



# Sleep loss in resident physicians: the cause of medical errors?

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This review begins with the history of the events starting with the death of Libby Zion that lead to the Bell Commission, that the studied her death and made recommendations for improvement that were codified into law in New York state as the 405 law that the ACGME essentially adopted in putting a cap on work hours and establishing the level of staff supervision that must be available to residents in clinical situations particularly the emergency room and acute care units. A summary is then provided of the findings of the laboratory effects of total sleep deprivation including acute total sleep loss and the consequent widespread physiologic alterations, and of the effects of selective and chronic sleep loss. Generally the sequence of responses to increasing sleep loss goes from mood changes to cognitive effects to performance deficits. In the laboratory situation, deficits resulting from sleep deprivation are clearly and definitively demonstrable. Sleep loss in the clinical situation is usually sleep deprivation superimposed on chronic sleep loss. An examination of questionnaire studies, the literature on reports of sleep loss, studies of the reduction of work hours on performance as well as observational and a few interventional studies have yielded contradictory and often equivocal results. The residents generally find they feel better working fewer hours but improvements in patient care are often not reported or do not occur. A change in the attitude of the resident toward his role and his patient has not been salutary. Decreasing sleep loss should have had a positive effect on patient care in reducing medical error, but this remains to be unequivocally demonstrated.

**Keywords: sleep loss-medical errors, changes in resident-review**

## RESPONSES TO A PATIENT'S DEATH FOCUSES ON SLEEP LOSS AS A CONTRIBUTORY CAUSE

### LIBBY ZION

In March of 1984 an 18-year-old young woman, Libby Zion (Asch and Parker, 1988), presented herself at 11:30 p.m. to the emergency room (ER) at New York Hospital, the teaching hospital for Cornell Medical School. She was told to go there by her father's doctor. In February, she had had a tooth extraction and was given Percodan (aspirin/oxycodone) for pain. A few days later she developed a fever and an ear-ache and was given erythromycin and chlorpheniramine by her doctor. Over the next few days the fever persisted and she had chills, myalgias and arthralgias. On the 4th of March her temperature reached 104°F and her father contacted his doctor who sent her to the emergency room (ER).

She was seen by a Junior Resident in the ER who obtained the additional history that she had started psychiatric treatment for stress in January of 1984 and her therapy included phenelzine which she took up to the day before coming to the hospital. She also stopped the erythromycin the day before because she felt too ill. She admitted to frequent marijuana use but denied the use of cocaine or other drugs. During the previous 2 months she had been given imipramine, flurazepam, diazepam, tetracycline and doxycycline but this was not elicited by the resident.

The patient during the physical examination was writhing and the resident believed it to be volitional. She had a temperature of 103°F and mild orthostatic blood pressure changes. Her right tympanic membrane was hyperemic; she had a soft murmur, a clear chest and petechiae on her right thigh. Her white blood count

was 18,000 and a chest film was normal. The patient was given intravenous fluids and one set of blood cultures was obtained. The resident spoke by telephone with the referring doctor and at 2:00 a.m. she was admitted and given acetaminophen. On the floor, she was examined separately by an Intern and another Junior Resident, both described agitation; the Junior Resident's diagnosis was Viral Syndrome with Hysterical Symptoms, the Intern's was Viral Syndrome. The resident ordered blood, urine and stool cultures; to withhold antibiotics; to stop the phenelzine; to treat the fever; to give 25 mg meperidine (Demerol) for agitation and shivering and to take routine vital signs.

At 3:30 a.m. the patient got intramuscular meperidine and the house officers left to care for other patients. Ms. Zion became more restless and confused and began thrashing around in bed. The Intern was called twice and by phone ordered restraints and then 1 mg. of Haloperidol. The patient was resting between 4:30 and 6:00 a.m. and the restraints were taken off. She took acetophenamin by mouth, got agitated again and her axillary temperature was 107.6°F. The Intern was called and ordered cold compresses and a cooling blanket. At 6:30 a.m., 7.5 h after coming to the hospital, Ms. Zion went into respiratory arrest and could not be resuscitated.

The cause of death was listed as Bilateral Bronchopneumonia by the Medical Examiner on March 6th, 1984. He noted "hyperpyrexia and sudden collapse shortly after injection of meperidine and haloperidol while in restraints for toxic agitation." The toxicologist found acetophenamin and antihistamines in the tissue. Radio-immune assay found a trace of cocaine in the patient's nostrils.

Blood immune assay found cocaine that gas chromatography did not confirm. The Medical Examiner saw cocaine as presumptive but not conclusive.

New York City (NYC) Council President Andrew Stein stated that mistakes caused many deaths in NYC hospitals. Libby Zion had worked for him as an interne.

The New York Times claimed that Ms. Zion had received inadequate care in the hands of overworked and under supervised house officers. Her father, Sidney Zion, an attorney, who worked as a reporter for the Times, persuaded the New York District Attorney to begin a grand jury probe. The grand jury gave a lengthy report in December, 1986. There were no criminal indictments, and the indictment was of graduate medical education. The jury felt five circumstances contributed to her death: (1) Ms. Zion had been examined in the ER by a Junior Resident who talked to her Doctor by phone and no ER staff person saw her; (2) Junior Residents and interns need to be supervised on-site at the time by Staff; (3) She was admitted at 2 a.m. to a house staff who had been working 18 h, they noted that there is a need to limit consecutive working hours for interns and Junior Residents; (4) there is a need to develop a set of rules for patients in restraint and how they will be treated; and (5) there is a need for a computerized system to monitor contraindicated drug interactions.

The New York State Health Department (World Almanac Video) in 1987 fined the New York Hospital \$13 million dollars for its sub-standard care of Libby Zion.

In February 1995, Libby Zion's parents brought a civil suit against the New York Hospital. The jury found New York Hospital not responsible for Ms. Zion's death but concluded that the hospital was negligent in assigning the Intern too many patients, even though this negligence was not found to be a proximate cause of her death. The jury concluded that the hospital was negligent with regard to the manner in which its house staff was supervised. The jury exonerated the hospital and found by a vote of five to one, that Libby Zion contributed to her own death by ingesting cocaine. They awarded the Zion's \$750,000 dollars for Libby's pain and suffering. The judge voided the decision because the evidence about cocaine should not have been admitted. The hospital suggested to the judge that the award be set at \$350,000 dollars, which was what was done.

