In 1999, the Institute of Medicine estimated that as many as 98,000 deaths per year are due to medical errors. The frequently used analogy is this is the equivalent of a fully loaded Boeing 747 crashing every working day, killing all on board. Even this analogy seems to have failed to incite the juror'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 are: 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 shift work hours. Medicine, however, literally and figuratively, is still at the bottom of this list.

<table>
<thead>
<tr>
<th>Job</th>
<th>Weekly cap</th>
<th>Maximum Shift</th>
</tr>
</thead>
<tbody>
<tr>
<td>Airline pilot</td>
<td>30 hours flying time (100 hours per month)</td>
<td>8 hours (per 24 hrs)</td>
</tr>
<tr>
<td>Tanker Shipboard Personnel</td>
<td>84 hours</td>
<td>15 hours (per 24 hrs)</td>
</tr>
<tr>
<td>Railroad Conductors</td>
<td>None</td>
<td>12 hours</td>
</tr>
<tr>
<td>Long-haul Truck Drivers</td>
<td>60 or 70 hours driving time per 7-or-8-day shift</td>
<td>14 hours on duty/ 11 hours driving</td>
</tr>
<tr>
<td>Medical residents</td>
<td>80 hrs per week average over four weeks</td>
<td>30 hours: 24 hours + 6 hours transitional duties¹</td>
</tr>
</tbody>
</table>

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 hours per shift as pilots. In 2003, the Accreditation Counsel for Graduate Medical Education (ACGME) limited the hours residents could work to an average of 80 hours per week over 4 weeks

and to 30-hour shifts.\(^2\) Even with the most permissive work hours in the safety professions, there are doubters within the medical profession, and there has been push back. Some even argue that shorter hours will increase errors.\(^3\) However, no one argues that physicians are immune to fatigue.

The most persuasive studies have been those that measure and compare cognitive and motor function between fatigue and blood alcohol levels. Dawson and Reid's seminal 1997 study used two groups, one with incremental alcohol intake, and the other without sleep, with testing at thirty-minute intervals. The effects of fatigue on performance were frightening.\(^4\)

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 residents working a 24 hour plus shift twice per week compared with those working 16 hours shifts.\(^5\) 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.\(^6\)

Subsequent analysis and opinions have extended this problem to mistakes made in other areas of medicine, including labor and delivery. Most who have handled labor and delivery cases have encountered the resident who continually read 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 with little rest. Dr. Steven Clark's chart and observations put these misreads in perspective.\(^7\)

\(^3\) Shishkin, Moves to Allow Medical Residents More Shut-Eye Rouse Opposition."
\(^4\) Dawson D., Reid K, Fatigue, alcohol and performance impairment, Nature 1997; 88:235
\(^5\) Landrigan C, Effect of Reducing Interns; Work Hours on Serious Medical Errors in Intensive Care Units, N Engl J Med 2004; 351:1838-48
\(^6\) Landrigan, 1843
Correlation Cognitive Performance with Sleep Deprivation and Ethanol Intoxication

<table>
<thead>
<tr>
<th>Sleep Deprivation Hours</th>
<th>Functional Serum Ethanol Level (%)</th>
</tr>
</thead>
<tbody>
<tr>
<td>17-19</td>
<td>0.05</td>
</tr>
<tr>
<td>19-21</td>
<td>0.08</td>
</tr>
<tr>
<td>24</td>
<td>0.10(^8)</td>
</tr>
</tbody>
</table>

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, a finding with potential special significance for both obstetric nurses and physicians who interpret electronic fetal heart rate monitor tracings.

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.\(^9\)

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.\(^10\)

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

The average practicing obstetrician gynecologist works hours significantly in excess of those allowed for younger resident physicians.\(^11\)

It is disappointing that with all the talk of safety in medicine that the hazard of

\(^8\) Clark, 136.e3
\(^9\) Clark, 136.e2
\(^10\) Clark, 136.e2
\(^11\) Clark, 136.e3
fatigue is still on the fringe of public awareness. It is also frightening that even though fatigue has been called the Achilles' heel of the medical profession, remedial action has been slow and inadequate.

