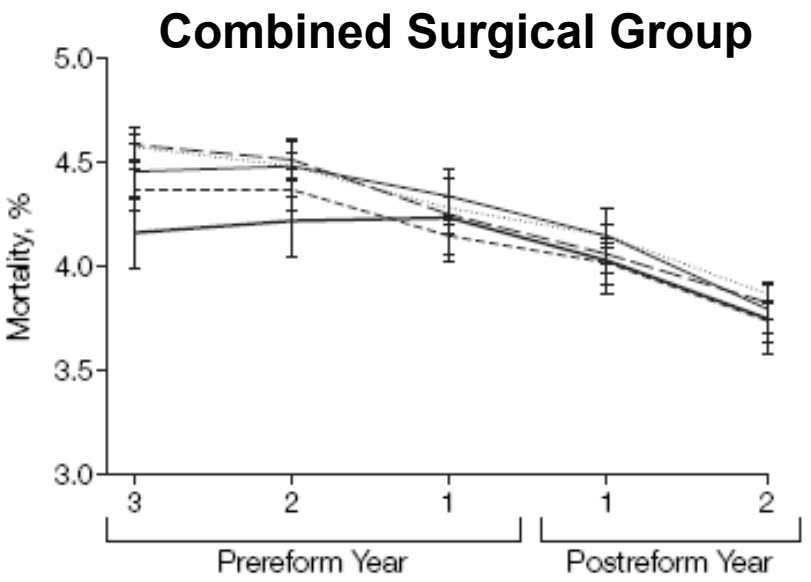
Mortality: Medicare Patients

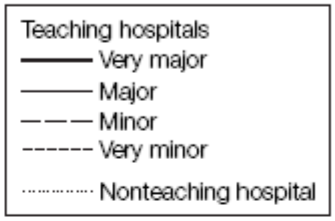
- Huge study
  - 8,529,595 admissions
  - 3321 hospitals
- Diagnoses
  - CHF, MI, GI bleed, Stroke
  - General, Ortho, or Vascular Surgery
- Classified hospitals as more vs. less teaching
- In-hospital or 30 day post admission deaths

Volpp 2007; JAMA 298: 975

Mortality: Medicare Patients







No Worsening or Improvement In Mortality.

Volpp 2007; JAMA 298: 975

FIRST Trial

- Flexibility In duty-hour Requirements for Surgical Trainees
- Randomized, cluster design
  - 118 general surgical residency programs with 154 hospitals
  - Stratified by death/serious complication rates
- 80 hours/week, call q3, 1 day off in 7
  - Waived maximal shift length and time off between shifts -> facilitate continuity

Bilimoria, NEJM 2016; 374:713-727

FIRST Trial

Table 1. Duty-Hour Requirements and Adherence Rates According to Study Group.*

Requirement Category	Standard-Policy Group		Flexible-Policy Group	
	Standard ACGME Policies	Adherent Programs†	Policies‡	Adherent Programs†
		no. (%)		*no. (%)*
Maximum shift length	PGY 1 (interns): Duty periods may not exceed 16 hr	59 (100)	PGY 1 (interns): Duty periods can exceed 16 hr	58 (100)
	PGY 2–5 (residents): Duty periods may not exceed 28 hr (24 hr plus 4 hr for transition)	59 (100)	PGY 2–5 (residents): Duty periods can exceed 28 hr (24 hr plus 4 hr for transition)	49 (84)
Minimum time off between shifts	Residents must have ≥8 hr off between shifts but should have 10 hr off between shifts	59 (100)	Residents are not required to have ≥8–10 hr off between shifts	47 (81)
	Residents must have ≥14 hr off after 24 hr of continuous duty	57 (97)	Residents are not required to have ≥14 hr off after 24 hr of continuous duty	51 (88)

Bilimoria, NEJM 2016; 374:713-727

FIRST Trial: Methods

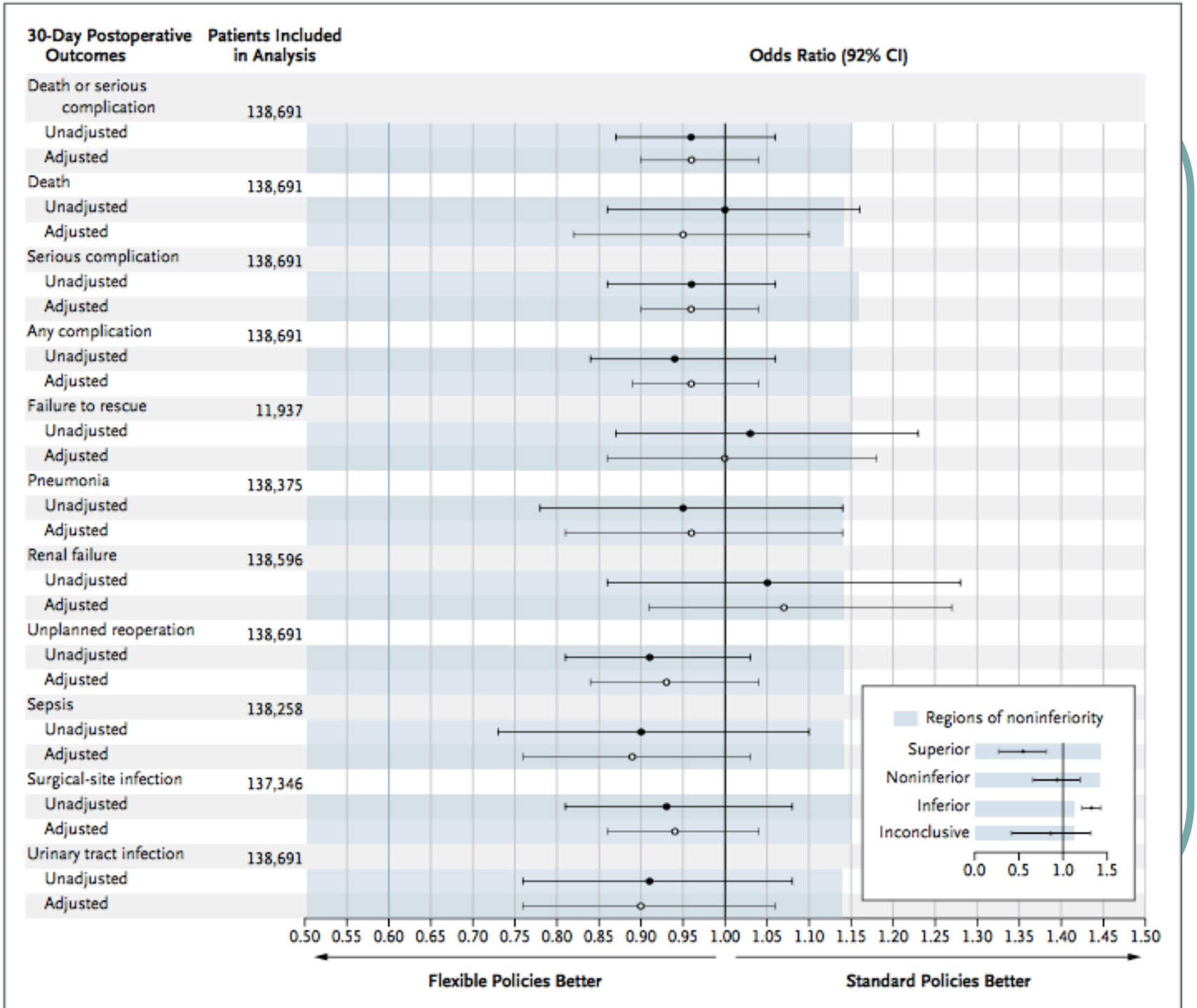
- Primary Outcomes
  - 30-day post-operative death/serious complication rate from ACS NSQIP
  - Resident outcomes
    - Satisfaction with quality of resident education and overall well being
    - Breaks in continuity of care
- Non-inferiority Trial
  - Absolute difference of 1.25% in 30-day rate

Bilimoria, NEJM 2016; 374:713-727

FIRST Trial: Results

- Mix of academic, community and military hospitals
- No significant differences in program or patient characteristics at baseline

Bilimoria, NEJM 2016; 374:713-727


30-Day Postoperative Outcomes
Patients Included in Analysis
Odds Ratio (92% CI)
Death or serious complication
138,691
Unadjusted
Adjusted
Death
138,691
Unadjusted
Adjusted
Serious complication
138,691
Unadjusted
Adjusted
Any complication
138,691
Unadjusted
Adjusted
Failure to rescue
11,937
Unadjusted
Adjusted
Pneumonia
138,375
Unadjusted
Adjusted
Renal failure
138,596
Unadjusted
Adjusted
Unplanned reoperation
138,691
Unadjusted
Adjusted
Sepsis
138,258
Unadjusted
Adjusted
Surgical-site infection
137,346
Unadjusted
Adjusted
Urinary tract infection
138,691
Unadjusted
Adjusted
Regions of noninferiority
Superior
Noninferior
Inferior
Inconclusive
0.0 0.5 1.0 1.5
0.50 0.55 0.60 0.65 0.70 0.75 0.80 0.85 0.90 0.95 1.00 1.05 1.10 1.15 1.20 1.25 1.30 1.35 1.40 1.45 1.50
Flexible Policies Better
Standard Policies Better