The attitude toward Ms. Zion implied by her writhing movements being labeled as volitional and the diagnosis of hysterical symptoms may have contributed to the nature of the response elicited from the house officers as her condition deteriorated. The prescribing of meperidine to a patient who had been taking phenelzine was probably the key to her death. These are of course after the fact speculations.

### THE BELL COMMISSION

As a consequence of the Libby Zion Grand Jury report, the New York State Commissioner of Health, David Axelrod, appointed a commission "The Ad Hoc Committee on Emergency Service" (The Bell Commission – with nine distinguished NY State academic physicians) and it made 19 recommendations (Final Report New York State Department of Health Ad Hoc Advisory Committee on Emerging Services, 1987) in October, 1987. These included: (1) on-site supervision in the ER by attending physicians and 12 h ER shifts; (2) 24 h on-site supervision in busy acute care inpatient

units; (3) improved working conditions; (4) more ancillary support; (5) guidelines for physical restraints; (6) more study of drug information systems; and (7) 80 h average/week over 4 weeks, and routinely not more than 24 consecutive hours per shift with one 24 h period off/week.

(In a note in JAMA in 2008 Dr. Bell reports that the 80-h rule was arbitrarily developed.)

None of the physicians on the Commission were sleep experts. The Bell Commission Report bibliography clearly takes note of the studies at the time related to performance impairment associated with sleep loss from prolonged wakefulness. Levinsky (1988), a Boston physician educator, in 1988 was of the opinion that there was "no evidence... that inadequate supervision and long work weeks were major causes of poor patient care." Questioning the role of inadequate supervision and long hours being the root causes of poor patient care continues to be expressed in some quarters and will be pursued throughout this essay.

### THE 405.4 RULE

In July 1989, Rule 405.4 of The New York State Health Code was made law in which post graduate trainees, residents, with inpatient care responsibility must meet the following criteria:

1. Criteria
  - a. The scheduled work week shall not exceed 80 h per week averaged over a 4-week period;
  - b. Such trainees shall not be scheduled to work for more than 24 consecutive hours;
  - c. for departments other than anesthesia, family practice, medical, surgical, obstetrical, pediatric or other services which have a high volume of acutely ill patients and where night calls are infrequent and physician rest time is adequate, the medical staff may develop and document scheduling arrangements other than those set forth in clauses (a) and (b) of this subparagraph; and
  - d. "On-call" duty in the hospital during the night shift hours by trainees in surgery shall not be included in the 24-h limit contained in clause (b) of this subparagraph and the 80-h limit contained in clause (a) of this subparagraph if:
    - (1) The hospital can document that during such night shifts post graduate trainees are generally resting and that interruptions for patient care are infrequent and limited to patients for whom the trainee has continuing responsibility;
    - (2) Such duty is scheduled for each trainee no more than every third night;
    - (3) A continuous assignment that includes nightshift "on-call" duty is followed by a non-working period of no less than 16 h; and
    - (4) Policies and procedures are developed and implemented to immediately relieve a post graduate trainee from a continuing assignment when fatigue due to an unusually active "on-call" period is observed.
2. The medical staff shall develop and implement policies relating to post graduate trainee schedules which prescribe limits on the assigned responsibilities of post graduate trainees, including but not limited to, assignment to care of new patients, as the duration of daily on-duty assignments progress.

3. ...shall require that on-duty assignments be separated by not less than 8 non-working hours. Post graduate trainees shall have at least one 24 h period of scheduled non-working time per week.
4. ...shall adopt and enforce specific policies governing dual employment...minimum that trainees notify the hospital of employment outside the hospital and hours devoted to such employment. Post graduate trainees who have worked the maximum number of hours permitted in (1) thru (4) (all of above plus ER below) shall be prohibited from working additional hours as physicians providing professional patient care service.
5. ER shift of 12 h and the commissioner can approve up to 15 h for attending physicians.

The jury in the Zion's civil case, Green (1995) felt, focused mainly on the house staff having too great a work-load, while the Bell commission had focused primarily on inadequate supervision. The Bell Commission however did comment on hours of work but it was not their emphasis. Ironically, the Zion case, Green believes has had its strongest effect on work hours.

Holzman and Barrett (2000) in exploring the consequences of the regulatory changes in training are of the opinion that there is little evidence that sleep deprivation is a serious cause of medical error. The changes in house officers working hours, they believe, have profound implications as it results in alterations in the time allocated to teaching, the ability to learn from patients admitted after the shift is over and increases the loss in continuity of care. More fundamentally there is a loss of professionalism as the residents begin to see themselves as hourly workers. They are most concerned that the time restrictions will weaken the doctor-patient relationship.

#### THE ACCREDITING COUNCIL FOR GRADUATE MEDICAL EDUCATION

The Accrediting Council for Graduate Medical Education (ACGME) (Accrediting Council for Graduate Medical Education, 2003) established program requirements July 1, 2003 related to resident duty hours and the working environment that covered: (1) the supervision of residents; (2) duty hours, (3) on-call activities, (4) moon lighting, (5) oversight, and (6) duty hour exceptions. Essentially the rules promulgated as law in New York State were adopted by the ACGME for all programs. The addition of a requirement that faculty and residents be educated to recognize signs of fatigue and to adopt and apply policies to prevent and counteract the negative effects of fatigue is of interest in the present context. The requirements are for on-site supervision at all times, an 80 h/week limit, 1 day off out of seven, 10 h between work days, no more than every third night for no longer than 24 h plus 6 h for completion and education, no new patients after 24 h and there are moonlighting limitations and all policies must be written.

A 1-year follow-up of the ACGME regulations showed programs were not following the regulations. Landrigan et al. (2006) found that overall 85.4% of residencies ( $n = 707$ ) had at least one rule violation: for the 30-h rule, 70.2%; for the 80-h rule, 68.8% and for the 7-day rule, 50.9%.

