Patient safety in the era of the 80-hour work week:
An evaluation of the ACGME duty hours policy

Julia Shelton¹, MD;
Sharon Phillips², MSPH; Patrick G. Arbogast², PhD, Marie R. Griffin³, MD, MPH; Michael D. Holzman¹, MD, MPH; William Nealon¹, MD; Benjamin K. Poulse¹, MD, MPH;

¹Department of General Surgery, ²Department of Biostatistics, ³Department of Preventive Medicine
Vanderbilt University Medical Center
Nashville, TN

Supported in part by AHRQ Health Services Training Grant #T32 HS0 13833-08
Background: Duty Hours

• Graduate medical education and work hours
  – Public perception of medical errors
  – New York State
  – ACGME

• Implementation of Duty Hours Policy
  – July 2003
  – July 2011
Background: Patient Safety

- Freedom from accidental injury
- Avoiding injuries or harm to patients from care that is intended to help them
- Ensuring patient safety “involves the establishment of operational systems and processes that minimize the likelihood of errors and maximize the likelihood of intercepting them when they occur.”
Background: Duty Hours and Patient Safety

• ACGME –
  – Patient safety
  – Resident well-being

• Public perception – long work hours leads to a decline in the quality of patient care
Study Question

• Has the 80-hour work week policy met its goals of improving patient safety?
# Methods

<table>
<thead>
<tr>
<th>Study Design</th>
<th>Interrupted time series analysis with concurrent control</th>
</tr>
</thead>
<tbody>
<tr>
<td>Data Source</td>
<td>Nationwide Inpatient Sample (1998-2007)</td>
</tr>
<tr>
<td>Study Group</td>
<td>All inpatient discharges from teaching hospitals</td>
</tr>
<tr>
<td>Control Group</td>
<td>All inpatient discharges from nonteaching hospitals</td>
</tr>
<tr>
<td>Intervention</td>
<td>ACGME 2003 duty hours policy</td>
</tr>
<tr>
<td>Outcomes</td>
<td>Patient Safety Indicators</td>
</tr>
<tr>
<td>Analysis</td>
<td>Autoregressive moving average model</td>
</tr>
</tbody>
</table>
# Study Groups

<table>
<thead>
<tr>
<th>Teaching Hospitals Discharges</th>
<th>Nonteaching Hospitals Discharges</th>
</tr>
</thead>
<tbody>
<tr>
<td>171,563,817</td>
<td>204,900,562</td>
</tr>
</tbody>
</table>
Outcomes

- AHRQ Patient Safety Indicators
  - Pneumothorax (PTx)
  - Post-operative hemorrhage or hematoma (HH)
  - Post-operative wound dehiscence (WD)
  - Accidental puncture or laceration (aPL)
  - Post-operative physiologic and metabolic derangements (PMD)
  - Post-operative pulmonary embolus or deep vein thrombus (PE/DVT)
### Results: Patient Safety Indicators pre-intervention and post-intervention rates

