

# Doctors Drunk with Fatigue

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Norman D. Tucker  
Sommers Schwartz PC  
2000 Town Center, Suite 900  
Southfield, MI 48075-1100  
(248) 355-0300  
[ntucker@sommerspc.com](mailto:ntucker@sommerspc.com)

In 1999, the Institute of Medicine (IOM) estimated that as many as 98,000 deaths per year are due to medical errors. The frequently used analogy; this is the equivalent of a fully loaded Boeing 747 crashing every working day and killing all on board. Even this analogy failed to incite the public's ire; mistakes happen, we are all human. But what if they knew that too often the 747 pilots were intoxicated?

We have known for years that fatigue impairs mental function. The national disasters attributable to fatigue are well known. Those often cited include: the Chernobyl Nuclear Plant Explosion, the Three-Mile Island nuclear accident, and the Exxon Valdez oil spill, just to name a few.

To guard against the well recognized hazards of fatigue, many occupations requiring high levels of mental alertness have severely restricted weekly and per shift work hours. Medicine, however, literally and figuratively, is still at the bottom of this list.

<u>Job</u>	<u>Weekly Cap</u>	<u>Maximum Shift</u>
Airline pilot	30 hours flying time (100 hours per month)	8 hours (per 24 hrs)
Tanker Shipboard Personnel	84 hours	15 hours (per 24 hrs)
Railroad Conductors	None	12 hours
Long-haul Truck Drivers	60 or 70 hours driving time per 7-or-8-day shift	14 hours on duty/ 11 hours driving
Medical residents	80 hrs per week average over four weeks	30 hours: 24 hours + 6 hours transitional duties <sup>1</sup>

The most glaring comparison is between pilots and residents. Residents are permitted to work three times as many hours per month and almost four times the per shift hours

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<sup>1</sup> Philip Shishkin, "Moves to Allow Medical Residents More Shut-Eye Rouse Opposition," *Wall Street Journal*, May 21, 2009.

as pilots. In 2003, the Accreditation Counsel for Graduate Medical Education (ACGME) limited resident's working hours to 80 hours per week, averaged over 4 weeks, and to 30-hour shifts.<sup>2</sup> Even with the most permissive work hours in the safety professions, there are medical profession doubters, and there has been push back. Some even argue that shorter hours will increase errors.<sup>3</sup> No one, however, argues that physicians are immune to fatigue.

The most persuasive studies have been those that measured and compared cognitive and motor function with fatigue and its equivalent blood alcohol levels. Dawson's and Reid's seminal 1997 study compared two groups. One consumed incremental amounts of alcohol. The other went without sleep. Each was given the same test at thirty-minute intervals. The effects of fatigue on performance were frightening.<sup>4</sup>

After 17 hours of sustained wakefulness...cognitive psychomotor performance decreased to a level equivalent to the performance impairment observed at a blood alcohol concentration of 0.05%.

After 24 hours of sustained wakefulness...cognitive psychomotor performance decreased to a level equivalent to the performance deficit observed at a blood alcohol concentration of roughly 0.10%.

While this study did not evaluate physicians in training, or those with specialized skills, it was the catalyst for the many studies that followed.

The Harvard Work Hours, Health and Safety Group, from July 2002 to June 2003, studied the medical errors made between first year residents working 24 hour plus shifts twice per week compared with those working 16 hour shifts.<sup>5</sup> Looking at 2203 patient-days and 634 admissions, they found those working 24 hours or more made 35.9% *more serious errors*. In the ICU setting, serious medication (20.8 percent) and diagnostic (5.6 percent) errors were most prevalent.<sup>6</sup>

Subsequent opinions have extended this analysis to mistakes in labor and delivery. Most who have handled obstetrical cases have encountered the resident who continually reads the strips as "reassuring tracings". As so often happens, these deliveries are during the night, or on weekends, when the shifts are likely to be long and

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<sup>2</sup> Accreditation Counsel for Graduate Medical Education, ACGME Duty Hours Task Force, [http://www.acgme.org/acWebsite/dutyHours/dh\\_index.asp](http://www.acgme.org/acWebsite/dutyHours/dh_index.asp) (Accessed December 28, 2010).

<sup>3</sup> Shishkin, "Moves to Allow Medical Residents More Shut-Eye Rouse Opposition."