FIRST Trial: Results

- No difference in perception of quality of education or overall well being
- Flexible:
  - less likely dissatisfied with continuity of care, OR 0.44 (0.32 – 0.6), $p < 0.001$
  - More likely dissatisfied with time for rest, OR 1.41 (1.06 – 1.89), $p = 0.02$
  - Less likely to leave operation 7.0 vs. 13.2%
  - Less likely to hand off active issue 32 vs. 46%

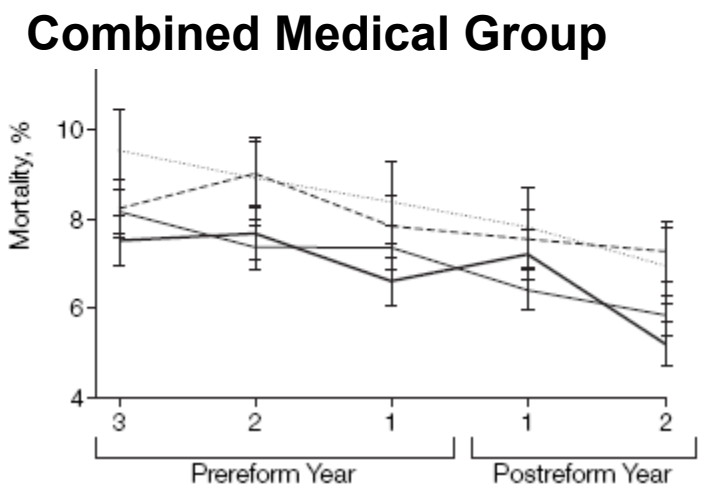
Bilimoria, NEJM 2016; 374:713-727

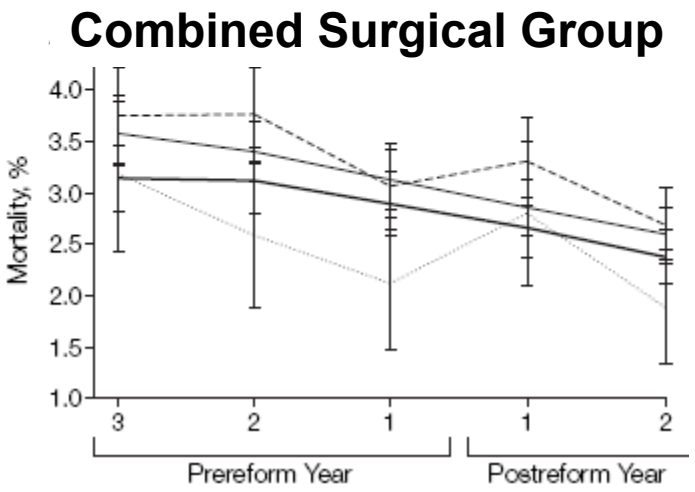
Mortality: VA Patients

- Identical study design, same authors
  - 318,636 admissions
  - 131 hospitals
- Diagnoses
  - CHF, MI, GI bleed, Stroke
  - General, Ortho, or Vascular Surgery
- Classified hospitals as more vs. less teaching
- In-hospital or 30 day post admission deaths

Volpp 2007; JAMA 298: 984

Mortality: VA Patients





Resident-to-Bed Ratio
- Quartile 1 (0-0.071)
- Quartile 2 (0.072-0.420)
- Quartile 3 (0.421-0.654)
- Quartile 4 (≥0.655)

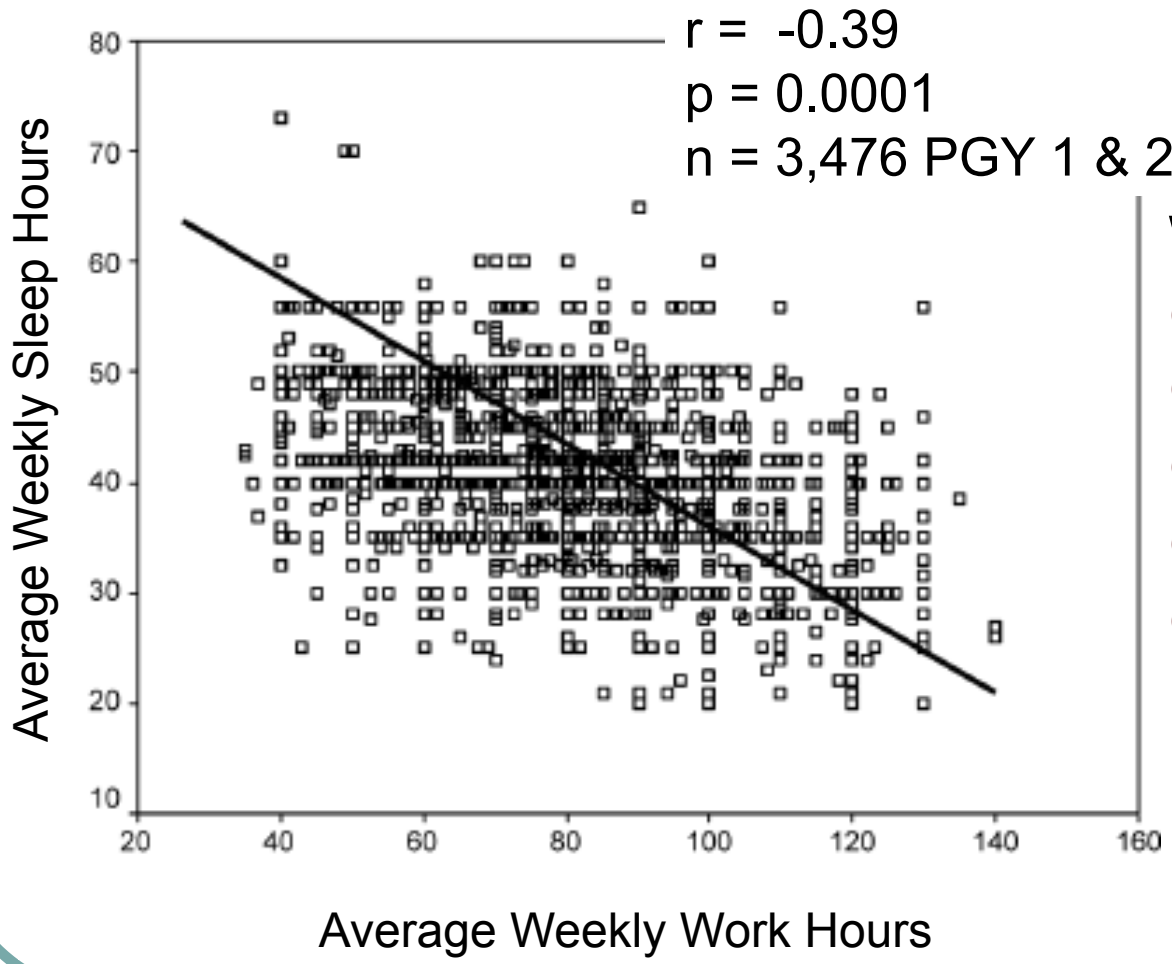
Medical mortality improved in teaching hospitals in year 2.
No change in surgical mortality.

Volpp 2007; JAMA 298: 984

Why Haven't Duty Hours Impacted Patient Mortality?

- Ability to compare patients cared for by residents vs. other staff is limited in these studies
- Change in rules may not have changed sleep times
  - Most programs still have lots of extended shifts
- Resident errors are caught because of supervision
- Competing effects: better rested but more handoffs
- Sleep deprivation doesn't matter (doubt this)

Self-reported Work and Sleep Hours



Weak Correlation

- Retrospective
- Call schedules
- Call intensity
- Individual need
- Choices

Baldwin, Sleep 2004

Duration of Interns' Reported Work and Sleep, Preimplementation vs Postimplementation of the ACGME Duty Hour Standards

Table 4. Duration of Interns' Reported Work and Sleep, Preimplementation vs Postimplementation of the ACGME Duty Hour Standards

	Preimplementation (95% CI)	Postimplementation (95% CI)	Change, %	*P* Value
Mean No. of weekly work hours*	70.7 (70.5-70.9)	66.6 (66.3-66.9)	−5.8	<.001
Mean duration of extended work shifts, h	32.1 (32.0-32.2)	29.9 (29.8-30.0)	−6.9	<.001
Mean longest period with no sleep, h	25.3 (25.1-25.4)	24.9 (24.7-25.0)	−1.6	.25
Mean nightly sleep duration, h	5.91 (5.88-5.94)	6.27 (6.23-6.31)	+6.1	<.001
Mean nightly sleep during extended shifts, h	2.69 (2.66-2.73)	2.57 (2.52-2.62)	−4.5	<.001

Abbreviations: ACGME, Accreditation Council for Graduate Medical Education; CI, confidence interval.
*Excludes vacation weeks and leaves of absence.

Nightly sleep increased by 21.6 minutes when not on call, but decreased by 7.2 minutes on call.