<table>
<thead>
<tr>
<th>Patient Safety Indicator</th>
<th>Institution Type</th>
<th>Pre-intervention rate (event/10K pt discharges)</th>
<th>Post-intervention rate (event/10K pt discharges)</th>
<th>p-value</th>
</tr>
</thead>
<tbody>
<tr>
<td>PTx - Iatrogenic Pneumothorax</td>
<td>NT</td>
<td>-0.13</td>
<td>0.08</td>
<td>0.14</td>
</tr>
<tr>
<td></td>
<td>T</td>
<td>-0.19</td>
<td>0.14</td>
<td>0.04</td>
</tr>
<tr>
<td>PEDVT - Postoperative Pulmonary Embolus or Deep Vein Thrombus</td>
<td>NT</td>
<td>0.65</td>
<td>0.59</td>
<td>0.01</td>
</tr>
<tr>
<td></td>
<td>T</td>
<td>1.67</td>
<td>0.14</td>
<td>0.75</td>
</tr>
<tr>
<td>HH - Postoperative Hemorrhage or Hematoma</td>
<td>NT</td>
<td>-0.12</td>
<td>0.04</td>
<td>0.71</td>
</tr>
<tr>
<td></td>
<td>T</td>
<td>-0.20</td>
<td>0.15</td>
<td>0.33</td>
</tr>
<tr>
<td>PMD - Physiologic or Metabolic Derangement</td>
<td>NT</td>
<td>0.05</td>
<td>0.15</td>
<td>0.18</td>
</tr>
<tr>
<td></td>
<td>T</td>
<td>0.18</td>
<td>0.07</td>
<td>0.49</td>
</tr>
<tr>
<td>aPL - accidental Puncture or Laceration</td>
<td>NT</td>
<td>-0.13</td>
<td>0.12</td>
<td>0.56</td>
</tr>
<tr>
<td></td>
<td>T</td>
<td>0.20</td>
<td>-0.53</td>
<td>0.17</td>
</tr>
<tr>
<td>WD - Postoperative Wound Dehiscence</td>
<td>NT</td>
<td>0.05</td>
<td>0.55</td>
<td>0.20</td>
</tr>
<tr>
<td></td>
<td>T</td>
<td>-0.01</td>
<td>0.72</td>
<td>0.07</td>
</tr>
</tbody>
</table>
Results
Results

Adjusted Rate of PE/DVT

- teaching vs nonteaching hospitals

Rate of PE/DVT/10K patient discharges

Discharge Quarter

Results

• There were no significant differences in rate trends or in immediate effects of the policy change
  – Post-operative hemorrhage or hematoma (HH)
  – Post-operative wound dehiscence (WD)
  – Accidental puncture or laceration (aPL)
  – Post-operative physiologic and metabolic derangements (PMD)
Conclusions

- Only PTx showed a significant effect after duty hour regulations in teaching hospitals; similarly, only PE/DVT showed a significant effect in nonteaching hospitals.
- Neither of these changes resulted in an improvement of the PSI.
- Due to the lack of consistent patterns of change, we conclude that there is no measurable effect of the policy change on these PSIs.

Supported in part by AHRQ Health Services Training Grant #T32 HS0 13833-08
# Patient Discharges by Teaching Status

**Table 1 – Total Yearly Patient Discharges by Teaching-Nonteaching Status**

<table>
<thead>
<tr>
<th>Calendar Year</th>
<th>Participating States</th>
<th>Sample Hospitals</th>
<th>Raw Discharges</th>
<th>Weighted Discharges</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td></td>
<td>T*</td>
<td>NT*</td>
<td>T</td>
</tr>
<tr>
<td>1998</td>
<td>22</td>
<td>195</td>
<td>787</td>
<td>3,132,644</td>
</tr>
<tr>
<td>1999</td>
<td>24</td>
<td>198</td>
<td>786</td>
<td>3,385,811</td>
</tr>
<tr>
<td>2001</td>
<td>33</td>
<td>172</td>
<td>814</td>
<td>3,167,539</td>
</tr>
<tr>
<td>2002</td>
<td>35</td>
<td>178</td>
<td>817</td>
<td>3,530,994</td>
</tr>
<tr>
<td>2003</td>
<td>37</td>
<td>175</td>
<td>817</td>
<td>3,507,256</td>
</tr>
<tr>
<td>2004</td>
<td>37</td>
<td>175</td>
<td>828</td>
<td>3,598,070</td>
</tr>
<tr>
<td>2005</td>
<td>37</td>
<td>164</td>
<td>890</td>
<td>3,293,582</td>
</tr>
<tr>
<td>2006</td>
<td>38</td>
<td>198</td>
<td>844</td>
<td>3,804,142</td>
</tr>
<tr>
<td>2007</td>
<td>40</td>
<td>191</td>
<td>851</td>
<td>3,758,898</td>
</tr>
</tbody>
</table>

