

Final Report

Systematic Review of the Literature on the Impact of
Variation in Residents' Duty Hour Schedules on Patient
Safety

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Contents

Abstract	3
Introduction	5
Methods	8
Results	12
Comment	20
References	24
Appendix A Data extraction form	
Appendix B Citations of articles included in the Review	
Appendix C Abstracts of articles included in the Review	

Systematic Review of the Literature on the Impact of Variation in Residents' Duty Hour Schedules on Patient Safety

Abstract

Background and Context: There is continuing debate as to how variation in residents' duty hour schedules affects patient safety. Some argue that long hours and sleep deprivation lead to systematic cognitive and other performance deficits, putting patients at risk. On the other hand, some proponents of long hours contend that truncated shifts and shortened workweeks diffuse direct responsibility for individual patients, and disrupt continuity of patient care.

Objectives: To summarize evidence related to the effect of variation in residents' duty hour schedules on patient safety.

Search Strategy: We searched the literature from 1950 to 2009 using Ovid SP MEDLINE, Scopus, PubMed and five other electronic databases. Approximately 5500 citations were identified.

Inclusion and Exclusion Criteria: We selected empirical studies that discussed the effect of fatigue or work hours on residents' performance. We further distinguished between performance measures that were considered valid proxies for patient safety and those that were less directly relevant. We excluded studies that examined residents' self-reports of the effects of work hour changes using interviews and questionnaire surveys. Studies that met criteria but reported on healthcare providers other than residents were excluded. Articles about patient safety training programs that weren't developed in response to duty hour changes were excluded.

Data Extraction: Data were extracted on research design, sample, dependent and independent variables using a defined protocol.

Data Synthesis: A set of 48 studies involving primary data collection was included in the analysis. Two subsets were identified based on the studies' definitions of the dependent variables examined. One subset, referred to as clinical studies (n=32), involved the use of widely-recognized clinical measures of patient outcomes and associated clinical processes such as mortality, morbidity and medical errors. The other method, referred to as laboratory studies (n=16), analyzed measures of residents' performance in laboratory settings using tests of cognitive and fine motor skills, and residents' performance in clinical simulations.

Although the laboratory studies frequently had higher internal validity than the clinical studies, nearly all were based on limited measurement of small samples of residents over brief time periods in single residency programs. Although about half of the clinical studies reported data from a single program, one-fourth were based on national, multi-institutional studies involving patient safety indicators for millions of patients.

The vast majority of the studies reported positive effects (27) or no effect (17) of duty hour limits on patient safety. However, the reports of large positive effects were based mainly on laboratory

studies using performance in clinical simulations and tests of cognitive and fine motor skills, or were derived from clinical studies in narrow settings such as intensive care units.

Comment: This systematic review revealed a paradox in the findings of over three decades of empirical research on duty hours and patient safety. The results of laboratory studies of resident performance on clinical simulations, and tests of cognitive and fine motor skills under conditions of sleep deprivation imply that placing limits on residents' duty hours should have strong positive effects on patient safety. However, the clinical studies of alternative duty hour schedules, as well as the follow-up studies on the impact of the New York and ACGME duty hour regulations have documented few measurable effects on patient safety.

Introduction

This report is a summary of a systematic review of the literature examining the relationship between resident duty hour schedules and patient safety performed by the Jefferson Medical College Duty Hours Review Group.

In May of 2009, this Group responded to a request for proposals from the ACGME, which was seeking a review of the scientific literature on resident duty hours and their relationship to a variety of outcomes. These included patient safety, residents' learning, and their work environment and personal well-being. Following an initial proposal that was designed to examine multiple domains, our Group in consultation with the ACGME, opted to perform a more focused review on duty hours and patient safety.

The Jefferson Medical College Duty Hours Review Group is multidisciplinary, with seven physicians and three non-physicians. Moreover, the physician representation was chosen across specialties, including Internal Medicine, Pediatrics and Surgery. The Group is also multigenerational, including members who completed residency training over five decades from the 1960's to the present. Some members of the Group have responsibilities related in graduate medical education. Some have studied issues related to duty hour schedules, residents' learning and patient care,¹⁻⁵ and have conducted systematic reviews of the literature on the measurement of professionalism in medicine⁶ and the impact of feedback on physicians' clinical performance.⁷ Therefore, the members of the Group were familiar with the current debate in the profession regarding duty hours and patient safety, and the associated body of literature.

Previous reviews have been conducted on this body of literature.^{8 9 10} While these reviews are well done, and brought to the forefront key concepts that have improved subsequent empirical studies in this area, they need to be updated given the increase in published work that is now entering the medical literature in the wake of the 2003 ACGME guidelines.