Landrigan, C. P. et al. JAMA 2006;296:1063-1070.

Summary: Duty Hours and Outcomes

- Even under AGCME duty hour rules, residents still work long hours
  - Insufficient financial and technical support for requirements
  - House officers unwilling to leave if urgent/ emergent patient care is needed
  - Sign-out inefficiencies
  - Medical culture

Summary: Duty Hours and Outcomes

- Limited impact of duty-hours alone on sleep time
- “Ownership” of patients and pass-offs remain problematic
- Requirements don’t stipulate how duty hours should be met
  - Big difference in time since last sleep in traditional extended shifts c/w shift work

Summary: Duty Hours and Outcomes

- 80 hour work week has not worsened patient mortality, and may have improved it
- Extended duration shifts ↑ risk to trainees
  - Motor vehicle crash, percutaneous needle injury
- Extended duration shifts ↑ risks to patients
  - Attentional failures
  - Medical errors
  - Surgical performance (simulator)
- Flexibile duty hours outcomes no worse for surgical residencies

What Can You Do to Improve Fatigue and Sleep During Shift Work?

- Quantity of Sleep
- Quality of Sleep
- Circadian Management

Essential Chronobiology

- Suprachiasmatic Nucleus (hypothalamus) is the master clock
- Zeitgebers: environmental stimuli that regulate and entrain SCN activity
  - Major Zeitgebers
    - Light
    - Endogenous melatonin
  - Minor Zeitgebers
    - Core body temperature
    - Social interactions / stress / physical activity
    - Food

Sleep Hygeine

- **Avoid natural and artificial light 1-2 hours before bedtime**
  - TV, laptops, cell phones
  - During night float, use blackout curtains in bedroom
- White noise / fan for light sleepers
- No hot baths/strenuous exercise before bed
- Lower thermostat
- Avoid food / alcohol before bed
- Set a routine

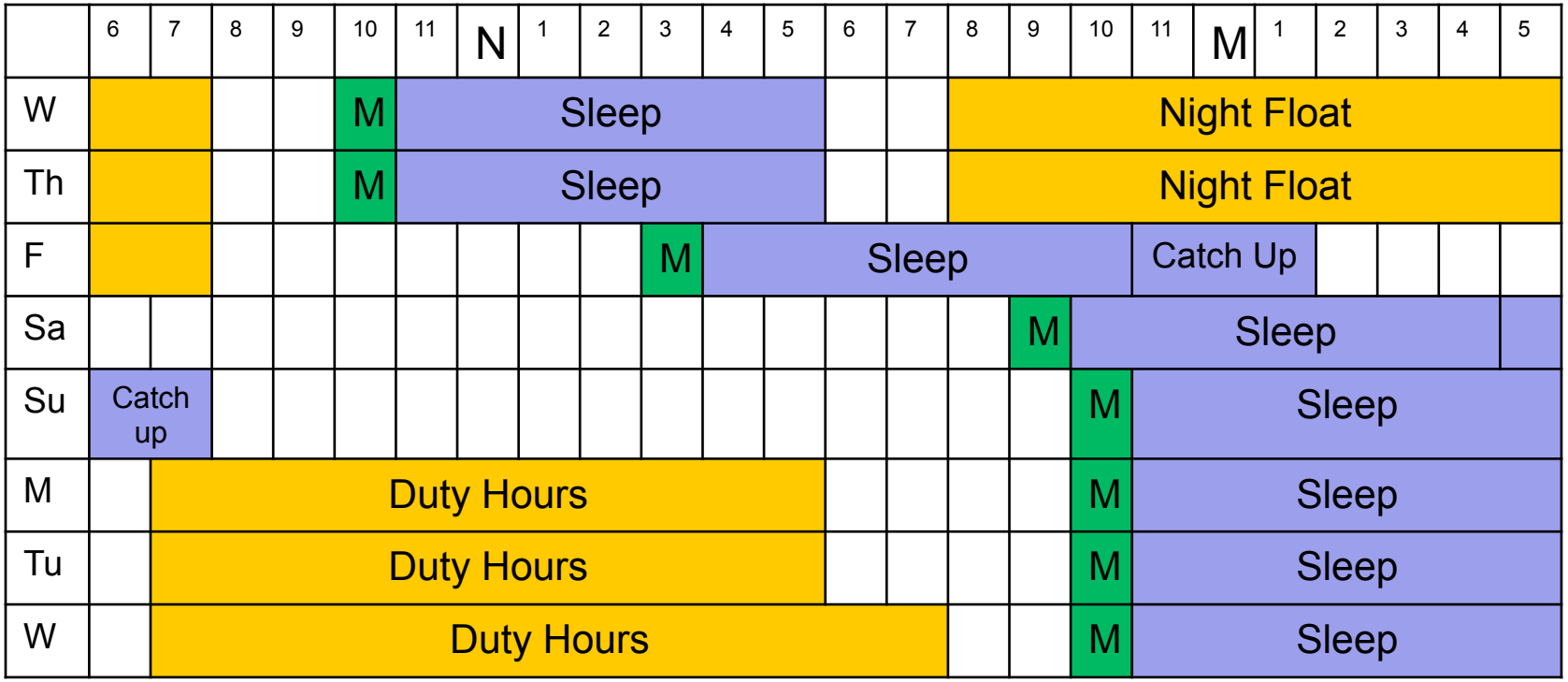
Role of Melatonin in Misaligned Circadian Rhythm

- Bright light causes suppression of endogenous melatonin
- A disrupted circadian rhythm causes any acquired sleep to be less restorative
- Exogenous melatonin has been shown to entrain the circadian rhythm
  - Dose 1mg PO 1 hour before bedtime
  - Interestingly, causes somnolence in only 30% of patients
  - Use non-delayed release formulations

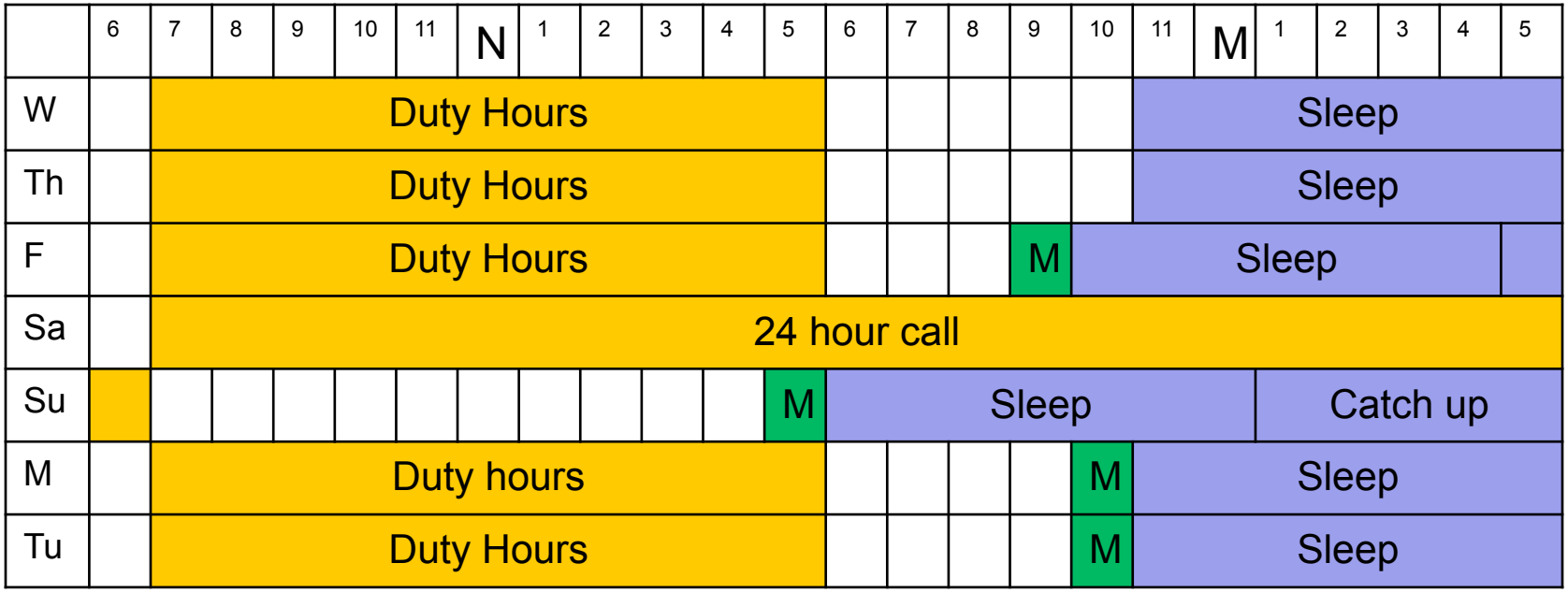
Transition from Days to NF

	6	7	8	9	10	11	N	1	2	3	4	5	6	7	8	9	10	11	M	1	2	3	4	5
W		Duty Hours															M	Sleep						
H		Duty Hours															M	Sleep						
F		Duty Hours																				M		
Sa	Sleep					Catch- up sleep																		
Su					M	Sleep									Night Float									
M					M	Sleep									Night Float									
Tu					M	Sleep									Night Float									
W					M	Sleep																		

Transition from NF to Days



24 hour Call


6 7 8 9 10 11 N 1 2 3 4 5 6 7 8 9 10 11 M 1 2 3 4 5
W
Duty Hours
Sleep
Th
Duty Hours
Sleep
F
Duty Hours
M
Sleep
Sa
24 hour call
Su
M
Sleep
Catch up
M
Duty hours
M
Sleep
Tu
Duty Hours
M
Sleep

Summary

- Fatigue is an immutable biologic process
  - Cannot acclimatize
  - Difficult to recognize in yourself
- Fatigue may be associated with medical errors and risk of accident, needle stick, health problems

Summary

- Attention to sleep hygiene and circadian management can increase sleep efficiency and effectiveness, thus reducing fatigue
- If you are having problems with fatigue seek help (your PD wants to know)
  - Before you wreck your career, health or life!