*Hospitals in the Nationwide Inpatient Sample (NIS) without a (T)eaching/(NT)nonteaching designation were excluded from this study.
Interrupted Time Series

Improvement

Possible Effect

Worsening

No Effect

PSI Rate ➔

Time ➔
Figure 1 – Adjusted Rates of PSIs by Teaching Status

*PSIs per 10,000 admissions per discharge quarter; note different scales on y-axis.
Vertical line on each graph represents the implementation of 80 hour work week.
† PTx: Prior to the policy change, PTx rates had been declining in both teaching (T) and nonteaching (NT) institutions. This decline slowed significantly in T hospitals (p-value 0.04) after the implementation of the 80 hour work week.
‡ PEDVT: Prior to the policy change, PEDVT rates were increasing in both T and NT hospitals. After the policy change the rates for PEDVT were noted to increase further in NT institutions p-value 0.01.)
ACGME Policy: the 80-Hour Work Week

• ACGME Duty Hours
  – **Must promote patient safety and resident well-being**
  – 80 hours/weekly
  – No more than 24 hours of consecutive call
  – Plus 6 hours for administrative and educational duties and to maintain continuity of care
  – 10 hour rest period in between shifts and after in-house call
  – No new patients accepted after 24 hours of call

• ACGME Effect
  – >8700 programs
  – ~130 specialties
  – Nearly 110,000

• Program Implementation - July 2003
Etiology of Suboptimal Care

- Sleep Physiology
- Fatigue
- Stress
- Culture of resident training
- Financial restrictions

- Implication: more hours → greater fatigue → increased provider errors → adverse patient events
Inadvertent Outcomes

– Handoffs
  • Increased frequency
  • Poorly conducted
– Lack of familiarity
– Decreased resident education
– Decreased technical instruction or practice
– Decreased clinical knowledge
Prior Work

• There is an ever growing body of “imperfect literature” regarding work hour restrictions and patient safety
• In a systematic review, Fletcher et al found 7 studies that addressed patient safety and duty hour restrictions
• Morrison and colleagues in their 2009 study addressed the question of Mortality and morbidity using the National Trauma Data Bank

• There are no studies that specifically address patient safety related to duty hour restrictions using national data
Hypothesis

• The question remains: Has the 80-hour work week policy met its goals of improving patient safety?

• There has been no change in patient safety as a result of the policy implementation
Standards

• IOM report

• The Agency for Healthcare Research and Quality (AHRQ) has established quality indicators (QIs) which have been designed to measure health care quality from readily available administrative data

• Patient Safety Indicators (PSIs) are one of these quality indicators and allow for identification of rates of adverse events during inpatient hospital stays

• In this study, we will define patient safety standards as the rate of adverse events of each selected patient safety indicator prior to the policy implementation

• These are Indicators – not definitive measures and they have limitations

Outcome Variables

– Foreign Body (FB)
– Pneumothorax (PTx)
– Post-operative hemorrhage or hematoma (HH)
– Post-operative physiologic and metabolic derangements (PMD)
– Post-operative pulmonary embolus or deep vein thrombus (PE/DVT)
– Post-operative wound dehiscence (WD)
– Accidental puncture or Laceration (aPL)
Methods

- Nationwide Inpatient Sample (NIS)
- 1998-2007
- Interrupted time series analysis
Results: PEDVT

Rate of PEDVT in Non-Teaching Hospitals

PEDVT rate (per 1000) vs. Discharge Quarter

PEDVT rate (per 1000)

Discharge Quarter
Results: PEDVT

Rate of PEDVT in Teaching Hospitals

PEDVT rate (per 1000)

Discharge Quarter
Results: PEDVT

Rate of PEDVT in Teaching and Non-Teaching Hospitals

PEDVT rate (per 1000)