<sup>4</sup> Dawson D., Reid K, Fatigue, Alcohol and Performance Impairment, *Nature* 1997; 88:235

<sup>5</sup> Landrigan C, Effect of Reducing Interns; Work Hours on Serious Medical Errors in Intensive Care Units, *N Engl J Med* 2004; 351:1838-48

<sup>6</sup> Landrigan, 1843

with little rest. Dr. Steven Clark's chart and observations put these misreads in perspective:<sup>7</sup>

Sleep Deprivation Hours	Functional Serum Ethanol Level (%)
17-19	0.05
19-21	0.08
24	0.10 <sup>8</sup>

What is the effect on a resident physician reading fetal monitor strips with an inebriated cognitive functional capacity?

*Sleep deprivation has been shown to negatively impact the ability of physicians to accurately interpret an electrocardiogram.*

Of particular concern in this regard is the finding that *errors in the interpretation of diagnostic tests with sleep deprivation are overwhelmingly false-normal interpretations.*

Sleep deprivation also *contributes to the inability to avoid making the same error again even after it has been recognized once, and perseverance in solutions that do not work, thus producing a vicious cycle leading to additional errors.*<sup>9</sup>

And, what about those situations where the resident waits, and waits, and waits to call for the c-section until the child has for too long been deprived of adequate oxygenation?

Sleep-deprived individuals take *longer time to make a decision* when faced with the need to do so and *lose the ability to adapt to changing circumstances.*

The ability to take *independent initiative is also impaired.*<sup>10</sup>

While much of the fatigue research has focused on residents as they have fixed and quantitative schedules, obstetrics is one specialty area where the attending physicians may have little control of his or her sleeping hours, and could well suffer from the same fatigue intoxication as their residents:

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<sup>7</sup> Clark S. Sleep deprivation: implications for obstetric practice in the United States. *Am J Obstet Gynecol* 2009; 201:136.e1-4.

<sup>8</sup> Clark, 136.e3

<sup>9</sup> Clark, 136.e2

<sup>10</sup> Clark, 136.e2

The average practicing obstetrician... works hours significantly in excess of those allowed for younger resident physicians.<sup>11</sup>

With all the talk about safety in medicine, fatigue hazards are still on the fringe of public awareness. Although fatigue has been called the Achilles' heel of the medical profession,<sup>12</sup> remedial action has been slow and arguably inadequate.

Public attention focused on medical fatigue 15 years ago in the now infamous Libby Zion case, tried in 1995 in New York.<sup>13</sup> The incident, which occurred in 1984, is a textbook example of residents working too many hours. One resident was asleep, the other was working a 36-hour shift. At 3 a.m., the fatal mistake was a medication error.<sup>14</sup> In 1989, the State of New York enacted legislation called the Libby Zion Law that limited resident working hours to 80 per week, and shifts to 24 hours with an added 3 hours to make patient transfers.<sup>15</sup> More than 2 decades later, notwithstanding the scientific evidence demanding fewer hours, restrictions on residents' work hours have changed little.

As noted above, in 2003 the ACGME limited resident duty hours to an *average* of 80 hours per week, and 30 hours per shift. This averaging permits a resident to work a hefty 60 hours one week, and an oppressive 100 hours the next. To put the obvious in perspective, there are only 168 hours in a week.

In April 2005, the American Organization of Nurses (AORN) House of Delegates voted to limit preoperative RN's shifts to no more than 12 hours in a 24-hour period and not more than 60 hours in a seven-day period.<sup>16</sup> Hopefully the difference permitted between nurse's and resident's working hours is not based on some elitist belief that nurses have less stamina than physicians.

In 2003, and reaffirmed in 2010, the American College of Emergency Room Physicians (ACEP) limited ER shifts to, "12 hours or less".<sup>17</sup>

Finally, in December 2008, the Institute of Medicine, after concluding that safety in medicine had not improved since their original 2000 study, made additional recommendations. Their conclusion: resident shift hours should not exceed 16 hours per shift unless an uninterrupted five-hour break for sleep is provided within shifts that

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<sup>11</sup> Clark, 136.e3

<sup>12</sup> Gaba D., Howard S., Fatigue Among Clinicians and the Safety of Patients, *N Engl J Med*; 347:16, October 17, 2002

<sup>13</sup> *New York Times*, Tuesday, February 7, 1995

<sup>14</sup> *The Washington Post*, November 28, 2006

<sup>15</sup> New York State Health Care Code, Section 405

<sup>16</sup> [http://www.aorn.org/PracticeResources/AORNPositionStatements/Position\\_SafeWorkOnCallPractices/](http://www.aorn.org/PracticeResources/AORNPositionStatements/Position_SafeWorkOnCallPractices/)

(Accessed March 7, 2010)