Summary: Duty Hours and Outcomes

- Effect on education and training has not been adequately addressed
  - What are the important outcomes?
  - Is questionnaire data adequate?
  - Board scores
  - Patient satisfaction surveys
- Residents like duty hour rules (mostly)
- Faculty are less sure

IOM Recommendations 2008

COMPARISON OF IOM COMMITTEE ADJUSTMENTS TO CURRENT ACGME DUTY HOUR LIMITS		
	2003 ACGME Duty Hour Limits	**IOM Recommendation**
Maximum hours of work per week	80 hours, averaged over 4 weeks	No change
Maximum shift length	30 hours (admitting patients up to 24 hours then 6 additional hours for transitional and educational activities)	• 30 hours (admitting patients for up to 16 hours, plus 5-hour protected sleep period between 10 p.m. and 8 a.m. with the remaining hours for transition and educational activities) • 16 hours 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 hours after shift length	• 10 hours after day shift • 12 hours after night shift • 14 hours after any extended duty period of 30 hours and not return until 6 a.m. of next day

IOM Recommendations 2008

Maximum frequency of in-hospital night shifts	Not addressed	4 night maximum; 48 hours off after 3 or 4 nights of consecutive duty
Mandatory time off duty	• 4 days off per month • 1 day (24 hours) off per week, averaged over 4 weeks	• 5 days off per month • 1 day (24 hours) off per week, no averaging • One 48-hour period off per month
Moonlighting	Internal moonlighting is counted against 80-hour weekly limit	• Internal and external moonlighting is counted against 80-hour weekly limit • All other duty hour limits apply to moonlighting in combination with scheduled work
Limit on hours for exceptions	88 hours for select programs with a sound educational rationale	No change
Emergency room limits	12-hour shift limit, at least an equivalent period of time off between shifts; 60-hour workweek with additional 12 hours for education	No change

AGCME Principles and Concerns

1. Patient Safety is primary
   - Direct: patients cared for by residents
   - Indirect: patients cared for by future attendings
2. Resident autonomy is eroding
   - PATH audits 1996 – 98: huge fines for teaching hospitals
   - Medical liability insurance crisis
   - Pressure on academic physicians to generate revenue
   - Duty hour standards – residents no longer have “pivotal role” on the teaching service

http://www.acgme.org/acWebsite/home/NascaLetterCommunity10_27_09f

AGCME Principles and Concerns

3. One size may not fit all
   - Each specialty has unique educational requirements
   - Impact of standards worse on higher level trainees
   - May be too lax for first year residents
   - Significant intra-individual variability in impact of sleep deprivation

http://www.acgme.org/acWebsite/home/NascaLetterCommunity10_27_09f

AGCME Principles and Concerns

4. Surprising impact on specialties not directly affected by duty hour rules
   - ↓ support for ER due to Medicine and Surgery limits
   - ↓ interaction with diagnostic radiology and multidisciplinary teams
   - Negative impact on faculty
5. Positive impact on residents

http://www.acgme.org/acWebsite/home/NascaLetterCommunity10_27_09f

AGCME Principles and Concerns

5. Positive impact on residents
   - Less depression
   - Better mix of learning sources
     - Faculty-organized
     - Peer-oriented
     - Self-directed
   - Not sleeping dramatically more
     - Fatigue is related to sleep and matching of workload to training

http://www.acgme.org/acWebsite/home/NascaLetterCommunity10_27_09f

AGCME Principles and Concerns

6. Are rigid rules better than softer accreditation standards
   - New York has had stricter rules for >10 years, with high fines for enforcement, but has no better compliance
   - Rigid rules conflict too much with professionalism

"Do you want a tired doctor?" may not have been the best way to present these changes to the public.

http://www.acgme.org/acWebsite/home/NascaLetterCommunity10_27_09f

The Future

- More research is needed
  - But evidence is accumulating that extended duration shifts are potentially dangerous
  - Shift-work may be safer, but will physicians like it better?
- Evaluations of novel (to physicians) techniques to combat sleepiness
  - Scheduled naps
  - Light therapy
  - Pharmaceutical agents
- More education is needed
  - SLEEP is IMPORTANT
- Technological assistance
  - How can the EMR help with continuity/discontinuity of care?

The Future

- I expect the 30 hour shift will be eliminated in the next ACGME rules
- Interventions unlikely to be cost-neutral

How Effective are the Duty Hour Rules?

- Mandatory reports to ACGME
  - 5.0% residency training programs noncompliant in first year
  - 3.3% violated 80-hour rule
  - Reliability of program self-report is questionable as noncompliance threatens accreditation

Landrigan, C. P. et al. JAMA 2006;296:1063-1070.

How Effective are the Duty Hour Rules?

- Web-based survey (again!)
  - Recruited after match and before beginning residency (minimize selection bias)
  - Estimate compliance of interns
  - Compare work and sleep hours before and after rule change (2002-03 AY to 2003-04 AY)

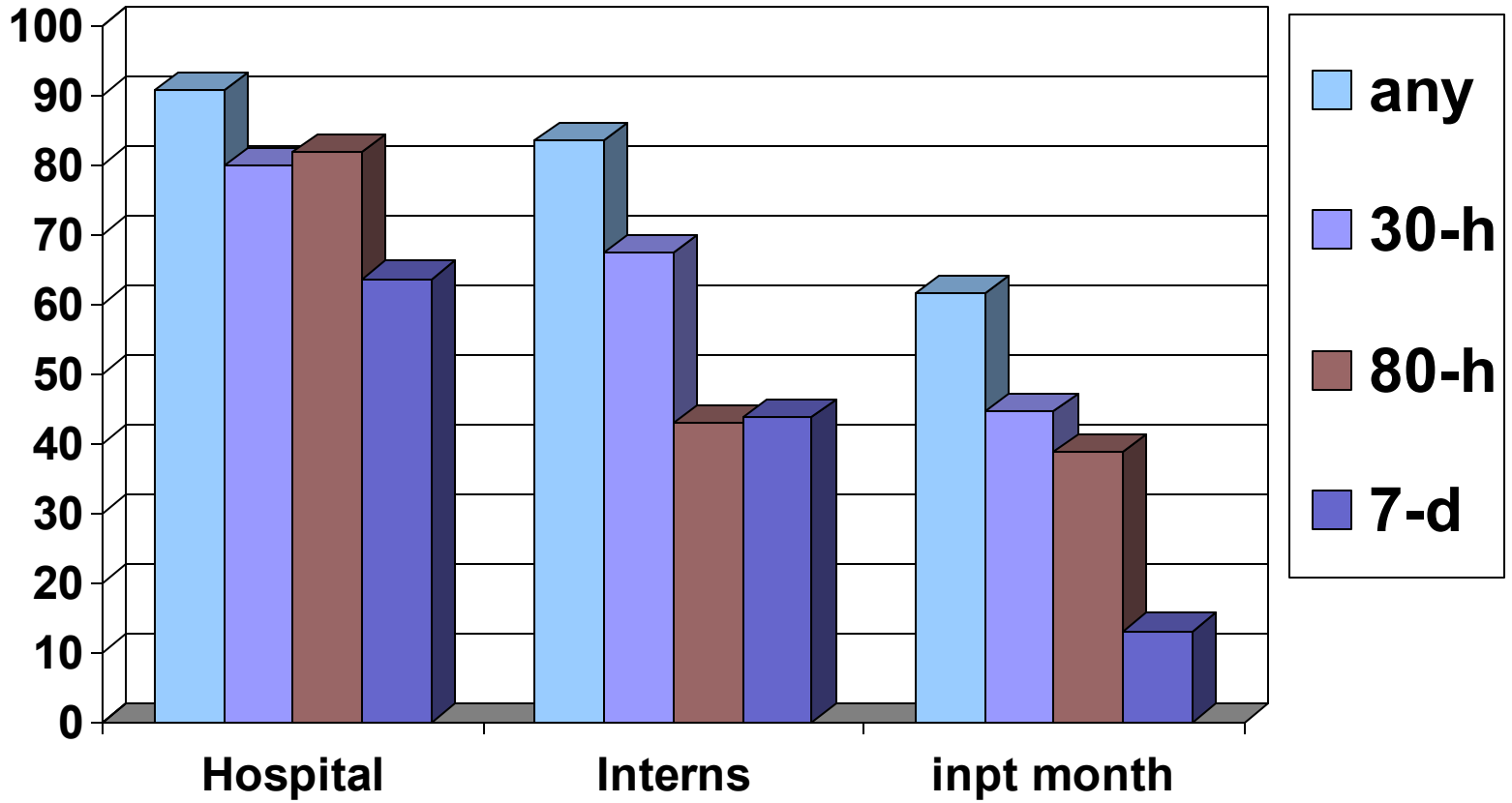
Landrigan, C. P. et al. JAMA 2006;296:1063-1070.

