Impact of Work Hour Regulation on Mortality in Teaching Hospitals: Some Findings and Future Directions

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Why duty hour reform for physicians in training?

- Pre-2003, residents commonly worked 100-120 hours per week, with continuous shifts as long as 80 hours

- Concerns about impact of acute and chronic sleep deprivation on cognitive performance

- Relative inexperience, heavy workloads, time pressure, lack of expertise make errors more likely
Resident work schedules exacerbate sleep deficits

- Long shifts
- Awoken frequently
- Alternate between daytime and nighttime
- Inadequate recovery time between shifts
- Cumulative fatigue exacerbates problems
  - Significant sleep inertia – may not even remember being woken up
  - Cumulative fatigue (from chronic sleep restriction and inadequate recovery sleep) may cause performance deficits similar to staying up all night
Libby Zion Laws – NY State 1988

- **Mandated:**
  - 80 hours per week averaged over 4 weeks
  - No more than 24 consecutive hours
  - At least 1 scheduled 24 hour break per week
  - Shifts in busy ERs not more than 12 hours
  - On-site supervision 24 hours per day, 7 days per week

- **Results:**
  - No relative improvements in mortality for AMI, CHF, pneumonia in teaching vs. non-teaching hospitals\(^1\)
  - Significant increases in proportion patients with at least one complication (35% vs. 22%, p=.002) and in delays in diagnostic tests (17% vs. 1.9%, P<.0001)\(^2\)
  - Compliance poor (60% of surgical residents exceeded 95 hours per week – 1997 audit)

\(^1\) Howard, Silber, Jobes JGIM 2005
\(^2\) Laine JAMA 1993
ACGME duty hour reform - 2003

• Strong negative feelings
  
  *recent restrictions in work hours are an ominous development because of their effect on patient care… [which] suffers with work hour reductions*¹

• Strong positive feelings
  
  *Specific limits on work hours are the centerpiece of efforts to prevent fatigue among workers in other hazardous industries. Such limits are needed in health care to eliminate egregious practices that pose high risk for patients*²

• What happened?

¹Charp, Annals Int Med 2004; ²Gaba and Howard NEJM 2002
Benefits – reduced fatigue

• Clear relationship between sleep deprivation and cognitive performance
  • In general, for every 1 hour reduction in work hours can expect about 20 minutes increased sleep
  • Caveat #1: while duty hour rules reduce total number of hours work per week, 30 hour shifts allowed
  • Caveat #2: we don’t know how much more residents are actually sleeping
Worsened continuity/more transitions

• Less hours in hospital makes more frequent pass-offs necessary
  • Many prognosticators have lamented this
  • Lack of computerized sign-out and standardized systems for sign-out makes passage of important information somewhat haphazard
• Studies have shown higher rates of adverse events in patients while “cross covered”\(^1\)

Impact on Mortality – the ultimate measure of patient safety

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ORIGINAL CONTRIBUTIONS

Mortality Among Hospitalized Medicare Beneficiaries in the First 2 Years Following ACGME Resident Duty Hour Reform .......... 975

Mortality Among Patients in VA Hospitals in the First 2 Years Following ACGME Resident Duty Hour Reform ........................................ 984

Association Between Funding and Quality of Published Medical Education Research .................................................. 1002

Medicine Residents’ Understanding of the Biostatistics and Results in the Medical Literature ........................................ 1010
D. M. Windish, S. J. Huot, M. L. Green
Study Cohort

- All unique patients admitted between July 1, 2000 and June 30, 2005 (3 years pre-reform, 2 years post-reform)
  - with principal diagnoses: AMI, CHF, GI bleed, or stroke or
  - DRG classification of general, orthopedic, or vascular surgery

- VA
  - 320,685 patients, 131 hospitals
  - Data from VA Patient Treatment File (PTF) and Beneficiary Identification Record Locator System (BIRLS), VA Office of Academic Affiliations

- Medicare
  - 8,529,595 patients, 3321 hospitals
  - Data from the Medicare Provider Analysis and Treatment File (MEDPAR), denominator files, Medicare Cost Reports

- VA hospitals are largest single site for residency training in the US, much more teaching intensive than non-VA
Effects measured by comparing pre-to post-reform changes in mortality in hospitals of differing teaching intensity

Logistic regression used to adjust for patient comorbidities, secular trends, hospital site where treated using “difference in differences”