<sup>17</sup> [http://www.acep.org/MobileArticle.aspx?id=29420&coll\\_id=54&parentid=748](http://www.acep.org/MobileArticle.aspx?id=29420&coll_id=54&parentid=748) (Accessed December 27, 2010)

last up to 30 hours.<sup>18</sup> Since the IOM is an independent, nonprofit organization that works outside of government and *only provides unbiased and authoritative advice* to decision makers and the public, it lacked the authority to enforce their recommendations.<sup>19</sup>

To put the IOM recommendation in perspective, at 16 hours per shift, this still exceeds the longest shift permitted in non-medical fields demanding a high level of mental vigilance. As listed above, tanker personnel may only work 15 hour shifts. All the other professions are less.

Without IOM enforcement authority, the acknowledged reality was that nothing would change until ACGME changed their standards. It is only when hospitals risk losing their ACGME accreditation for their residency programs for violation of residents' working hours, and all the Medicare and Medicaid money that goes with it, would changes be adopted. When the Yale University School of Medicine general surgery residents were found to have been working 100 hours or more per week, the ACGME spoke, and the hours were changed.<sup>20</sup>

Responding to the pressure from the IOM, on June 23, 2010, Dr. Thomas Nasca, Chief Executive of ACGME, wrote to the nearly 9000 accredited programs, alerting them to changes under consideration, and asking for feedback. A task force reviewed the research, held hearings, and had the responsibility to draft new standards. The cutoff for comment was August 9, 2010, as the plan was to implement any changes by July 1, 2011. The issue that created the most controversy between the IOM and ACGME was the work hours per shift. Should the IOM's 16 hour shifts apply to all residents, or should there be some compromise?<sup>21</sup>

While the IOM's pushed shorter shifts, based on the research that rested residents make fewer mistakes, the medical profession's resistance to the new proposal surprisingly rarely discussed the specifics of these earlier fatigue studies. The opposition focused on four areas: cost, lack of continuity of care, lack of proper training,<sup>22</sup> and the prospect that the Occupational Safety and Health Administration (OSHA) could intervene and dictate residents work hours as work safety standards.<sup>23</sup> On September 23, 2010, Public Citizen, as a consumer advocacy group, and on behalf of many medial organizations, filed its 2<sup>nd</sup> petition for OSHA to intervene and limit

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<sup>18</sup> <http://www.iom.edu/~media/Files/Report%20Files/2008/Resident-DutyHours/residency%20hours%20revised%20for%20web.ashx> (Accessed December 28, 2010).

<sup>19</sup> <http://www.iom.edu/About-IOM.aspx> (Accessed December 28, 2010).

<sup>20</sup> *New York Times*, May 9, 2002, Metro Briefing, Connecticut, New Haven: Yale Surgery Accreditation.

<sup>21</sup> Nasca T., Day S.H., Amis E.S., The New Recommendations on Duty from the ACGME Task Force, *N Engl J Med* 2010, 363: e3.

<sup>22</sup> ACGME Task Force on Quality Care and Professionalism Response to Public Comments, <http://acgme-2010standards.org/pdf/dh-TaskForceResponsesComments.pdf> (Accessed December 27, 2010).

<sup>23</sup> Ingelhar J., The ACGME's Final Duty-Hour Standards — Special PGY-1 Limits and Strategic Napping, *N Engl J Med* 2010; 363:1589-1591

residency work hours. Although that petition is still pending, the request is a familiar one:

- (1) A limit of 80 hours per week, without averaging;
- (2) A limit of 16 consecutive hours per shift for *all* residents.<sup>24</sup>

Unquestionably the cost would be substantial. If the IOM's changes were adopted, some estimated that the cost could be \$1.1 billion to \$2.5 billion annually. The estimated cost to each teaching hospital to replace the resident's time with substitute providers (nurses, physician assistants, or physicians) could be \$3.2 million annually. To add additional residents, the predicted cost for each hospital was estimated to be \$900,000 to \$3.5 million annually.<sup>25</sup>

While continuity of care or more frequent hand offs, and less hours of training, were frequently cited concerns, there was an undercurrent attitude in many of these responses.

*This forced change diminishes a critical experience that previously contributed to defining a physician as having a profession rather than just a job. Personally, we would rather be cared for by a fatigued professional who feels responsible for our care than by a well-rested shift worker who does not.*<sup>26</sup>

In the end, there was a compromise. On September 28, 2010, ACGME announced their decision. Shift hours were limited to 16 hours per shift, but only for PGY-1 – first year residents.<sup>27</sup> After the resident's first year, 30 hours of continuous duty were still permitted. There was no explanation of how or why, after just 12 months of training, one develops immunity to fatigue's impact on cognitive function.