#### INSTITUTE OF MEDICINE REPORT "TO ERR IS HUMAN"

The Institute of Medicine (IOM) in 1999 issued a report "To Err is Human" (Kohn et al., 1999) that claimed 44,000 deaths a year occurred in hospitals because of errors and that the figure might be as high as

98,000. This estimate is Libby Zion writ large and sent a shock wave through the medical and administrative community intensifying their concern about patient safety. Examples of errors included adverse drug events, improper transfusions, surgical injuries and wrong side surgery, suicides, restraint related injuries or deaths, falls, burns, pressure ulcers, and mistaken patient identities. The types of errors may be diagnostic, i.e., delay in diagnosis, not getting an indicated test, the use of outmoded tests or therapy and not acting on results of monitoring or tests; treatment, i.e., errors in performance of an operation, procedure or test; errors in dose or method of using a drug, avoidable delay in treatment or responding to a test; preventive, i.e., failure to provide prophylactic treatment and inadequate monitoring or follow-up and other, i.e., communication and equipment failure. Errors occur primarily in intensive care units, operating rooms and emergency departments, and I assume would be less frequent in psychiatry. The cause is a lack of system, not a "bad apple" problem.

The goal the IOM hoped to achieve is a 50% reduction in deaths in 5 years. Licensing authorities pay little attention to error and medical liability and health insurance does not support studying errors. What is needed is a regulatory and market based initiative. The strategy for improvement described in the IOM report includes: (1) a national focus to increase knowledge about safety, (2) the mandatory reporting of errors to provide data to learn about errors, (3) raising performance standards through professional organizations and health care providers, and (4) implementing safety systems in health care provider systems.

The opinion has been expressed that the estimate of error related deaths in the hospital by the IOM might be exaggerated. The issue that is raised is to establish the base line death rate before attributing the deaths to medical error. The 98,000 figure came from a Harvard study of deaths in New York City (NYC) hospitals (Brennan et al., 1991) and the 44,000 from a Utah-Colorado study (Thomas et al., 1999) of adverse events. The Harvard study had looked at 31,429 admissions to NYC hospitals in 1984 from which 7,743 cases likely to have an adverse reaction were selected. A chart review found a medical error in 1278 (16.5%) and 173 died (13.5% = 173/1278) at least in part as a result of the error. Without a base rate, one cannot say if the adverse event caused death as the studies were observational (McDonald et al., 2000) The calculated death rate for the total sample was (31,439  $\times$  0.034 death rate in NYC hospitals in 1984) 13.8% or 1069 deaths, so the death rate in adverse and non-adverse reactions is similar. To claim a huge number of preventable deaths from uncontrolled studies is premature. The point is that the total sample died at the same rate as a selected group with a high probability of adverse medical error so how can the claim be made that the error is the factor causing deaths. The claim by an author of the original study that the rate is not exaggerated hinges on his position that one cannot calculate the excess mortality due to adverse events in the Harvard study (Leepe, 2000). These errors were not minor events in seriously ill people. In negligent deaths, he notes that 88% of those attributed to error, 14% were minor events in seriously patients that tripped the balance and in 86% the error was a major factor leading to death (unpublished data). The author cites other studies, e.g., that surgical infections cause 20,000 deaths annually. In an epoch preaching evidence based medicine to claim effects from questionably appropriate data may reflect concerns that are understandable but not necessarily defensible.

The numbers of deaths due to medical errors are extrapolations derived from the NYC and Utah-Colorado studies to all hospital admissions in the United States, from 7,743 patients in NYC to 36 million hospital admissions nationally to arrive at the 98,000 deaths per year nationally and from 14,732 patients in Utah-Colorado to 36 million hospital admissions to estimate the 44,000 annual deaths from medical errors. These are a series of extrapolations that require an extreme regularity in medical care and medical error across the country.

The progress has been insufficient an assessment 5 years after the I.O.M. report points out (Wachter, 2004). Stronger regulations have helped such as from the Joint Accreditation Commission for Hospitals (JACHO) as have some early changes in information technology and work force organization and training. Error reporting systems have had little impact and there is no improvement in accountability. The problem stems from the lack of coordination seen in inventions of the 1960s and 1970s, e.g., the Intensive Care Units (ICU) with so many specialists seeing the patient. In an ICU there are 1.7 errors/patient/day and 1/3 are life threatening, most are do to communication errors. Four issues limit our ability to meet the challenge of safety: (1) an outdated mental model for medical mistakes, (2) collective inattention to patient safety, (3) a reimbursement system that provides no incentives for safety, and (4) a fragmented organizational structure. Areas of corrective activity include: (1) regulation, (2) error reporting systems, (3) information technology, (4) the malpractice system and other accountability vehicles, and (5) workforce and training issues.

Has the IOM report been a help or a hindrance considering the disruption it caused and the limited progress that has been made in patient safety? Might the error in the reports title refer now to the problems engendered by the report rather than the incidence of medical errors it set out to decrease? Consultant reports without follow through too often may aggravate rather than alleviate.

It appears that the Libby Zion Grand Jury report begat the Bell Commission that begat the 405.4 rule and the Zion family's Civil Suit begat the I.O.M. report that begat the ACGME regulations. It is essential to our understanding to examine the studies of the effect of sleep loss on performance; first in the controlled laboratory situation and then in the real life situation of medical practice.

## LABORATORY STUDIES OF SLEEP DEPRIVATION

A large number of important decisions have been made restricting the number of hours a resident can work based on the assumption that medical errors are significantly determined by the amount of sleep the resident has had. It is appropriate to look at the results of controlled laboratory studies of the effect of sleep loss or sleep reduction on various aspects of performance. The first studies of total sleep deprivation were done between 1894 and 1896. The estimate is that 1,000 studies of sleep deprivation have been reported in the past 10 years. The effects of sleep loss studies cannot separate whether the effects are the result of sleep loss or prolonged wakefulness.