Several reviews relevant to duty hours and patient safety have been published. For the purposes of this report, we will summarize key concepts that have shaped the current discussions and in many cases guided subsequent investigations that are described in our review.

In 2002, Veasey and others performed a literature review with a goal of summarizing the data on the effects of fatigue on cognitive function, resident performance and resident health. They also sought data on the effectiveness of any proposed countermeasures for sleep loss in medical trainees.⁸ This review considered studies in which residents were tested using simulators or neurobehavioral instruments, and studies in which resident performance was examined in the provision of patient care. Several key points were raised here that were important in the process of our review, and for consideration of its findings. This includes the need to ascertain the impact of both acute and chronic sleep deprivation in any described scheduling intervention or fatigue experiment. In other words, if a study showed no effect of acute sleep deprivation on performance, was it because its control group subjects' baseline performance was already impaired due to superimposed chronic sleep deprivation, making measurable differences from any acute fatigue in their colleagues serving as intervention subjects less likely? Additionally, they pointed out the importance of evaluating interventions for their control of other important factors such as timing of testing in relation to circadian nadirs, stimulant intake and even ambient

conditions in the testing environment. Another important feature of this review was its separate analysis of surgical and non-surgical residents. In their analysis of 10 studies involving surgical residents, two important points were proposed. First, was that the evidence available for their review pointed to skill decrements in procedural skills for surgical residents, “demonstrating that this group is not immune to the effects of sleep loss.” The second point that surgical residents may be more vulnerable to fatigue when using fine motor skills than when performing a task using cognitive skills. For non-surgical residents, the data from 23 studies was reviewed. Again, laboratory studies were the dominant investigative model. The review pointed out the variability in the results of these studies, and critical methodological questions raised in their analysis. In their discussion of countermeasures, this group concluded that “Napping – as little as 30 minutes every 3 hours – and occasional low dose caffeine may provide safe countermeasures for prolonged shifts”, while acknowledging that this had not yet been evaluated with well constructed scientific studies with residents.

One systematic review was led by Kathlyn Fletcher, MD in 2005.⁹ This review, which was limited to studies looking at patient outcomes, examined seven publications in detail. Their discussion was important for the concerns it raised about the evidence available. The variability of interventions used and outcomes studied proved to make even the seven studies examined quite heterogeneous. Even studies that appeared to study similar interventions were complicated by differences in how these were applied. For example, the role of residents on “Night Float” rotations (often utilized as solutions to duty hour reductions in these studies) varied greatly. In some these residents were used to cross-cover patients, and in others they had primary admitting responsibility. These differing job descriptions have much different implications for continuity during the initial period of an inpatient admission, a very critical period of intense medical decision making and intervention. The majority of the studies analyzed also did not adjust for differences outside of duty hour interventions, and the authors emphasized the concern this raised for unmeasured confounding. Finally, and perhaps most importantly, the authors reminded us of the important and often inverse relationship between reduction in work hours and continuity of care.

Ingrid Philibert reported on a meta-analysis of sleep loss and performance in 2005.¹⁰ The objectives of that study were “To explore the effect of sleep loss on cognitive function, memory and vigilance in resident physicians and non-physicians and on residents’ clinical performance.” 60 studies were considered in this analysis. Importantly, investigations were considered in the context of type of task studied, profession of its subjects and the length and type of sleep loss experienced by its participants. Twenty of the studies considered here involved physicians, and forty involved non-physicians. While the numbers of physicians and non-physician subjects were similar (959 vs. 1,028), it was acknowledged that 40% of the physician sample came from one large study. Important results proposed included the central finding that there was a reduction in cognitive performance of approximately one standard deviation in subjects with sleep loss. It was also found that the effect of sleep loss appeared to be greater in non-physicians than for physicians. Additionally the author’s model suggested that the detrimental effects of fatigue were larger for vigilance and clinical performance than memory and cognitive function. Moreover, the author points out that there was an incremental effect displayed by meta analysis, with sleep loss of greater than 54 hours having a larger effect on performance than that of 30 hours. Finally, the analysis found that chronic partial sleep loss also resulted in reduced performance. In her discussion, Philibert proposed that smaller effects seen in the studies of physicians were likely

secondary to variation in the quantity of sleep loss in their subjects, as well as the familiar issue of chronic sleep loss in the “rested cohort”. Additionally, concern was raised that the amount of impairment suggested for sleep deprivation of 24 to 30 hours was significant, and this overlapped with the longest period of potential sleep loss allowed in the current ACGME duty hour standards. Finally, she raised concern that important aspects of physician performance could not be analyzed secondary to lack of primary studies. These included task duration, pacing and complexity.