Discharge Quarter

Non-Teaching Hospitals

Teaching Hospitals
Conclusions: PEDVT

• There is no significant change in the PEDVT rates as a result of the implementation of the ACGME duty hours policy
Results: aPL

Rate of APL
in Non-Teaching Hospitals

Rate per 1K APL
Results: aPL

Rate of APL in Teaching Hospitals
Results: aPL

Rate of APL
in Teaching and Non-Teaching Hospitals

Rate per 1K APL

Dqtr_Year

Non-Teaching
Teaching
Conclusions: aPL

• The rate of aPL does not change as a result of the intervention
Results: PTx

Rate of PTx in Non-Teaching Hospitals
Results: PTx

Rate of PTx in Teaching Hospitals

Rate per 10K PTX

Dqtr_Year
Results: PTx

Rate of PTx in Teaching and Non-Teaching Hospitals

Dqtr_Year

Teaching Non-Teaching
Conclusions: PTx

• There is a non-significant trend toward lower rates of PTx in the Teaching Hospitals.
Result Review

Rate of PEDVT in Teaching and Non-Teaching Hospitals

Rate of APL in Teaching and Non-Teaching Hospitals

Rate of PTx in Teaching and Non-Teaching Hospitals
Study Limitations

• The events used to calculate PSIs are rare
• Definition may vary and thus affect coding
• Denominator not specific enough
• Underreporting → artificially low rate
• Screening → artificially high rate
• Case mix bias (should be addressed by propensity score)
• New York State is included in all years of our analysis
Implications:

• Patient safety is multi-factorial
• Measures of patient safety may be inadequate
• It is difficult to implement effective, productive changes if we cannot adequately evaluate patient safety
Next Steps