### TOTAL SLEEP DEPRIVATION

It has been found that about one-third of young adults are sleep deprived. Sleep time it has been calculated should be 8.2 h. Sleep loss affects mood more than cognitive tasks, which in turn are

affected more than psychomotor performance. Interestingly, sleep deprivation affects psychomotor performance in a dose response fashion, more the speed than the accuracy of performance. The effects of sleep loss are similar to those of alcohol ingestion. The variability in a subject's motivation affects the results obtained in these studies.

### Acute total sleep loss

Sleepiness is inferred from subjective reports, the Multiple Sleep Latency Test (MSLT), Electroencephalographic (EEG) changes, and looking at a subject's face. Variables that determine the impact of acute total sleep loss include: (1) sleep and circadian influences, i.e., the amount and the distribution of prior sleep. The length of time awake explains 30% of the variance in alertness, while circadian time accounts for only 5% of the variance. Naps correct 5% of alertness variance, napping decreases some what the effects of sleep loss; (2) arousal system influences: (a) activity-exercise reverses some effects but only briefly, i.e., for 30 min, (b) bright lights-shifts circadian rhythm but does not increase alertness, (c) noise – increases alertness in sleep deprived individuals but not in normals, (d) temperature – there is no data on the effect of a cold environment on performance, (e) posture – sitting or standing counteracts sleepiness, (f) drugs – do have a positive effect on performance but not in the non-sleepy, i.e., amphetamine, caffeine can be like a 3 h nap, pemoline, modafinil and cocaine; however, nicotine has no effect and alcohol increases sleepiness with one night of sleep loss having the same effect on performance as a 0.10% Blood Alcohol Content, (g) interest-has not been studied, (h) motivation-can reverse one night of sleep loss – i.e., monetary rewards, public feed back of results and knowledge that the deprivation will soon be over, (i) history of exposure to sleep loss – with repeated sleep loss performance becomes worse as motivation decreases; (3) subject characteristics : (a) age plays a minor role, older people actually show a smaller performance decrease, and (b) personality and psychopathology – (1) sleep loss leads to mood change, yet improves depression, (2) increased sleepiness and perceptual distortions occur in 80% of people, depends on work-load, visual demands and length of deprivation, (3) paranoid thoughts are worse at night, e.g., 2% of 350 normals deprived 112 h resemble paranoid schizophrenics, gone after sleep; also sleep loss in chronic schizophrenics can reactivate acute psychotic symptoms; (4) test characteristics – the characteristics of tests sensitive to sleep loss are those that are (1) longer-10-50 min, (2) with little feed back-(motivation), (3) with external pacing-so cannot adjust alertness, (4) have a memory or vigilance component – 50% of residents report having fallen asleep driving, 90% of these reports are from after night call, (5) are monotonous and (6) newly learned.

### Physiologic effects of sleep deprivation

The physiologic effects of sleep deprivation: (1) neurologic-minor and reversible, after 205 h of being awake one gets mild nystagmus, hand tremor, some slurred speech, ptosis, hyperactive gag and deep tendon reflexes, and increased pain sensitivity. A linear decrease in alpha occurs with increasing sleep loss (to 10 s after 24 h loss) and an increase in delta, brain activity decreases in prefrontal, parietal and thalamic areas and sleep deprivation can activate a seizure. Recovery from sleep loss is delta sleep first then REM sleep and recovery

occurs more quickly than the amount of sleep lost, but the various aspects of performance recover at different rates; (2) autonomic changes – there is a minor, small decrease in body temperature; (3) biochemical changes – there is no increase in sex or adrenal hormones and perhaps a decrease, thyroid hormone increases and those hormones dependent on sleep for rhythmicity or appearance are affected, e.g., nor-adrenaline, prolactin and growth hormone; (4) immune function-many changes, decreased killer cell activity and number and an increase in infections associated with exercise, (see chronic sleep loss); and (5) gene expression – some seen and are responsive to nor-adrenergic activity.

### SELECTIVE SLEEP DEPRIVATION OR SLEEP FRAGMENTATION

Selective sleep deprivation, i.e., stages of sleep-appears to have no effect as performance is a function of time asleep. Sleep fragmentation reduces the restorative effect of sleep similar to total sleep deprivation and the amount of fragmentation correlates with daytime sleepiness. Partial Sleep Deprivation when acute, affects vigilance if subject has had only 3 h of sleep. The effects of chronic partial sleep loss accumulate over time and with 3 h sleep you get performance decrements. Insomniacs do not suffer from chronic partial sleep loss and do not show comparable performance decrements.

### CHRONIC SLEEP LOSS

Chronic Sleep loss studies show (1) cognitive impairment, e.g., a 40% reduction in sleep for 5 days reduces vigilance and simple reaction times but not all performance measures, accumulation occurs and if have to sleep during the day get larger decrement effects; (2) sleep propensity changes – in a dose response manner-1/2 h decrease in sleep and propensity increases 27% up to 72%; (3) sleepiness and mood changes – subjective sleepiness does not predict performance decrement but underestimates it, plateaus after four nights, mood disturbance is negative and decreases motivation, over 6–8 months of chronic sleep loss get blurry vision, dry eyes, hunger and headaches; and (4) increased risks of auto accidents.

Physiologic effects of chronic sleep restriction-(1) behavioral impairment, (2) physiologically increased sleep propensity, (3) endocrine and immune activity alterations, and (4) elevated mortality with self-reported long and short sleep 9 and 6.5 h. EEG Power – changes, but does not predict performance, slow eye lid closure associated with vigilance lapses, drowsiness if driving and accidents on simulators increase, no alpha change over 14 days of 4–6 h per night, but there is an alpha decrease with total acute loss (see above); Endocrine and Metabolic – reduces circulating Growth hormone, Leptin, and Thyroid axis hormones. One night of sleep restriction can lead to a change in catecholamines, a decrease in thyroid axis hormones, cortisol, prolactin, luteinizing hormone and estradiol and decreased glucose tolerance. Longer partial loss can alter Leptin and lead to weight gain, and nocturnal increase in cortisol. Immune and Inflammatory Effects – changes in natural killer cell activity, interleukin-6, lymphokine-killer cell activity, soluble tumor necrosis factor-alpha receptor-1. Antibody response is slowed in sleep-restricted state but recovers over a few weeks. Febrile response can be attenuated; Cardiovascular Effects – in sleep-restricted state you see increased cardiovascular events and morbidity. Mechanism may be inflammatory as C-reactive protein (CRP), an inflammatory marker predictive of cardiovascular disease; increases with total and partial sleep loss.