Based on our understanding of these reviews, other previous work and the ACGME's specific interests, the Group agreed that the following specific question would guide the search:

What is known about the relationship between variation in residents' duty hour schedules and patient safety?

It was understood that the review would focus on studies of the direct effects of duty hour schedules on patient safety. It was not to include studies of the effects of duty hour schedules on other parameters, such as alternative staffing and handoffs that might subsequently affect patient care, unless the study included measures of resident performance or patient outcomes.

Four sections of this report follow. The **Methods** section describes the protocol that we developed for the review and its implementation. The **Results** section summarizes the research reports included in the systematic review, the key features of the subsets of studies reviewed, and the substantive findings on duty hour schedules and patient safety. A **Comment** section interprets our findings, acknowledges the review's limitations, and critiques the quality of published research on duty hours and patient safety.

Methods

Development of Protocol

We began to develop the protocol for the systematic review in June 2009 based on our previous experience,^{6,7} the previously published reviews addressing duty hour limits described in the previous section, and our Group's understanding of the review question. We developed a draft data extraction form and outlined a brief analysis plan during the development of the protocol.

Review Question and Objectives

After completing the protocol in mid July, we began the formal search for articles related to the question, "How does variation in residents' duty hour schedules affect patient safety?" Although we believed that this review question and related objectives had been specified clearly in the protocol, we proceeded to test this assumption by coding a sample of 16 articles, using the coding form and protocol. The form and associated procedures were revised accordingly.

Search Strategy and Management of Citations and Abstracts

We searched OvidSP MEDLINE, PubMed (for more recent articles), Scopus, CINAHL, ERIC, PsycINFO, Campbell Collaboration library, and Cochrane Database of Systematic Reviews and looked at association and governmental agency webpages. We reviewed reference lists in key articles and identified citing references for major articles identified in the search.

We expected to find the most relevant publications in MEDLINE. Therefore, we performed the preliminary searches during development of the protocol using OVIDSP MEDLINE to identify search terms and to characterize the nature of the articles to be reviewed. Subject headings of acceptable articles were examined for additional terms.

We examined the MEDLINE records of relevant articles found in the reference lists of other reviews or research studies to locate additional subject headings and key phrases. These were added to the search strategy. Representative components of the MEDLINE search strategy are summarized in Table 1.

**Table 1. Representative Examples of Terms Used in
Search Strategy for OVIDSP MEDLINE Database: MEDLINE [OVID - 1950-]**

1. exp Education, Medical, Graduate/ or exp “Internship and Residency”/ or exp “Fellowships and Scholarships”/ or Hospitals, Teaching/
2. exp “Education, Veterinary”/ or exp pastoral care/ed or exp education, pharmacy/ or Internship, Nonmedical/ or dental.hw.
3. (clinical trial or Multicenter Study or Evaluation Studies or Meta-Analysis or Validation Studies).pt.
4. (Case-Control Studies or Cohort Studies or Comparative study or Cross-Over Studies or Cross-Sectional Studies or Epidemiologic Studies or Feasibility Studies or Follow-Up Studies or Intervention Studies or Longitudinal Studies or Multicenter Study or Pilot Projects or Prospective Studies or Retrospective Studies or Sampling Studies).sh.
5. study.ti. or (study or studied or random\$).ab.
6. risk reduction behavior/ or risk assessment/ or risk factors/
7. accidents/ or safety/ or accidents, occupational/ or exp accident prevention/ or Malpractice/ or exp Medical Errors/ or exp Iatrogenic Disease/
8. exp Needlestick Injuries/
9. “Wounds and Injuries”/mo, pc, ep, et [Mortality, Prevention & Control, Epidemiology]
10. morbidity/ or mortality/ or fatal outcome/ or fetal mortality/ or hospital mortality/ or infant mortality/ or maternal mortality/ or perinatal mortality/
11. exp Death/ or exp “Cause of Death”/
12. (unsafe or harm\$ or safety or injur\$ or risk\$ or oversight or adverse or mortality or forget\$ or protect\$ or near-miss\$ or death\$ or error\$ or mistak\$).mp.
13. Reaction time/ or Problem Solving/ or exp memory/
14. exp “Personnel Staffing and Scheduling”/ or Time factors/ or Workload/ or After-Hours Care/ or Physician’s Practice Patterns/ or (physician extender\$ or hospitalist\$).mp.
15. exp Fatigue/ or exp sleep disorders/ or exp Sleep/ or Work Schedule Tolerance/
16. Clinical Competence/ or exp pathologic processes/ep, pc or exp quality indicators, health care/ or exp “outcome and process assessment (health care)”/ or exp quality assurance, health care/ or Quality of Health Care/ or Peer Review, Health Care/
17. (on-call or overnight or postcall or float or night shift\$ or call schedule\$).mp.
18. (sleep\$ or fatigu\$ or wakeful\$ or exhaust\$ or alert\$ or fitness\$ or concentrat\$ or attentive\$).mp.
19. Patient Transfer/ or exp “Referral and Consultation”/ or Continuity of Patient Care/ or (handover\$ or handoff\$ or changeover\$).mp.
20. Documentation/ or communication/ or communication barriers/ or information dissemination/
21. patient care/ or aftercare/ or “episode of care”/ or exp perioperative care/ or preoperative care/ or subacute care/
22. residency review committee\$.mp.
23. exp “Joint Commission on Accreditation of Healthcare Organizations”/
24. (EWTD or European Work Time Directive or European Working Time Directive or Accreditation Council for Graduate Medical Education or ACGME or New Deal or 80-hour or calman\$ or post-calman\$ or Modernising Medical Careers).mp.