• Repeat Analysis for remaining PSIs

• Propensity Scores
References

- [http://www.acgme.org/acWebsite/newsRoom/newsRm_acGlance.asp](http://www.acgme.org/acWebsite/newsRoom/newsRm_acGlance.asp)
- Committee on Optimizing Graduate Medical Trainee (Resident) Hours and Work Schedules to Improve Patient Safety. Resident duty hours: enhancing sleep, supervision, and safety. Washington, DC: Institute of Medicine, 2008.
<table>
<thead>
<tr>
<th>PSI</th>
<th>Definition</th>
</tr>
</thead>
<tbody>
<tr>
<td>1. Complications of anesthesia</td>
<td>Cases of anesthetic overdose, reaction, or endotracheal tube misplacement per 1,000 surgery discharges. Excludes codes for drug use and self-inflicted injury.</td>
</tr>
<tr>
<td>2. Death in low-mortality DRGs*</td>
<td>In-hospital deaths per 1,000 patients in DRGs with &lt;0.5% mortality. Excludes trauma, immunocompromised, and cancer patients.</td>
</tr>
<tr>
<td>3. Decubitus ulcer</td>
<td>Cases of decubitus ulcer per 1,000 discharges with lengths of stay ≥ 5 days. Excludes patients with paralysis or in MDC 9 or MDC 14 and patients admitted from long-term care facilities.</td>
</tr>
<tr>
<td>4. Failure to rescue*†</td>
<td>Deaths per 1,000 patients having developed specified complications of care during hospitalization. Excludes patients aged ≥75 years, neonates in MDC 15, patients admitted from long-term care facilities, and patients transferred to or from other acute care facilities.</td>
</tr>
<tr>
<td>5. Foreign body left during procedure*</td>
<td>Discharges with foreign bodies accidentally left in during procedures per 1,000 discharges.</td>
</tr>
<tr>
<td>6. Iatrogenic pneumothorax*†</td>
<td>Cases of iatrogenic pneumothorax per 1,000 discharges. Excludes trauma, thoracic surgery, lung or pleural biopsy, or cardiac surgery patients and patients in MDC 14.</td>
</tr>
<tr>
<td>7. Selected infections due to medical care</td>
<td>Cases of secondary ICD-9-CM code 9993 or 00662 per 1,000 discharges. Excludes patients with immunocompromised state or cancer.</td>
</tr>
<tr>
<td>8. Postoperative hip fracture</td>
<td>Cases of in-hospital hip fracture per 1,000 surgical discharges. Excludes patients in MDC 8, patients with conditions suggesting fracture present on admission, and patients in MDC 14.</td>
</tr>
<tr>
<td>9. Postoperative hemorrhage or hematoma</td>
<td>Cases of hematoma or hemorrhage requiring procedures per 1,000 surgical discharges. Excludes patients in MDC 14.</td>
</tr>
<tr>
<td>10. Postoperative physiologic and metabolic derangements</td>
<td>Cases of specified physiologic or metabolic derangement per 1,000 elective surgical discharges. Excludes patients with principal diagnoses of diabetes and with diagnoses suggesting increased susceptibility to derangement. Excludes obstetric admissions.</td>
</tr>
<tr>
<td>11. Postoperative respiratory failure</td>
<td>Cases of acute respiratory failure per 1,000 elective surgical discharges. Excludes patients in MDCs 4 and 5 and obstetric admissions.</td>
</tr>
<tr>
<td>12. Postoperative pulmonary embolism or deep vein thrombosis*</td>
<td>Cases of DVT or PE per 1,000 surgical discharges. Excludes obstetric patients.</td>
</tr>
<tr>
<td>13. Postoperative sepsis</td>
<td>Cases of sepsis per 1,000 elective surgery patients with lengths of stay &gt; 3 days. Excludes principal diagnosis of infection or any diagnosis of immunocompromised state or cancer and obstetric admissions.</td>
</tr>
<tr>
<td>14. Postoperative wound dehiscence*†</td>
<td>Cases of reclosure of postoperative disruption of abdominal wall per 1,000 cases of abdominopelvic surgery. Excludes obstetric admissions.</td>
</tr>
<tr>
<td>15. Accidental puncture or laceration*†</td>
<td>Cases of technical difficulty (e.g., accidental cut or laceration during procedure) per 1,000 discharges. Excludes obstetric admissions.</td>
</tr>
<tr>
<td>16. Transfusion reaction*</td>
<td>Cases of transfusion reaction per 1,000 discharges.</td>
</tr>
</tbody>
</table>

Adapted from AHRO.10

DRG = diagnosis-related group; MDC = major diagnostic category (MDC 4 = respiratory system; MDC 5 = circulatory system; MDC 8 = musculoskeletal system and connective tissue; MDC 9 = skin, subcutaneous tissue, and breast; MDC 14 = pregnancy, childbirth, and puerperium; MDC 15 = newborn and other neonates [perinatal period]).

*Endorsed by the National Quality Forum.
†Adopted by the Centers for Medicare and Medicaid Services.
**PSI limitations**

<table>
<thead>
<tr>
<th>PSI Name</th>
<th>Definition</th>
<th>Validity Concerns</th>
<th>Strength of Evidence</th>
</tr>
</thead>
<tbody>
<tr>
<td>Foreign Body Left During Procedure (PSI 5)</td>
<td>Discharges with foreign body accidentally left in during procedure per 1,000 discharges. Excludes trauma, thoracic surgery, lung or pleural biopsy, or cardiac surgery patients, and MDC 14.</td>
<td>Rare, Stratification suggested, Denominator unspecific</td>
<td>0 Coding 0 Explicit Process 0 Implicit Process 0 Staffing</td>
</tr>
<tr>
<td>Iatrogenic Pneumothorax (PSI 6)</td>
<td>Cases of iatrogenic pneumothorax per 1,000 discharges. Excludes trauma, thoracic surgery, lung or pleural biopsy, or cardiac surgery patients, and MDC 14.</td>
<td>Denominator unspecific</td>
<td>0 Coding 0 Explicit Process 0 Implicit Process 0 Staffing</td>
</tr>
<tr>
<td>Postoperative Hemorrhage or Hematoma (PSI 9)</td>
<td>Cases of hematoma or hemorrhage requiring a procedure per 1,000 surgical discharges. Excludes MDC 14.</td>
<td>Stratification suggested, Case mix bias, Denominator unspecific</td>
<td>± Coding ± Explicit Process + Implicit Process 0 Staffing</td>
</tr>
<tr>
<td>Postoperative Physiologic and Metabolic Derangement (PSI 10)</td>
<td>Cases of specified physiological or metabolic derangement per 1,000 elective surgical discharges. Excludes patients with principal diagnosis of diabetes and with diagnoses suggesting increased susceptibility to derangement. Excludes obstetric admissions.</td>
<td>Condition definition varies</td>
<td>- Coding 0 Explicit Process 0 Implicit Process - Staffing</td>
</tr>
</tbody>
</table>
### PSI limitations (continued)