How Effective are the Duty Hour Rules?

- No mention of ACGME rules in survey
  - “Hours spent physically awake in the hospital, classes or workplace”
  - “Hours spent studying outside of the hospital”
  - “Hours of sleep at school, the workplace or the hospital”
  - Other questions on alcohol, caffeine, job performance
- Participants
  - 2737 in 2002-03, and 1278 in 2003-04
  - Confidentiality assured

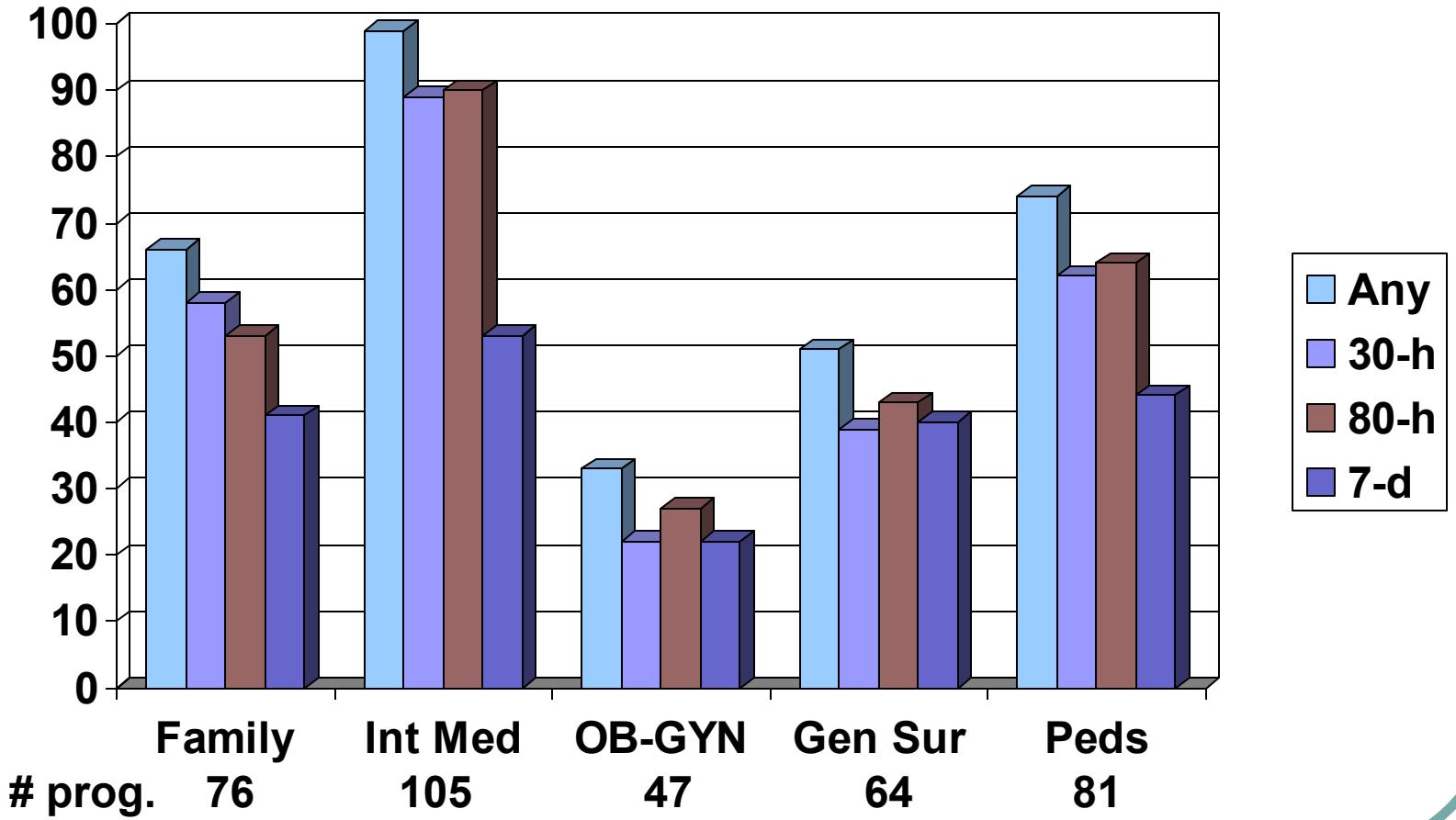
Landrigan, C. P. et al. JAMA 2006;296:1063-1070.

Proportion of Hospitals, Interns and Inpatient Intern-Months with Violations



Landrigan, C. P. et al. JAMA 2006;296:1063-1070.

Proportion of Residency Programs with Interns Violating ACGME Rules



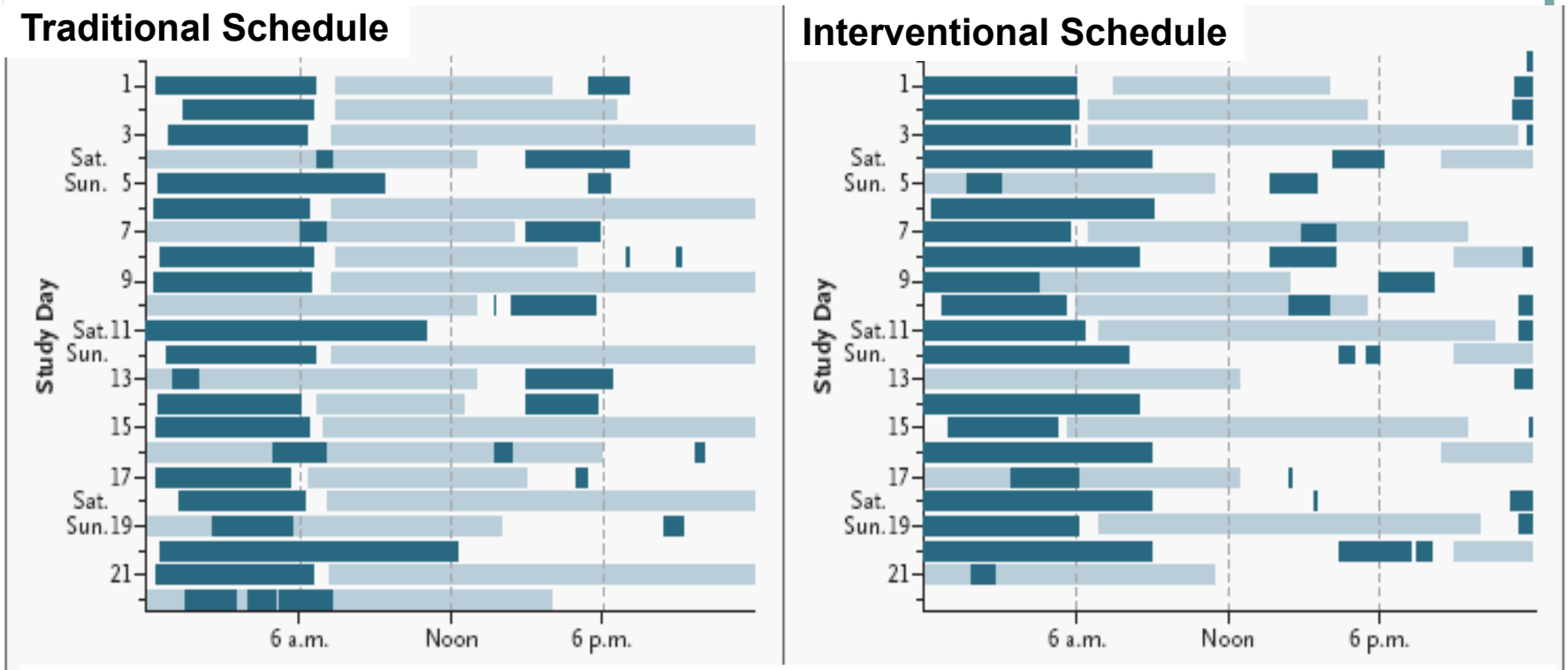
Landrigan, C. P. et al. JAMA 2006;296:1063-1070.