Kevin Volpp, MD, PhD.
Analysis of Medicare patients
Trends in mortality similar by teaching status

Figure 1. Unadjusted Trends in Mortality for Combined Medical Groups by Teaching-Intensive Hospital Status

Error bars indicate 95% confidence intervals, calculated using the binomial distribution. The Accreditation Council for Graduate Medical Education duty hour regulations were implemented on July 1, 2003. Preform year 3 included academic years 2000-2001 (July 1, 2000, to June 30, 2001); preform year 2, academic year 2001-2002; preform year 1, academic year 2002-2003; postform year 1, academic year 2003-2004; and postform year 2, academic year 2004-2005. For combined medical group, a significant divergence was found before the onset of the duty hour reform (by Wald $\chi^2$ test, $P=.04$), due to patterns observed for patients with stroke. No significant divergence was found in the degree to which mortality changed from preform year 1 to either postform year for combined medical group or combined medical group excluding stroke. Significance levels assess whether trend from preform year 1 to postform years 1 and 2, respectively, differed for more vs less teaching-intensive hospitals.

Kevin Volpp, MD, PhD.  
Volpp KG et al. JAMA; 2007: 298 (9): 975-983.
No significant relative change in mortality rates in accordance with teaching intensity.

Table 3. Adjusted Odds of Mortality After Duty Hour Reform in More vs Less Teaching-Intensive Hospitals

<table>
<thead>
<tr>
<th>Patient Categories</th>
<th>Total No. of Cases</th>
<th>Resident-to-Bed Ratio × Postrefom Year 1a</th>
<th>P Value</th>
<th>Resident-to-Bed Ratio × Postrefom Year 2a</th>
<th>P Value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Medical conditions</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Acute myocardial infarction</td>
<td>970 184</td>
<td>0.97 (0.89-1.05)</td>
<td>.46</td>
<td>0.93 (0.86-1.02)</td>
<td>.12</td>
</tr>
<tr>
<td>Stroke</td>
<td>933 225</td>
<td>1.08 (1.00-1.16)</td>
<td>.04</td>
<td>1.08 (1.01-1.16)</td>
<td>.03</td>
</tr>
<tr>
<td>Gastrointestinal bleeding</td>
<td>763 765</td>
<td>1.12 (0.97-1.30)</td>
<td>.11</td>
<td>0.84 (0.81-1.10)</td>
<td>.44</td>
</tr>
<tr>
<td>Congestive heart failure</td>
<td>1 196 294</td>
<td>0.90 (0.80-1.00)</td>
<td>.054</td>
<td>1.03 (0.92-1.14)</td>
<td>.65</td>
</tr>
<tr>
<td>Combined medical</td>
<td>3 863 468</td>
<td>1.03 (0.98-1.07)</td>
<td>.30</td>
<td>1.03 (0.99-1.08)</td>
<td>.18</td>
</tr>
<tr>
<td>Combined medical, excluding stroke</td>
<td>2 930 243</td>
<td>0.97 (0.91-1.03)</td>
<td>.27</td>
<td>0.95 (0.90-1.01)</td>
<td>.13</td>
</tr>
<tr>
<td>Surgical categories</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>General surgery</td>
<td>1 707 287</td>
<td>1.04 (0.95-1.15)</td>
<td>.39</td>
<td>0.97 (0.88-1.07)</td>
<td>.58</td>
</tr>
<tr>
<td>Orthopedic surgery</td>
<td>2 578 190</td>
<td>1.12 (0.99-1.27)</td>
<td>.07</td>
<td>1.04 (0.92-1.18)</td>
<td>.52</td>
</tr>
<tr>
<td>Vascular surgery</td>
<td>380 650</td>
<td>1.00 (0.89-1.13)</td>
<td>.98</td>
<td>1.02 (0.90-1.14)</td>
<td>.81</td>
</tr>
<tr>
<td>Combined surgical</td>
<td>4 666 127</td>
<td>1.05 (0.98-1.12)</td>
<td>.15</td>
<td>1.01 (0.95-1.08)</td>
<td>.67</td>
</tr>
</tbody>
</table>

Abbreviation: CI, confidence interval.

*a* The interaction terms (resident-to-bed ratio × postrefom year 1) and (resident-to-bed ratio × postrefom year 2) measure whether there is any relative change in the odds of mortality in more vs less teaching-intensive hospitals. Models are also adjusted for age, sex, comorbidities, common time trends, and hospital site where treated.