There was no reduction to the 80 hour week averaged over 4 weeks. In fact, the new rule's exceptions could substantially extend monthly hours:

VI.G.4.b).(3) In *unusual circumstances*, residents, on their own initiative, may remain beyond their scheduled period of duty to continue to provide care to a *single patient*. Justifications for such extensions of duty are limited to reasons of *required continuity for a severely ill or unstable patient, academic importance of the events transpiring, or humanistic attention to the needs of a patient or family*.

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<sup>24</sup> <http://www.citizen.org/hrg1917> (Accessed December 28, 2010)

<sup>25</sup> Nuckols T., Bhattacharya J., Cost Implications of Reduced Work Hours and Workloads for Resident Physicians, *N Engl J Med* 2009; 360:2202-15.

<sup>26</sup> Albert R., Wiener C., To the Editor, New Recommendations on Duty Hours from the ACGME, 2010, *N Engl J Med* 3 63; 1680.

<sup>27</sup> [http://www.acgme.org/acWebsite/home/Common\\_Program\\_Requirements\\_07012011.pdf](http://www.acgme.org/acWebsite/home/Common_Program_Requirements_07012011.pdf) (Accessed December 26, 2010)

Another exception permits another 24 hours to be added to the monthly averages:

VI.G.1.a) Duty Hour Exceptions. A Review Committee may grant exceptions for up to 10% or a *maximum of 88 hours* to individual programs *based on a sound educational rationale*.

The new regulations also reference a subtle and prevalent perception about fatigue in medicine. Many of the opposition statements come close to suggesting doctors are immune to fatigue. At worst, they think they can effectively work through it, or will be able to recognize the symptoms in time to avert problems. ACGME seemed to endorse this attitude:

VI.C. Alertness Management/Fatigue Mitigation. The program must: educate all faculty members and residents *to recognize the signs of fatigue and sleep deprivation...* [and] educate all faculty members and residents *in alertness management and fatigue mitigation processes*;

The problem with these proposed solutions— like alcohol, *fatigue lies to us*. We laugh at the stories, “Officer, I’m not drunk” but fatigue deceives the brain in the same fashion.

Subjects were *largely unaware of these increasing cognitive deficits*, which may explain why the impact of chronic sleep restriction on waking cognitive functions is often assumed to be benign.<sup>28</sup>

With the exception of first year residents, the IOM’s concerns were ignored and the new regulations are more permissive. This may have been a practical decision – most programs would or could not comply with stricter hours by the July 1, 2011, deadline.

We know many programs presently fail to comply with the 2003 hour restrictions. Landrigan’s Harvard Work Hours, Health and Safety Group in 2006, found interns failed to comply 83.6% of the time; more than 10 times the violations reported to ACGME.<sup>29</sup>

What would happen if all residency programs had to comply with more restrictive hours within the next few months?

[M]ost residency programs *currently lack the policies and plans necessary for compliance with the proposed new requirements*, which suggests that most will need to *radically overhaul schedules and curricula in order to comply* with new recommendations by the proposed July 2011 implementation date.

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<sup>28</sup> Van Dongen HP, Maislin G, Mullington JM, Dinges DF. The cumulative cost of additional wakefulness: dose-response effects on neurobehavioral functions and sleep physiology from chronic sleep restriction and total sleep deprivation. *Sleep* 2003; 26:117-26.

<sup>29</sup> Landrigan C., Interns’ Compliance With Accreditation Council for Graduate Medical Education Work-Hour Limits, *JAMA*. 2006; 296: 1063-1070

[D]irectors of *small programs at community hospitals* are less enthusiastic about limiting the duty-hour period may suggest that *implementation may face more challenges in such settings*.<sup>30</sup>

Interestingly, Nuckols, who performed the above cost analysis based on the IOM's recommendations, did a similar analysis for ACGME after their proposed changes were official. With shift hours limited to only first year residents, the costs would be substantially less. He also attempted to calculate the savings shorter shifts would likely produce by eliminating preventable adverse events (PAE). Although a number of assumptions had to be made, the societal and medical costs saved, or prevented, could be as much as \$12 billion per year.<sup>31</sup> Net costs, even with shorter hours for all, would not appear to be a sound opposition argument.

Two facts are indisputable. Lawyers and doctors do think differently; at least plaintiff's attorneys. The science is not questioned. After 16 hours of continuous work, people, including doctors, think and react as if intoxicated. After 24 hours we might as well be drunk.