Impact of Fatigue on Satisfaction

	Reduced Hours (N = 420)			Other Group (N = 1350)		
Fatigue frequently or always effects…	**2003**	**2004**	**Change**	**2003**	**2004**	**Change**
Quality of care you provide	14.6	9.2	-5.4	6.5	6.1	-0.4
Ability to provide support to pts.	28.4	17.4	-11	15.3	11.2	-4.1
Ability to learn	50	33.8	-16.2	25.9	24.8	-1.1
Overall satisfaction as resident/fellow	41.3	23.8	-17.5	24.5	22.9	-1.6
Safety of patients	7.0	2.9	-4.1	3.7	3.7	0

Jagsi, 2006; Acad Med 81:1059

Subjective Work and Sleep Hours



Example of one intern's hours on Traditional and Interventional Schedules

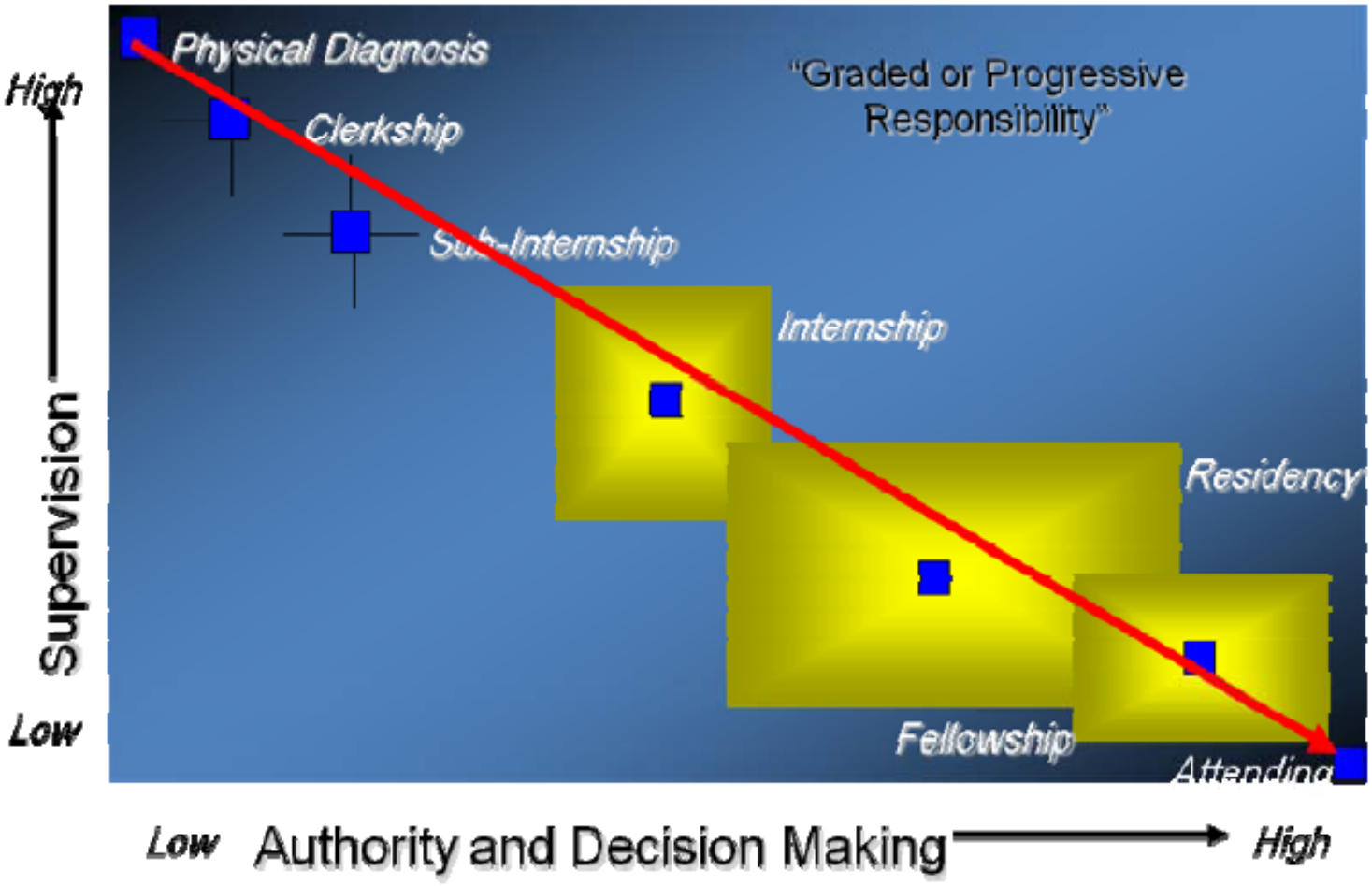
Work **Sleep**

Lockley 2004, NEJM 351: 1829

Players in the Duty Hours Debate

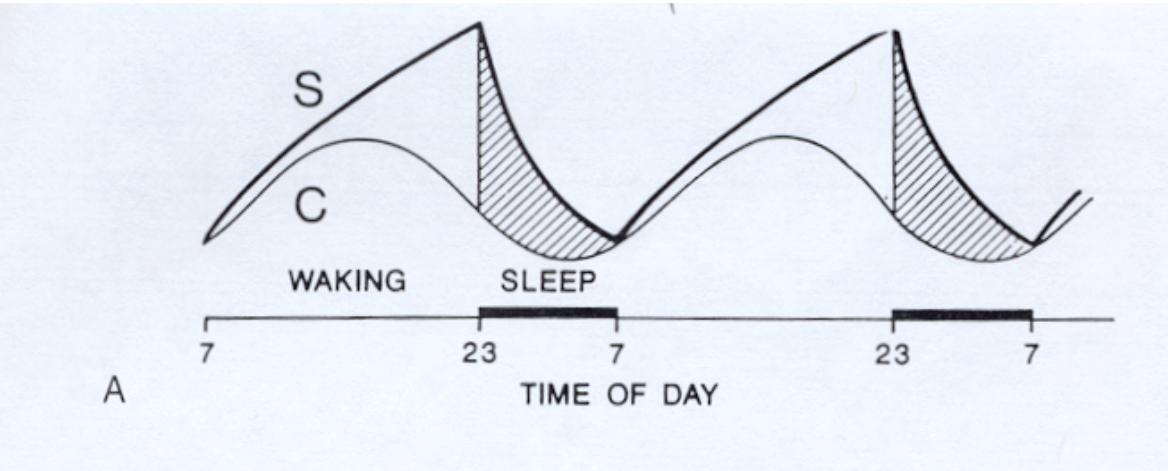
- Trainees
  - Health
  - Education
  - Quality of Life
- Training Programs
  - Education
  - Preference for the tried and true
- Patients
  - Safety
  - Quality of Care
  - Continuity of Care
- Hospitals
  - Cost/Efficiency of Care
  - Safety
- Government and other entities that pay for health care

Progressive Responsibility in Medical Education



http://www.acgme.org/acWebsite/home/NascaLetterCommunity10_27_09f

Regulation of Sleep and Wakefulness: Two Process Model



S = Sleep Homeostasis

C = Circadian

Adapted from Borbely Hum Neurobiol, 1982 and Daan, Am J Phys 1984

Physiologic vs. Manifest Sleepiness

- Masking of physiologic signal
  - Motivation
  - Environment
  - Posture
  - Activity
  - Light
  - Food/Drug intake
- Unmasking
  - Heavy meal
  - Warm room
  - Long distance driving
  - Boring lectures
- Factors don't ***cause*** sleepiness

Sleep Deprivation

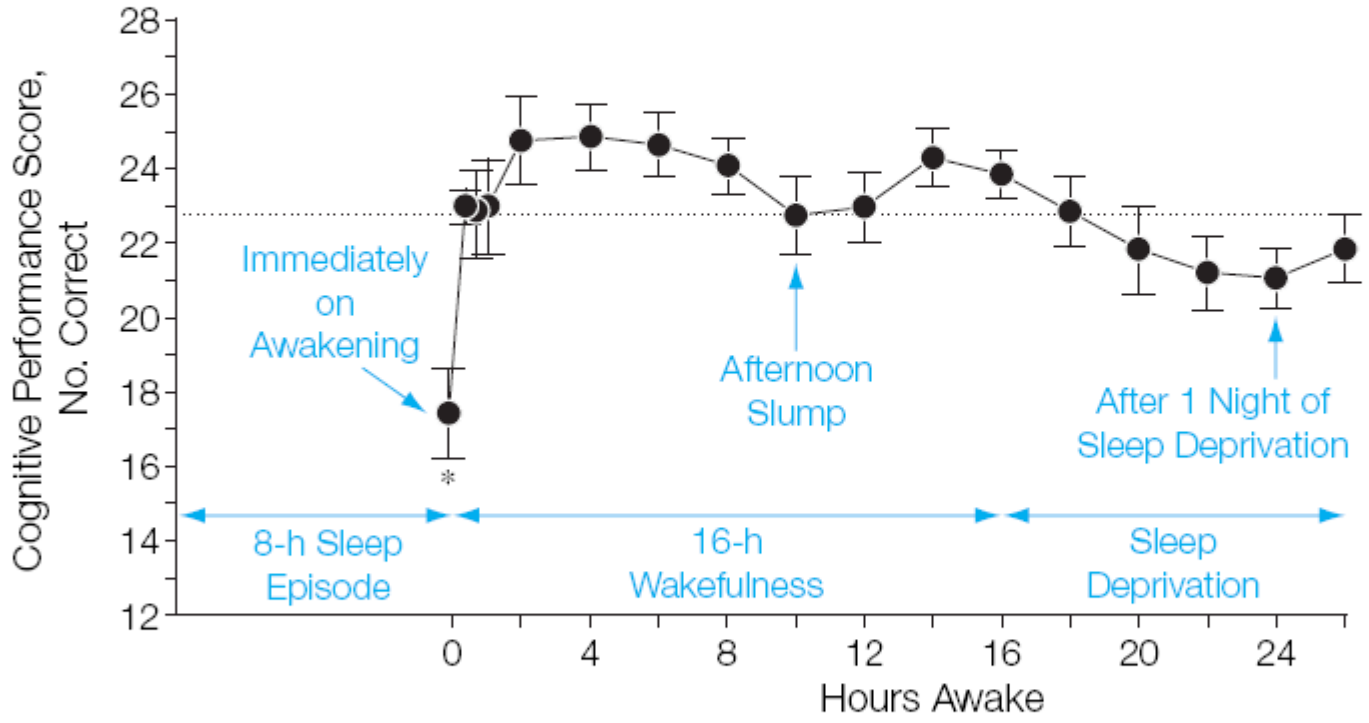
- Acute
- Chronic
- ACSD
  - Acute on Chronic Sleep Deprivation
- Subjective sleepiness consistently overestimates performance – subjects perceive they are less impaired than they actually are