It is apparent, from controlled laboratory studies that sleep loss, both acute and chronic, results in impaired function. Most strikingly the functions that are impaired are mood, cognition and psychomotor performance. The important question that remains is whether the impairments that have been demonstrated in the laboratory can be shown to occur in the clinical situation and to have serious consequences. Does the difference make a difference; is the question to be asked?

### STUDIES OF SLEEP LOSS IN THE CLINICAL SITUATION

Considerable doubt has been expressed as to whether the available evidence on the effects of sleep loss on patient care and learning justifies such a radical change in the training of house officers as has been instituted. Baldwin and Daugherty (2004) based on a survey of 3,604 house officers concluded, “Capping residents work hours is unlikely to fully address the sleep deficits and resulting impairments reported by residents.” Question has been raised (McCall, 1988; Petersen et al., 1994) whether the changes themselves might cause serious problems in patient care and learning, e.g., more “hand-offs” from one doctor to another because of shift changes causing more errors in care, interfering with seeing the unfolding of the development of an illness, interrupting the doctor-patient relationship, decreasing opportunities in learning to do procedures or participating in rounds or seminars and damaging the development of a professional persona as physicians by their becoming hourly/shift workers. These problems have been addressed to some degree in response to the mandated limitations on hours of work. Follow-up studies support many of these concerns and will be discussed later in this essay. It is clear that in the laboratory acute and chronic sleep loss impairs performance in a systematic manner (Bonnet, 2000a,b; Dinges et al., 2000). The question remains if the deleterious effect of sleep loss can be demonstrated in the actual clinical situation.

The design of studies will illuminate or limit our understanding of the effect of sleep loss on the performance of the resident. The questionnaire studies call attention to certain aspects of the problem but are limited by being retrospective and subjective and influenced by the vagaries of memory and the overt and covert demand characteristics of the questions being asked and the motivations of the subjects. The observational/interventional studies both simulated and directly observed provide us with our most cogent information.

### QUESTIONNAIRE STUDIES

Certain aspects of the impact of the work situation require the opinion of the residents and the use of questionnaires is appropriate. There are four questionnaire studies that are directed at how Internal Medicine residents feel, three explore the result of the work time limitation and one the residents' view of medical errors and their cause. Baldwin and Daugherty (2004) in a very detailed questionnaire study noted that that work hours and sleep hours were significantly correlated ( $r = 0.39$ ), but not robustly. Twenty percent of all residents' report sleeping less than 5 h/night with 66% averaging less than 6 h/night. Those reporting averaging less than 5 h per night were more likely to report serious accidents or injuries, conflict with other professional staff, use of alcohol, use of medications to stay awake, noticeable weight change, working

in an impaired condition and having significant medical errors. Baldwin concludes that capping resident work hours is unlikely to fully address the sleep deficits and resulting impairments residents report. Gopal et al. (2005) compares residents' answers 1 month before and 1 year after the ACGME rule change. The residents reported decreased emotional exhaustion and decreased depression and depersonalization. Personal accomplishment and quality of care were unchanged and there were fewer educational conferences. Residency satisfaction had decreased. Goiten et al. (2005) compared answers from 2 years before to after ACGME mandated change in work hours and found fewer residents with emotional exhaustion but more noting a negative effect on patient care and on their education. However, most residents approved of lowering hours despite the negative effect on patient care and education. Jagsi et al. (2005) reports on residents' experiences with adverse events that two-thirds considered significant. The most common adverse reactions were with medications and procedures. Residents saw errors as due to excessive work hours, inadequate supervision, and hand-offs to other doctors. Therefore, he concludes that the causes of errors are multi-factorial.

Kashner et al. (2010) surveyed residents who rotated through V.A. facilities before and after the cap on hours. Medical residents reported a clear improvement overall in their experience, surgeons' an improvement in some areas while the data did not permit a comment of the effect on psychiatric residents.

Griner et al. (2010) studied surgical attending educators perspective of the limit on work hours on surgical residents. These residents are seen as having a lower work ethic, less developed technical skills, decision-making ability and sense of patient ownership than residents who had worked before the hourly cap.

Residents who get the least sleep have the most difficulty, some however report feeling better with a cap on hours of work, residency satisfaction improved but satisfaction with the educational experience decreased. The educators were concerned that the resident experience did not create the attitudinal and technical achievements needed for good practice. Limiting work hours will not solve the problems associated with on-call work for residents and may make patient care worse.

#### LITERATURE REVIEWS OF STUDIES OF SLEEP LOSS

There have been seven literature reviews or editorials of studies of sleep loss and resident performance. Samkoff and Jacques (1991) reviewed the clinical sleep loss literature from 1970 to 1989. She described studies that described the deleterious effect of sleep loss on mood and attitudes and on acuity in prolonged vigilance tasks, but found no effect on manual dexterity, reaction times and short-term memory on short tests. Medical errors were found on routine, repetitive tasks that require sustained vigilance. Green (1995) concluded in 1995 that the evidence on the harms and benefits of reduced hours was mixed as most residents, 51%, report serious errors because they have too many tasks to do and 41% attribute errors to fatigue and overwork. Interestingly, 42% of residents report not following ACGME rules. Green concludes that there is no confirmation that long hours harm patients or residents and that hours should be reduced for ethical reasons as it will encourage professional values and attitudes as residents', who are overtired, get irritable and develop non-professional attitudes, cynicism and

a dislike for patients. What is needed is adequate supervision, the use of night floats and more help from others in routine tasks. Lydic (2002) in an editorial notes that Howard et al. (2002a) has reviewed the evidence about the negative influence of sleep deprivation in car crashes caused by sleepiness and found 100,000 crashes with 71,000 injuries and 1,550 deaths. This is tragic but not the same as medical errors. Medical education Howard says is negatively influenced by sleep loss. Moderate sleep deprivation of 17–19 h has a performance impairment that is equal to that found with alcohol intoxication. Sleep loss alters endocrine function, host defense and autonomic control. But does it lead to errors in patient care?