Public attention focused on fatigue mistakes 15 years ago in the now infamous Libby Zion case, tried in 1995 in New York. 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, and at 3 a.m., the fatal mistake was a medication error. The State of New York in 1989 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. More than 2 decades later, notwithstanding the scientific evidence demanding fewer hours, restrictions on residents' work hours have changed little.

The ACGME, as noted above, in 2003, 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. Hopefully this difference between permitted nurses and residents working hours is not based on the belief that nurses have less stamina than physicians.

Finally, in December 2008, the Institute of Medicine (IOM) made additional recommendations, which included that on-duty resident hours should not exceed 16 hours per shift unless an uninterrupted five-hour break for sleep is provided within shifts that last up to 30 hours.

The reality is that nothing will change until ACGME changes their standards. It is only when hospitals risk loosing their ACGME accreditation for violation of resident's working hours, or their residency programs, and all the money that goes with it, will they change. 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. It will be interesting to see how far the ACGME will go this next year with their anticipated updating of the restrictions on residents' hours.

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

13 New York Times, Tuesday, February 7, 1995

14 The Washington Post, November 28, 2006

15 New York State Health Care Code, Section 405


The resident duty hours section of the common program requirements are currently being revised. We anticipate that they will be finalized and ready for implementation on July 1, 2011.\textsuperscript{19}

There is opposition to implementing further restrictions on residents' hours, and the concern is an old one - money. If the IOM's incremental changes were adopted, it is 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) is $3.2 million annually. To add additional residents, the predicted cost for each hospital is estimated to be $900,000 to $3.5 million annually.\textsuperscript{20}

While these authors do not claim to speak for the entire medical profession, I suspect the bottom line analysis will be the same:

Averting preventable adverse events may, in addition to reducing the costs of inpatient medical care, avert malpractice claims, preserve the hospital's reputation, and improve patient throughput, but these latter effects on hospital profitability appear to be modest and unpredictable.\textsuperscript{21}

If the changes were highly effective, they could prevent patient harm at reduced or no cost to society. However, financial incentives for teaching hospitals are not well aligned with the implementation of these reforms.\textsuperscript{22}

So then, how does one fix a problem that daily threatens the lives of so many patients? Did those writing on this predicament slip a message in the bottle, hoping it would wash ashore and be read by the plaintiffs bar? Clark opines that perhaps obstetrical litigation is the wake up 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.\textsuperscript{23}

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.\textsuperscript{24}

The sources to document the resident’s hours are plentiful: copies of individual residents scheduled hours, ACGME reports on hours worked, redacted surgical and labor and delivery logs, and perhaps even audit logs of other records where the individual

\begin{itemize}
  \item \textsuperscript{19} C:\My Documents\AAJ Professional Negligence Newsletter\Literature\ACGME Accreditation Council for Graduate Medical Education.mht (Accessed March 7, 2010)
  \item \textsuperscript{21} Nuckols, 2210
  \item \textsuperscript{22} Nuckols, 2213
  \item \textsuperscript{23} Clark, 136e2.
  \item \textsuperscript{24} Gaba, 1251.
\end{itemize}
making the entry is identified by one's initials. We know this is fertile ground for discovery as a survey by Landrigan's Harvard Work Hours, Health and Safety Group in 2006 found interns failed to comply with the present extended hours 83.6% of the time; more than 10 times the violations reported to ACGME. With all this information, and the supporting scientific evidence, why are there so few cases pursuing this issue?

Perhaps the reluctance is best stated in a question asked last year after a presentation on fatigue in medicine, “Why would we go to all that trouble since we still have to prove the resident violated the standard of care?” I would respectively suggest because standard of care evidence meets the burden of proof; evidence that a resident was fatigued to the functional level of a drunk certainly would not hurt on the burden of persuasion. Hopefully, we all make our prima fascia case. The real hurdle in winning malpractice cases is persuasion; convincing the jury that our explanation is more believable than the defense's. I do not think there would be much question of the value of this evidence if the doctor had been in an auto accident.

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, 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.

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25 Landrigan C., Interns' Compliance With Accreditation Council for Graduate Medical Education Work-Hour Limits, JAMA. 2006; 296: 1063-1070