Sleep Inertia

- Impaired cognition, grogginess, and disorientation commonly experienced upon awakening
- Occurs whether waking is spontaneous or induced, and may be worse if awakening is from slow wave sleep
- Severe performance decrements lasting up to 20 minutes

Sleep Inertia

Figure. Cognitive Performance on Awakening From Sleep Compared With Subsequent Sleep Deprivation



Wertz, JAMA 2006

Impact of Duty Hours on Sleep, Work Hours and Safety

- Prospective Cohort Study in 3 Pediatric training programs before and after duty hour rules
- Several weeks of self-reported daily logs near end of academic year
- Self report of occupational exposure to blood or body fluid, actual and near miss MVA, and medical errors
- Objective assessment of medication errors on inpatient wards

Landrigan, Pediatrics 2008

Minimal Change on Sleep or Work Duration

TABLE 3 **Residents' Reported Work Hours and Sleep, Before and After Implementation of the ACGME Duty Hour Standards**

	Duration, Mean ± SD, h		Change, %	*P*
	Before Implementation	After Implementation		
Daily work duration[a]	8.6 ± 7.5	8.6 ± 7.4	0	.94
Duration of extended work shifts	29.3 ± 3.2	28.5 ± 2.4	−2.7	<.001
Daily sleep duration	7.4 ± 2.7	7.5 ± 2.7	+1.4	.49

[a] Values include vacation days, weekends, and ambulatory rotations (weekly work hours: 60.3 vs 60.4 hours/week).

Landrigan, Pediatrics 2008

Minimal Change on Medication Errors

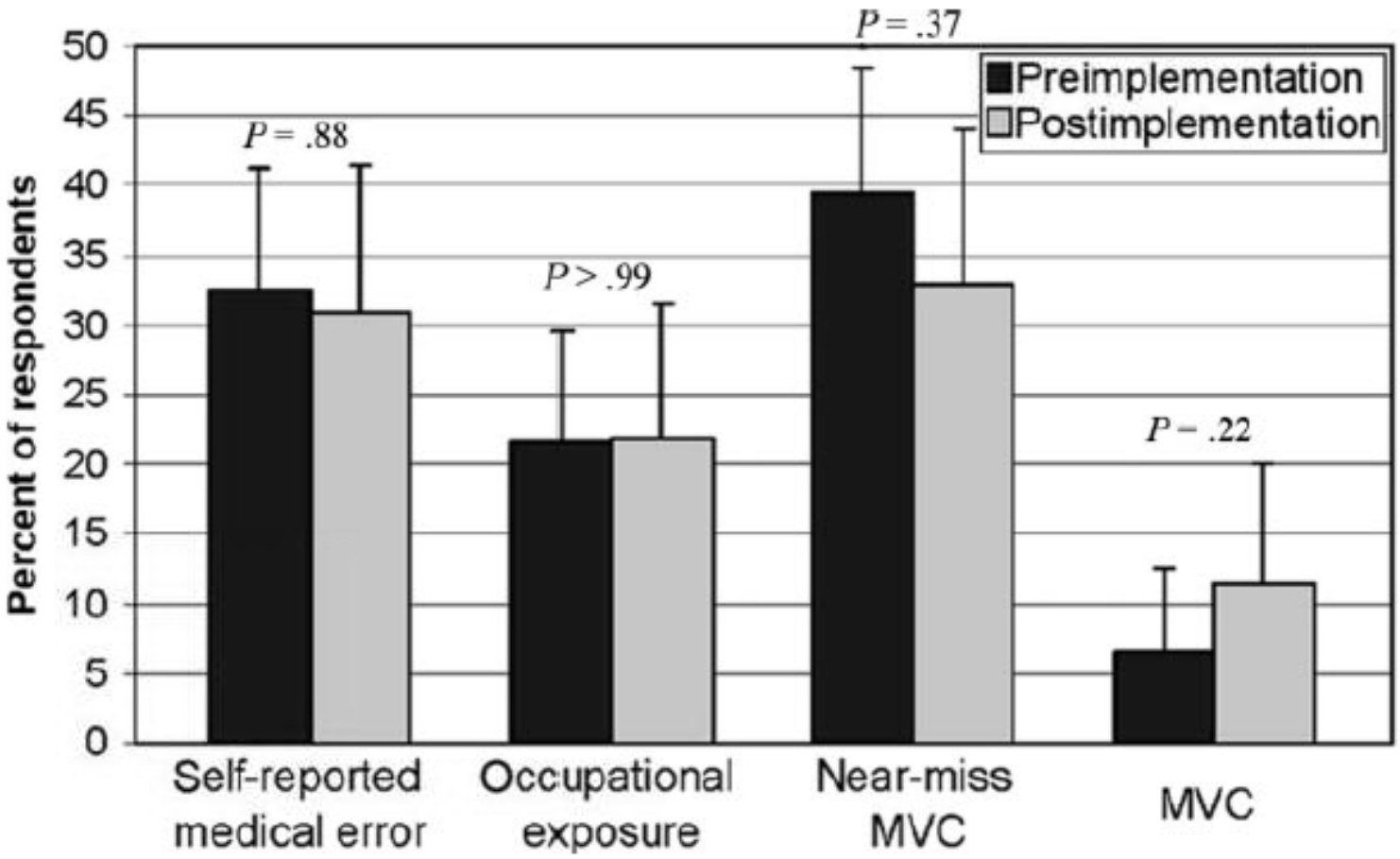
TABLE 4 Medication Error Rates, Before and After Implementation of the ACGME Duty Hour Standards

	Before Implementation		After Implementation		*P*[a]
	No.	Error Rate, Estimate (95% CI), Cases per 100 Orders	No.	Error Rate, Estimate (95% CI), Cases per 100 Orders	
No. of orders	8003		8115		
No. of errors					
Total	103	1.29 (1.06–1.56)	122	1.50 (1.26–1.79)	.25
Preventable adverse events	5	0.06 (0.03–0.15)	5	0.06 (0.03–0.14)	>.99
Potential adverse events	60	0.75 (0.58–0.96)	56	0.69 (0.53–0.90)	.71
Intercepted potential adverse events	38	0.47 (0.35–0.65)	32	0.39 (0.28–0.56)	.47
Nonintercepted potential adverse events	22	0.27 (0.18–0.42)	24	0.30 (0.20–0.44)	.88
Medication errors with little potential for harm	38	0.47 (0.35–0.65)	61	0.75 (0.59–0.96)	.03
No. of resident physician ordering errors	85	1.06 (0.86–1.31)	112	1.38 (1.15–1.66)	.08

[a] Fisher's exact test.