Swide and Kirsch (2007) reviewed the data across specialties and are of the opinion that the educational environment and quality of life for residents is better but are unsure if patient safety or the quality of education is any better.

Howard et al. (2002a) makes a series of observations on the risk to patients and health care providers from sleep loss. Anesthesiologists have noted that in 5,600 reports of critical incidents, fatigue was a factor in 3% (168) of cases. Needle sticks are related to carelessness and increase with sleep loss. Night work for students has a 50% risk of sustaining a blood borne pathogen. Female residents have more pre-term deliveries if they have worked 100 h, increased pregnancy induced hypertension, pre-term labor and small babies. No change in mortality was found after the time rule was implemented. Howard proposes to manage alertness in health care by (1) education, (2) naps (40 min), (3) caffeine (15–30 min after ingestion) one gets an effect for 3–4 h but other drugs are problematic, (4) scheduling, and (5) sleep health and sleep illnesses information. He concludes that there should be no changes without data.

Fletcher et al. (2005) has reviewed the sleep loss literature from 1966 to 2005 on changes to counteract the effects of resident work hours, fatigue or sleep deprivation. Interventions include night and day floats, extra cross coverage and physician extenders. Results are mixed on operative experiences, test scores and satisfaction but improved for quality of life. We need information on the link between resident quality of life and the quality of patient care. Fletcher concludes that poor study design makes interpretation difficult and that the long-term effects on resident education is unknown. Resident life quality improved with reduced hours of work but the relationship of quality of life to quality of patient care remains to be demonstrated. Dawson and Zee (2005) reviews sleep loss studies in an editorial and notes that work hours reduction, according to Fletcher, leads to a self-reported improved quality of life with a decrease in stress and an increase in personal and study time and a better mood. Senior staff however were concerned about residents having a decrease in experience by doing fewer procedures, observing less continuity of care and developing a shift work mentality leading to a weakened professionalism. We do not know how a decrease in response times, vigilance and driving performance relates to performing medical tasks. Performing like you would with blood alcohol levels of 0.04–0.05% is suggested by comparable performance levels found in residents who are sleep deprived and subjects with these blood alcohol levels. I doubt that it is like being treated by an intoxicated doctor as some have suggested.

Veasey et al. (2002) in an extensive review of the effect of sleep loss on residents performance note that "most documentation of medical error is neither systematic nor complete... The role of

insufficient sleep in preventable adverse events is not known.” Their focus is on corrective measures to counteract sleep loss and fatigue in residents.

Philibert (2005) in a meta-analytic study of sleep loss and performance reviewed the literature from 1971 to 2003, found 60 studies with usable data, 20 of which were of resident physicians and 7 of which measured effects on clinical tasks, tests of clinical performance or simulations. She concluded that “sleep loss of less (even) than 30 h reduced a physician’s overall performance...” but warned that the results were tentative because of the limited sample size and the heterogeneity of studies.

Levine et al. (2010) provide the most recent review, 2010, of the effects of reducing or eliminating shifts over 16 h. They found that 7 of 11 studies were associated with improvements in patient safety. The method for rating the articles as positive or negative was not provided in the methods section. In reading the descriptions of the results reported, I rated three positive, six negative and two mixed. The authors point out that many studies utilized a pre-post design which is subject to a time-series bias. Other problems might be noted such as the use of questionable comparison groups.

#### **STUDIES OF THE EFFECT OF A REDUCTION IN WORK HOURS ON PERFORMANCE**

What effects have been observed following the reduction in resident work hours? Dawson and Zee (2005) has said that without linking effects of work hour restrictions to patient safety, a decision to reduce hours is speculative. Fletcher et al. (2004) reviewed the literature on work hours and patient safety from 1966 to 2004. She found seven studies that made system changes, which included float systems and unspecified schedule changes and who examined outcomes that included mortality, adverse events and medication errors. Some studies showed improvement, some no change and some got worse. Reduced work time for pediatric residents showed no differences. In another study with a night float change; there were fewer medication errors while fevers, deaths and readmissions remained unchanged. Deaths after the reduced work hours in New York State were introduced due to the 405.4 law (The New York State Health Code), showed no death rate change in New York City hospitals. In a study in which a night float was used there was no change in mortality or delay of procedures but complications and test delays increased perhaps because of cross coverage. Another study showed cross coverage was associated with more tests being ordered. Comparing primary coverage to cross coverage to a night float (Petersen et al., 1994) found primary coverage had the lowest risk of adverse events and cross coverage more risk than a night float. Fletcher concluded that the evidence on patient safety was insufficient to inform the process of reducing resident work hours.

Privette et al. (2009) noted, in the 14,610 surgical cases reviewed, that the implementation of the hours cap on a surgical service was followed by a reduction in mortality and provider related complications. The improvement was thought to be related to decreased resident fatigue and greater faculty involvement.

An English study (Mcintyre et al., 2010) showed no change in the standard of patient care comparing the European hourly cap system post restriction to pre-restriction, but there was a paradoxical increase in resident sick leave.

Fletcher et al. (2005) also examined the literature from 1966 to 2005 on the effect of work hour reductions on residents’ lives. She found 54 articles with interventions that included night and day floats, extra cross coverage and physician extenders. Outcomes for resident education were operative experience, test scores and satisfaction; while quality of life outcomes were the amount of sleep and the sense of well-being. Studies had design limitations and did not study links between residents’ quality of life and the quality of patient care. Her conclusions were that interventions suggested that the resident’s quality of life is improved with work hour limitation, which Green (1995) believes would improve professionalism, but poor study design limits interpretation. The long-term effect on resident education of work hour reduction is unknown. We need to study the links between residents’ quality of life and the quality of patient care. Self perceived resident error (West et al., 2006) is common in Internal Medicine residents which results in a great deal of stress and the residents are then at a higher risk to perceive error in the future.