<table>
<thead>
<tr>
<th>PSI Name</th>
<th>Definition</th>
<th>Validity Concerns</th>
<th>Strength of Evidence</th>
</tr>
</thead>
<tbody>
<tr>
<td>Postoperative PE or DVT (PSI 12)</td>
<td>Cases of deep vein thrombosis or pulmonary embolism per 1,000 surgical discharges. Excludes obstetric patients.</td>
<td>Underreporting or screening</td>
<td>+ Coding</td>
</tr>
<tr>
<td></td>
<td></td>
<td>Stratification suggested</td>
<td>+ Explicit Process</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td>+ Implicit Process</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td>± Staffing</td>
</tr>
<tr>
<td>Postoperative Sepsis (PSI 13)</td>
<td>Cases of sepsis per 1,000 elective surgery patients, with length of stay more than 3 days. Excludes principal diagnosis of infection, or any diagnosis of immunocompromised state or cancer, and obstetric admissions.</td>
<td>Condition definition varies</td>
<td>± Coding</td>
</tr>
<tr>
<td></td>
<td></td>
<td>Adverse consequences</td>
<td>0 Explicit Process</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td>0 Implicit Process</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td>0 Staffing</td>
</tr>
<tr>
<td>Postoperative Wound Dehiscence (PSI 14)</td>
<td>Cases of reclosure of postoperative disruption of abdominal wall per 1,000 cases of abdominopelvic surgery. Excludes obstetric admissions.</td>
<td>Case mix bias</td>
<td>0 Coding</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td>0 Explicit Process</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td>0 Implicit Process</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td>0 Staffing</td>
</tr>
<tr>
<td>Accidental Puncture or Laceration (PSI 15)</td>
<td>Cases of technical difficulty (e.g., accidental cut or laceration during procedure) per 1,000 discharges. Excludes obstetric admissions.</td>
<td>Underreporting or screening</td>
<td>± Coding</td>
</tr>
<tr>
<td></td>
<td></td>
<td>Unclear preventability</td>
<td>0 Explicit Process</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td>0 Implicit Process</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td>0 Staffing</td>
</tr>
</tbody>
</table>
Policy: ACGME 80-hour work week

- National patient safety movement
- VA patient safety programs
- Sleep physiology/Sleep medicine
- Stress inoculation
- Joint commission
- Patient safety-Duty hours literature review:
  - Patient handovers
  - Impact of duty hour restrictions on educational outcomes
  - Resident safety and duty hour schedules

- Reiteration that patient safety is the “prime directive”\(^5\)
  - Experiential learning of the resident is crucial to patient safety
  - Responsibility for safety and outcomes is shared within the microsystem of care. Oversight and redundancy assure prevention of errors
Acknowledgements

- Ben Pouluse MD MPH
- Mike Holzman MD MPH
- Sharon Phillips MSPH
- Patrick Arbogast PhD
- Kyla Terhune MD
- John Tarpley MD