So, how does one fix a long standing institutional problem that daily threatens the lives of so many patients and costs billions of dollars due to preventable injuries? Did some physicians writing on this predicament slip a message in the bottle, hoping it would wash ashore and be read by the plaintiff's bar? Dr. Clark opines that perhaps the perceived obstetrical litigation crisis is the wakeup call:

It is possible that these factors, coupled with the prevalence of false-normal test *interpretation by sleep-deprived physicians* contribute to the frequency with which failure to recognize and respond to an abnormal fetal heart rate tracing *results in obstetric litigation*.<sup>32</sup>

Dr. Gaba is less subtle,

Malpractice suits alleging that a clinician's fatigue caused harm have also been *surprisingly rare. An increase in such allegations would provide a major incentive to change work practices*.<sup>33</sup>

What would happen if fatigue claims moved beyond residents to include practicing physicians? What if we eliminated the counter arguments of continuity of care (resident's hand offs with more shift changes) and fewer hours of training, by focusing

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<sup>30</sup> Antiel R., Thompson S., ACGME Duty-Hour Recommendations — A National Survey of Residency Program Directors, *N Engl J Med* 2010; 363:e12(5).

<sup>31</sup> <http://acgme-2010standards.org/pdf/dh-CostAnalysisfor2011CPRs.pdf> (Accessed December 29, 2010).

<sup>32</sup> Clark, 136e2.

<sup>33</sup> Gaba, 1251.

on attending physicians performing elective surgeries after 24 hours without sleep? How would the medical profession respond if an attorney made the following argument?

Should a surgeon [be allowed] to perform *elective surgery after having been awake for more than 24 hours?*

*Sleep deprivation adversely affects clinical performance and impairs psychomotor performance as severely as alcohol intoxication.*

In surgery, there is an *83% increase in the risk of complications* (e.g., massive hemorrhage, organ injury, or wound failure) in patients who undergo elective daytime surgical procedures performed by attending surgeons who had less than a 6-hour opportunity for sleep between procedures during a previous on-call night.

80% [of patients] say they would request a different provider in such circumstances.

*Hospitals should prohibit the performance of elective surgical procedures when an attending surgeon or anesthesiologist is acutely sleep-deprived.*

Such prohibitions *should be standard practice.*

If an attorney made such an argument, I have no doubt it would be described as another trial lawyer's frivolous claim. However, lawyers need not spend time thinking about such new theories as these, including the above, are being provided by physicians knowledgeable in the risks of providing medical care while fatigued.<sup>34</sup>

The respect and deference given the medical profession makes medical safety a difficult problem to solve. To simplify the issue, would we be having this debate if the doctor, instead of wearing a white coat, held a steering wheel in his or her hands?

[D]rivers in both the United States and Great Britain have already been convicted of *vehicular homicide for driving when impaired by sleepiness*. Furthermore, the state of New Jersey has recently amended its vehicular-homicide statute to add to the *definition of reckless driving "driving after having been without sleep for a period in excess of 24 consecutive hours,"* a revision that explicitly subjects drivers in that state to a conviction of *criminal homicide* under such circumstances. *Similar legislation is pending in New York, Massachusetts, and Michigan.* Moreover, appeals courts in two states have ruled that an *employer's responsibility for fatigue related crashes can continue even after an employee has left work*, similar in concept to the liability incurred by people who serve alcohol to drivers who are subsequently involved in alcohol-related motor vehicle crashes.

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<sup>34</sup> Nurok M., Czeisler C., Sleep Deprivation, Elective Surgical Procedures, and Informed Consent, *N Engl J Med*, 2010, 363:27

The Department of Surgery at the *University of Michigan* has taken the initiative to address this concern by offering round-trip taxicab vouchers to surgical residents on request.<sup>35</sup>

Lawyer: Doctor, you are absolutely positive that when you entered the intersection the light was still green?

Doctor: Absolutely!

Lawyer: Isn't it likely doctor that you were distracted or not paying attention as you entered the intersection?

Doctor: No chance, I'm a physician, professionally trained to be vigilant and observant, particularly where the safety of others is concerned.

Lawyer: And you feel you were vigilant and observant even though at the time your cognitive function level was the equivalent of a blood alcohol level of 0.10?

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<sup>35</sup> Barger LK, Cade BE, Extended Work Shifts and the Risk of Motor Vehicle Crashes among Interns, *N Engl J Med* 2005, 125-34, 132-133.