*b* Units for odds ratios compare hospitals with a resident-to-bed ratio of 1 with hospitals with a resident-to-bed ratio of 0 (nonteaching).
Robustness tests

- Results robust to:
  - Eliminating patients admitted to hospitals in NY State (earlier implementation of Libby Zion law)
  - Eliminating patients admitted from nursing homes (may have been treated less aggressively)
  - Changes in rate of coding in comorbidities
     - Results without adjusting for comorbidities had similar results
  - In cases where test of controls was rejected, using pre-1 as referent group instead of entire pre-reform period
Analysis of VA patients
VA hospitals much more teaching intensive

- Medicare

Table 2. Characteristics of Included Hospitals

<table>
<thead>
<tr>
<th>Resident-to-Bed Ratio, Category (Range)</th>
<th>Nonteaching (0)</th>
<th>Very Minor Teaching (&gt;0-0.049)</th>
<th>Minor Teaching (0.050-0.249)</th>
<th>Major Teaching (0.250-0.599)</th>
<th>Very Major Teaching (0.600-1.090)</th>
</tr>
</thead>
<tbody>
<tr>
<td>No. (%) of facilities</td>
<td>2298 (69.2)</td>
<td>308 (9.3)</td>
<td>411 (12.45)</td>
<td>195 (5.9)</td>
<td>109 (3.3)</td>
</tr>
<tr>
<td>No. (%) of admissions</td>
<td>4313,981 (50.6)</td>
<td>1,231,262 (14.4)</td>
<td>1,791,242 (21.0)</td>
<td>797,822 (9.4)</td>
<td>395,200 (4.6)</td>
</tr>
</tbody>
</table>

*Percentages may not total 100 due to rounding. Included 3321 facilities and 8,529,595 admissions.

- VA Hospitals

Table 2. Characteristics of Included US Veterans Affairs Hospitals

<table>
<thead>
<tr>
<th>Resident-to-Bed Ratio, Percentile (Range)</th>
<th>0-25 (0-0.071)</th>
<th>26-50 (0.072-0.420)</th>
<th>51-75 (0.421-0.654)</th>
<th>76-90 (0.655-0.867)</th>
<th>&gt;90 (0.868-1.794)</th>
</tr>
</thead>
<tbody>
<tr>
<td>No. (%) of facilities</td>
<td>32 (24.4)</td>
<td>34 (26.0)</td>
<td>33 (25.2)</td>
<td>19 (14.5)</td>
<td>13 (9.9)</td>
</tr>
<tr>
<td>No. (%) of admissions</td>
<td>27,378 (8.6)</td>
<td>66,801 (20.7)</td>
<td>127,096 (39.9)</td>
<td>59,006 (18.5)</td>
<td>39,356 (12.4)</td>
</tr>
</tbody>
</table>

*Percentages may not total 100 due to rounding. Included 131 facilities and 318,636 admissions.
Significant relative improvement in mortality among medical patients in post-reform year 2

Table 3. Adjusted Odds of Mortality After Duty Hour Reform in More vs Less Teaching-Intensive Hospitals

<table>
<thead>
<tr>
<th>Patient Categories</th>
<th>Total No. of Cases</th>
<th>Resident-to-Bed Ratio × Postreform Year 1 (^a)</th>
<th>Resident-to-Bed Ratio × Postreform Year 2 (^a)</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Odds Ratio (95% CI (^b))</td>
<td>(P) Value</td>
<td>Odds Ratio (95% CI (^b))</td>
</tr>
<tr>
<td>Medical conditions</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Acute myocardial infarction</td>
<td>32,170</td>
<td>1.11 (0.79-1.56)</td>
<td>.57</td>
</tr>
<tr>
<td>Stroke</td>
<td>27,434</td>
<td>0.84 (0.57-1.23)</td>
<td>.36</td>
</tr>
<tr>
<td>Gastrointestinal bleeding</td>
<td>36,035</td>
<td>1.22 (0.81-1.84)</td>
<td>.35</td>
</tr>
<tr>
<td>Congestive heart failure</td>
<td>50,266</td>
<td>1.00 (0.74-1.37)</td>
<td>.99</td>
</tr>
<tr>
<td>Combined medical</td>
<td>145,905</td>
<td>1.08 (0.91-1.29)</td>
<td>.39</td>
</tr>
<tr>
<td>Combined medical, excluding acute myocardial infarction</td>
<td>113,735</td>
<td>1.02 (0.82-1.25)</td>
<td>.89</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Surgical categories</th>
<th>Total No. of Cases</th>
<th>Resident-to-Bed Ratio × Postreform Year 1 (^a)</th>
<th>Resident-to-Bed Ratio × Postreform Year 2 (^a)</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Odds Ratio (95% CI (^b))</td>
<td>(P) Value</td>
<td>Odds Ratio (95% CI (^b))</td>
</tr>
<tr>
<td>General surgery</td>
<td>79,574</td>
<td>0.92 (0.64-1.33)</td>
<td>.67</td>
</tr>
<tr>
<td>Orthopedic surgery</td>
<td>73,209</td>
<td>0.87 (0.47-1.63)</td>
<td>.67</td>
</tr>
<tr>
<td>Vascular surgery</td>
<td>21,997</td>
<td>0.74 (0.43-1.27)</td>
<td>.27</td>
</tr>
<tr>
<td>Combined surgical</td>
<td>174,780</td>
<td>0.89 (0.68-1.17)</td>
<td>.41</td>
</tr>
</tbody>
</table>