Parthasarathy (2005) reviews evidence for change in work hours that suggest that we can attribute medical errors to long hours which also effects physician driving, health and well-being, needle sticks (Ayas et al., 2006) and serious staff conflicts. However he concludes that work intensity rather than hours is the cause (Baldwin and Daugherty, 2004). He quotes the Harvard Intern Studies that a 16-h work-limit reduced both attentional failures and serious medical errors 22% (Landrigan et al., 2004; Lockley et al., 2004) interns made six times as many diagnostic errors on traditional shifts. In another study he notes that physician learning is impaired by the mandated reduction in hours as they see fewer procedures and have a 49% decrease in clinic time. Residents report they have an improved quality of life and more time for reading. Faculty sees a decrease in patient care and education. Yet Namdari et al. (2010) report an increase of total publications by orthopedic residents after the hourly cap.

Parthasarathy’s (2005) solution to sleep deprivation effects is a 16-h limit, a night float, power naps (Arora et al., 2006) and educating residents about sleep hygiene and providing free cab rides home after call. He believes we should compare any new system to what preceded it.

In a study of compliance with the ACGME time regulations 1 year after they were instituted, Landrigan et al. (2006) found overall that 85.4% of residencies ( $n = 707$ ) had at least one rule violation. There were 70.2% violations of the 30-h rule; 68.8% of the 80-h rule and 50.9% of the 7-day rule. In Psychiatry ( $n = 36$ ) 86.1% had at least one rule violation; 69.4% violated the 30-h rule; 50.0% the 80-h rule and 58.3% the 7-day rule. Across all Hospitals ( $n = 314$ ) 90.8% had at least one violation; 79.8% violated the 30-h rule; 81.8% the 80-h rule and 63.6% the 7-day rule. In Pennsylvania Hospitals ( $n = 20$ ) any violation was 100%; a 30-h violation, 75%; an 80-h violation, 90% and a 7-day violation, 75%. In Illinois Hospitals ( $n = 16$ ) any violation, 81.3%; a 30-h violation, 75%; an 80-h violation, 68.8% and a 7-day violation, 56.3%. In New York Hospitals ( $n = 29$ ) any violation, 79.3%; a 30-h violation, 41.4%; an 80-h violation, 75.9% and a 7-day violation, 58.6%. First year non-compliance was the rule.

## OBSERVATIONAL/INTERVENTIONAL STUDIES

Post-call sleepiness (Howard et al., 2002b) was demonstrated comparing Mean Multiple Sleep Latency Test scores of residents finishing call, to those that were starting a day shift, to those who had had extended sleep for 4 days. The results showed little difference between those post-call and those starting their day. The greatest difference was between these two groups and those who had been getting extended sleep (baseline 6.7 min, post-call 4.9 and extended sleep 12.0). Residents are chronically sleep deprived and an on-call session is superimposed on that of chronic deprivation. Forty-nine percent of residents were unable to predict how long it took them to fall asleep, again pointing out that subjective predictions in relationship to sleep and sleepiness are not very accurate. This study is interesting but not directly linked to safety in patient care.

There are simulation studies done with the Mist-VR simulator, which essentially measures manual dexterity. Two such studies (Grantcharov et al., 2001; Eastridge et al., 2003) show clear performance impairment comparing sleep deprived to rested surgical residents. One of which (Grantcharov et al., 2001) speculates on strategies to decrease the decrement in the sleep deprived while the other (Eastridge et al., 2003) raises the crucial prior question, do errors on the MIST-VR translate into poor performance in the real operating room? A third study (Lehmann et al., 2010) (Lehmann17a) utilizing the simulator showed no effect on performance or cognitive function of being on-call one night. A retrospective study (Haynes et al., 1995) that examined post-operative complications comparing the results of sleep deprived and rested surgical residents found no difference. This retrospective study deals with the actual clinical situation and is not a simulation and leads to the conclusion that the simulation differences may well be of a difference that makes no difference.

A simulation study (Howard et al., 2003) that tries to mimic more closely the real life clinical situation was done comparing the performance on a 4-h daytime anesthesia simulation task of six anesthesia residents who were well rested to six who were awake for the previous 24 h, and probably were chronically sleep deprived as well. On tests during the simulation a progressive deterioration of alertness, mood and performance was found. The sleep deprived residents during the simulation period slept more and were less alert than the rested residents. Importantly there was no difference between the two groups in the clinical management of a pulmonary or cardiovascular problem introduced during the 4 h of observation. The study does not support that crucial clinical task performance was affected by sleep loss, but the small number of subjects and the difficulty in complex task analysis limits generalizability from this study.

A summary of evidence in a report from the National Research Council entitled "Sleep Disorders and Sleep Deprivation: An Unmet Public Health Problem" (Colten and Altevogt, 2006) states "Long hours and extended shifts among hospital workers are known to contribute to the problem," i.e., deaths due to medical errors. They point to two studies that found a doubling of errors by surgical residents in simulated laparoscopic surgery (Grantcharov et al., 2001; Eastridge et al., 2003), to Baldwin's questionnaire study (Baldwin and Daugherty, 2004) reviewed above that concluded that "...capping hours of work would not deal with on-call work problems,"

and to an intervention study, The Intern Sleep and Patient Safety Study (Landrigan et al., 2004; Lockley et al., 2004), that will be discussed below. There may be sufficient evidence to support their conclusion of sleep loss contributing to medical errors but certainly not decisively.