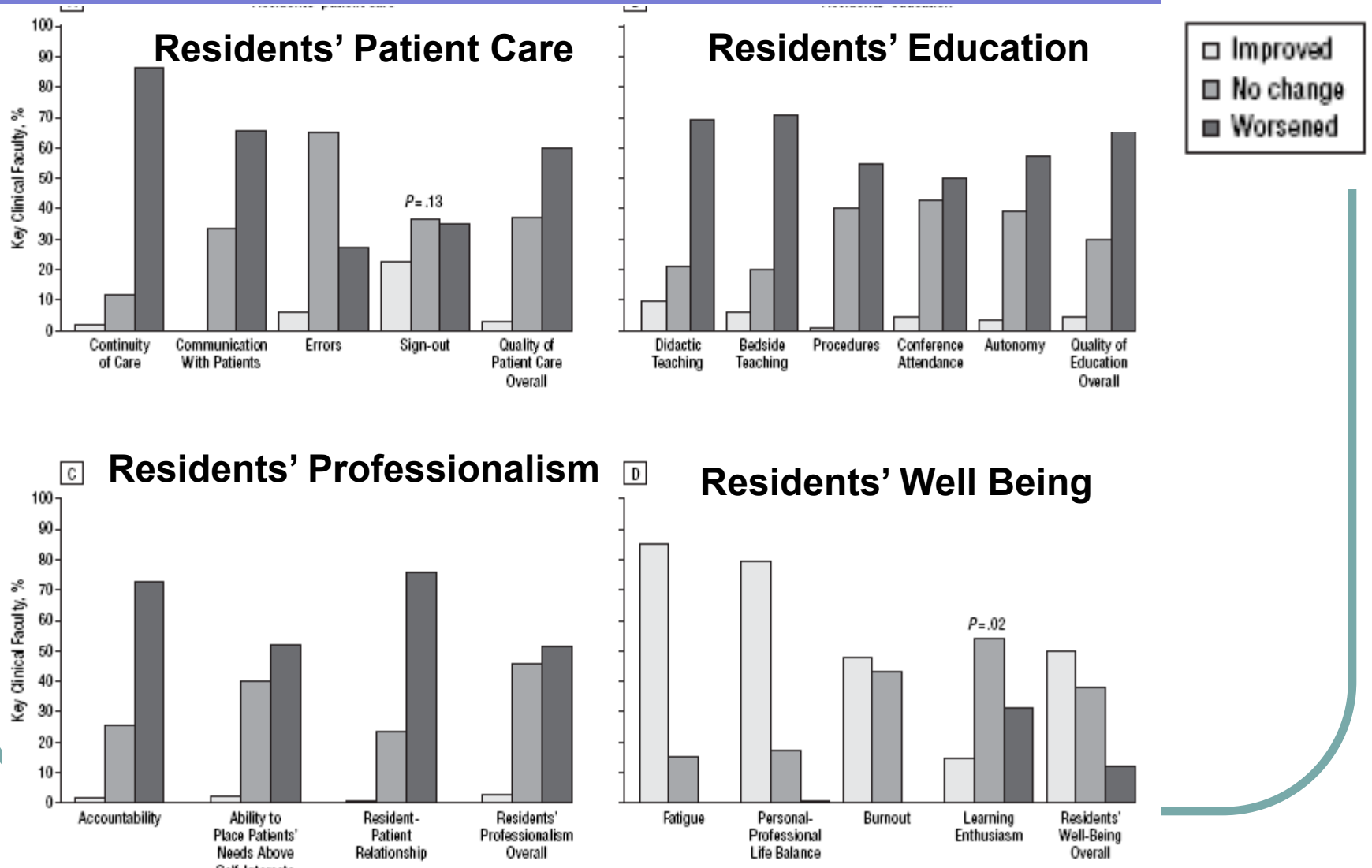
Landrigan, Pediatrics 2008

Minimal Change on Self-Reported Adverse Events



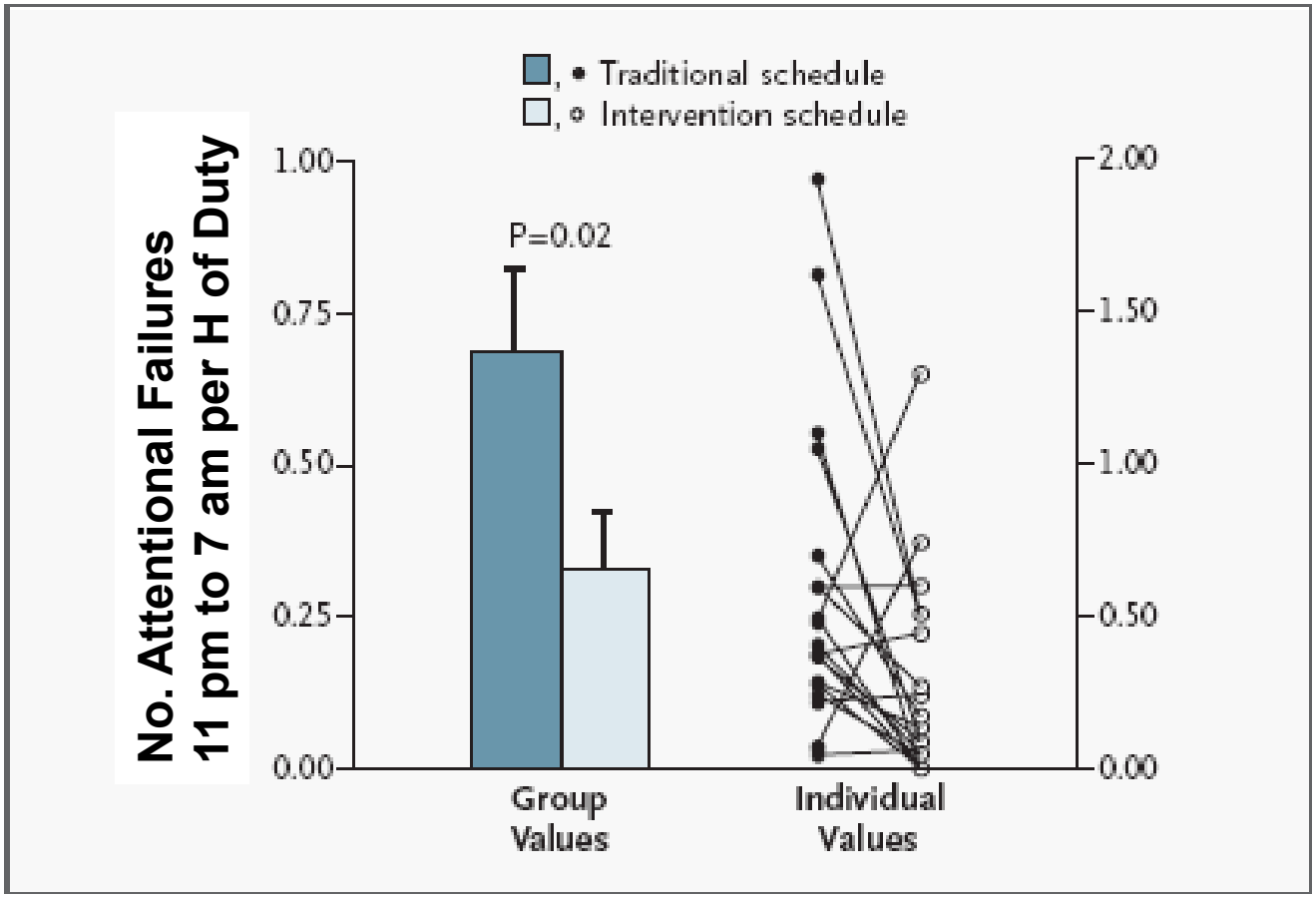
Landrigan, Pediatrics 2008

Faculty Opinion on Duty Hour Changes



Reed, 2007: Arch Int Med, 167:1487

Attentional Failures: Slow Rolling Eye Movements



Lockley 2004, NEJM 351: 1829

Medical Error Definitions

- Serious medical error – causes harm, potential to cause harm
  - Intercepted or Nonintercepted
- Adverse event – any injury due to medical management
  - Nonpreventable or Preventable
- Serious medication error – drugs, blood or fluid
- Serious procedural error
- Serious diagnostic error – H & P, ordering or interpretation of a diagnostic test

Landrigan 2004; NEJM 351:38

Adverse Error Study Design

- Detection of Medical Errors
  - Direct observation by 6 physician observers
    - Intensive pre-study training
  - Chart review
  - Voluntary reports
  - Computerized event-detection monitoring
- Classification of errors by physicians who were not observers
  - κ for adverse event or serious medical error = 0.90
  - κ for preventability of adverse events = 0.80
- No differences in patient characteristics

Landrigan 2004; NEJM 351:38

Mortality: Trauma Service

- National Trauma Data Bank
- 500,000 admissions
  - Voluntary participation
  - Under reporting of deaths and complications

Overall Clinical Outcomes Before and After Implementation of the 80-h Work Week

	Pre-80-h work week (2001–2002)	Post-80-h work week (2004–2005)	*P* value
Mortality rate	4.64%	4.46%	<.0001
LOS days	6	5.8	0.0003
ICU days	6.2	6.1	0.014
Vent days	7.6	7.5	0.047

Morrison, 2008. J Surg Res

Mortality: Trauma Service

Clinical Outcomes for Nonteaching and University Hospitals Before and After Implementation of the

Mortality Rates by Injury Severity Score (ISS) for the Pre-80 h Work Week and Post-80 h Work Week Time Periods

	Mortality rates by ISS*	
ISS	Pre-80-h work week	Post-80-h work week
[0, 15]	1.21%	1.30%
[15, 5]	6.44%	5.47%
[25, +]	34.50%	30.64%

* P value < 0.0001.

rk week

95% CI	P value
(3.69, 4.02)	<0.0001
(4.94, 5.11)	0.0307
(0.9, 1.0)	0.0004
(1.2, 1.3)	<0.0001
(1.9, 2.1)	0.0253
(2.0, 2.1)	0.0006
(4.8, 4.9)	<0.0001
(5.7, 5.8)	0.2657

Morrison, 2008. J Surg Res