Abbreviation: CI, confidence interval.

\(^a\) The interaction terms (resident-to-bed ratio × postreform year 1) and (resident-to-bed ratio × postreform year 2) measure whether there is any relative change in the odds of mortality in more vs less teaching-intensive hospitals. Models are also adjusted for age, sex, comorbidities, common time trends, and hospital site where treated.

\(^b\) Units for odds ratios compare hospitals having a resident-to-bed ratio of 1 with hospitals having a resident-to-bed ratio of 0 (nonteaching).

Kevin Volpp, MD, PhD.

How large were these effects?

Medical patients: Improvement in mortality from pre-1 to post-2 of 0.70 percentage points (11.1%) for hospitals in 75th compared to 25th percentile

Kevin Volpp, MD, PhD.

Robustness checks

• Results robust to:
  
  • Eliminating patients admitted to hospitals in NY State (earlier implementation of Libby Zion law)

  • Eliminating patients admitted from nursing homes (may have been treated less aggressively)

  • Changes in rate of coding in comorbidities
    • Results without adjusting for comorbidities had similar results

  • In cases where test of controls was rejected, using pre-1 as referent group instead of entire pre-reform period
Results Summary

- Medicare
  - No significant relative changes in mortality for either medical or surgical patients in post-reform year 1 or post-reform year 2

- VA
  - No significant relative changes in mortality in post-reform year 1 or 2 for surgical patients
  - Significant relative improvement in mortality in post-reform year 2 for medical patients
Limitations

• Measure only one outcome, mortality
  • Ongoing studies measuring other patient outcomes
  • Educational outcomes not measured

• No information on actual hours worked
  • Makes this effectiveness, not efficacy study
  • Likely there has been a delta in work hours, greatest in surgical programs

• Potential for unmeasured confounding
  • QI efforts within VA generally system-wide
  • Medical results robust to exclusion of AMI
  • Results robust to adjustment for underlying differences in trends pre-reform
Why no improvement in quality among Medicare patients?

- **Design flaws**
  - 30 hour shifts allow acute sleep deprivation
  - Current design does not respect circadian rhythms
  - Sleep inertia at night when paged

- **Implementation**
  - Compliance likely incomplete; may be worse than in VA hospitals, given higher work intensity

- **Offsetting factors**
  - Worsened continuity
  - Work intensity
  - Sicker patients
Why improvement in some groups but not others?

• VA vs. Medicare
  • VAs more teaching intensive (“dose response”)
  • Work intensity lower in VA?
  • Better information systems may have mitigated some of continuity of care problems

• Medical vs. surgical
  • Differences in balance between reduction in fatigue and continuity?
  • Differences in compliance?
  • Differences in effort to address discontinuity through structured sign-out, increased attending involvement?
What research is needed

- Evaluation of impact on patient outcomes using other measures
- Assessment of mechanisms and societal costs
- Assessment of educational outcomes
- Experimentation using other designs for duty hour reform, with careful evaluation of costs and benefits
Implications for improving patient safety and quality of care

• New approaches to duty hour reform should:
  • Address acute and cumulative sleep deprivation
  • Respect circadian rhythms
  • Build in mechanisms for improved continuity of care
  • Consider whether workloads are appropriate
  • Carefully measure societal costs and benefits
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  • Lisa Bellini, MD, University of Pennsylvania

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