Two clinical observational/interventional studies "The Intern Sleep and Patient Safety Study (ISPSS)" (Landrigan et al., 2004; Lockley et al., 2004) were performed as part of the Harvard Work Hours, Health and Safety Study. The studies involved 20 interns working on intensive care units (CCU or MICU). One (Philibert, 2005) was directed at the effect of weekly work hours on sleep and attentional failures. The interns were studied during two 3-week rotations on the intensive care units. Subjects kept daily sleep logs and work logs and had 72–96 h of continuous portable polysomnography (PSG) once a week. The logs were highly significantly correlated with the PSG and direct observation of work schedules. They had a traditional schedule [mean = 84.9 h/week (range 74.2–92.1)] and a 16 h/shift intervention schedule [mean = 65.4 h/week (range 57.6–76.3)]. Attentional failures were defined as the intrusion of slow rolling eye movements into PSG confirmed episodes of wakefulness during working hours expressed as the number of 30 s epochs of wakefulness that contained at least one rolling eye movement. Interns on the intervention schedule slept 5.8 h more per week and slept more in the 24 h prior to each working period. Attentional failures were reduced from 0.69/h (5.5/8 h) to 0.33/h (2.6/8 h) during the 11 p.m. to 7 a.m. work period. The reduction was only clear in 13 of the 20 interns. There also was a reduction in attentional failures from 7 a.m. to 10 p.m. of 50% but it was only a statistical trend. The authors suggest that the attentional failures may impede the intern's ability to care for patients and their education. Napping before the night shift may have attenuated the effect, as might the use of caffeine. The study is exemplary in attempting to capture the sleep changes that underpin the attentional changes of interest. The limitations of very small numbers of subjects with a reduction of attentional lapses of only 53% and clear effects in only 65% of interns all need to be taken into account before recommendations for schedule change can be supported. The lapses, which occur six times during 8 h and may be less than 30 s in length may have no consequence.

The Second Intern Sleep and Patient Safety Study (Landrigan et al., 2004) probably of the same 20 interns as the previous study compared the rates of serious medical errors made by interns working a traditional schedule with extended (24 h or more) work shifts every other shift (an every third night call schedule) to working an intervention schedule that eliminated extended work shifts and reduced the number of hours worked per week. Two physicians' blind to condition independently rated each medical incident. Serious medical errors were categorized as preventable, adverse events (injured patient), intercepted (caught before it reaches the patient) and non-intercepted (reaches patient but causes no detectable harm) medical errors.

There was no significant difference in rates of total adverse events (preventable plus non-preventable) between the traditional and interventional schedule. Serious medical errors by interns overall were reduced very significantly during the intervention schedule compared to the traditional schedule from 176/1,000 patient days to 91/1,000 patient days; a reduction of 48.3% (176–91/176). The authors' conclusion was that eliminating work shifts and reducing



the number of hours' interns' work/week can reduce serious medical errors in the intensive care unit. It appears that the serious medical error statistical difference is due to the statistical difference in intercepted (an error that did not reach the patient) and not non-intercepted serious errors (a serious medical error is one that reaches the patient but causes no clinically detectable harm). These are differences that apparently make no difference!

Further, the same change in medical errors was true for the entire intensive care unit; 250/1000 patient days at the time of the traditional intern schedule to 144/1000 patient days during the intern's intervention schedule. The study could not be double blind because of the change in intern schedule. There was a 47.6% reduction (259–144/250) in medical error from the traditional to the intervention period for the unit as a whole independent of the reduction attributed to the intern's improvement suggesting that monitoring during this period may have increased and reduced the error rate without changing working hours in the remainder of the staff, suggesting a Hawthorn like effect.

The results raise question about attributing change to the schedule change unless only the interns were working, which is clearly not the case. One cannot really attribute change to a decrease in hours as change in errors occurred across the entire unit. The study is of questionable support for the value of a schedule change reducing errors and leading to safer patient care. It remains to be demonstrated whether the decrease in the rate of serious medical errors by interns will translate into a reduction in the rate of actual adverse events.

#### SLEEP LOSS EFFECTS AND MEDICAL ERRORS IN PSYCHIATRY

Six studies have been done examining the effect of sleep loss or medical errors in psychiatric residents or psychiatrists. Landrigan et al. (2006) shows that 1 year after the implementations of the ACGME rules on work hours in 36 psychiatric residencies 90.8% had at least one rule violation and violations for the 30-h rule were 69.4%; the 80-h rule, 50.0%; and the 7-day rule, 58.3%. The results are similar to overall residencies.

Ford (1983) did a survey of depression and stress in 376 interns and residents and got a one-third response. One-third of the reporting interns' were depressed or stressed and 13% of

residents. Both saw depression in over half of their colleagues. Thirteen to 21% have sought treatment. Druss et al.'s (1996) residents at Yale report improved well-being, educational experience and clinical performance after a night float system was introduced. Their faculty was favorable about the night float system as well. If residents are less irritable, it should be good for work with patients. Baldwin and Daugherty (2004) has noted that only 13% of psychiatric residents reported 55 or less hours of sleep/week on the average compared to 22% across all residencies.

Castberg et al. (2006) studied the understanding of Acute Drug Reactions (ADR) and noted that psychiatrists reported bothersome ADR's occurred 2.4 to 9.3 times and to practitioners more than residents. Knowledge about the association of receptor site blockade with a specific ADR, varied from 37% to 76% of respondents. Knowledge of ADR's was incomplete. Stubbs et al. (2006) found only 22 serious errors in 22,036 prescriptions (0.09%) written in a week in nine out and inpatient services by psychiatrists.

#### FINAL STATEMENT

We are in the troubling situation in which important changes have been made in time scheduling for residents to improve patient care which may have made care worse and we are unable to find definitive evidence to support the change. Our laboratory studies have shown conclusively that extended time awake impairs performance. Further our intuition leads us to believe it. Dawson and Zee (2005) is of the opinion that indirect evidence links fatigue with reduced patient safety but the link between hours of work and patient safety is less clear so for him a decision to reduce hours is speculative. Our colleagues writing for the National Research Council are persuaded of the link (Colten and Altevogt, 2006). Yet our two best empirical studies (Landrigan et al., 2004; Lockley et al., 2004) fail to demonstrate that extended prior wakefulness results in serious, harmful medical error in the clinical situation. Despite our commitment to evidence based medicine, it is an unacceptable conclusion. Sleep loss, ought to make a difference in clinical care, but demonstrating it convincingly remains to be done.

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