Most of the other databases used in the search are not specific to medicine and health care. Therefore, we were able to use simpler search strategies for these databases. The exception was the Scopus database, which is mostly searchable only using text terms.

Reference Lists and Citing Articles

The review of reference lists and citing references meant we were reviewing the same citations many times. The Scopus database simplified this process somewhat, as reference lists and citing references can be sorted in tabular format. This made it possible to compare these new citations against those which had already been screened and downloaded. But this was still a laborious and repetitive process.

Management of Citations and Abstracts

We developed a local database using *RefWorksTM* to maintain citations and abstracts and to review tracking data. These records also linked to the full text of these articles, when available through the Thomas Jefferson University Library. We exported citations directly from most of the databases. MEDLINE records were used wherever duplicate citations were found in searches of other databases because of their standardisation and level of detail. Duplicate copies of Scopus records were retained because of their links to citing references.

The titles, abstracts and subject headings of citations were reviewed for relevance before the records were downloaded. As the inclusion and exclusion criteria were further developed, citations were sorted into corresponding folders for further review, for example articles that reported on surveys about perceived patient safety. When the database grew sluggish as records were included, rejected citations were moved to a second *RefWorksTM* database, rather than being deleted. This was used in screening newly identified references.

The *RefWorksTM* records were customized to include fields where the research team could note the search strategy used, and fields from the coding form (type of study, sample size), any comments on inclusion/exclusion criteria, the folder in which the citation was sorted, and reviewer to whom assigned and reviewer comments. Custom output formats were developed for checklists of articles to discuss further or obtain.

A blog site was created with links to the different folders, with a description of inclusion and exclusion criteria. Key documents, like the ACGME's request for proposals, were linked from the site, as was the search strategy and notes on exclusion points to be resolved. Articles that were newly added to the database were highlighted on the page by an automatic alerting system using RSS ("Really Simple Syndication").

Screening of Abstracts and Selection of Articles

Beginning in July 2009 one of the authors (MG) visually screened the title and abstract of the citations identified by the electronic searches and classified each as *For Review*, *Background*, *Reviews and Meta-Analyses*, *Non-English*, *Articles older than 1989*, *Articles about Resident Wellbeing*, *Comments (letters to the Editor and Editorials)*, *Articles about Perceived Quality of Care*, *Articles that did not specify Resident study sample*, *Articles missing one of the three components (residents sample, patient safety or hours)*.

Additional notes were added that reflected the main points of the inclusion criteria to qualify these decisions for secondary screening. These notes enabled other reviewers to examine the citations in batches.

Some non-English language articles were retrieved in the search and were screened when an abstract was available in English. Unfortunately, the time and resources available prevented their inclusion in the review.

Data Extraction

We developed a three-page structured coding form. (Appendix A). The first set of items involved the source of the citation, review tracking and the reviewer's global rating of the study's quality and overall evaluation of the effect of duty hour limits on patient safety.

The second set of items was related to the design and sample of the study, including a classification of the type of empirical study, the unit of analysis and number of subjects, the reviewers' rating of the quality of data collection, the timing of the data collection in relation to major initiatives such as New York (NY 405) and ACGME 2003 regulations.

The third section covered the scope of the number of residency programs involved, the total number of residents involved, the duration of the data collection, the level of residents, their specialty, the clinical site and nationality.

Another group of items was related to the characteristics of the independent variable, and the dependent, or outcome variables. The options for dependent variables were developed in relation to the construct of patient safety developed for the study. These options ranged from the well-established and reliable criterion of mortality, through morbidity, to other process indicators such as hospital readmissions, delays in test ordering, and medical errors. Also included were options for residents' performance in clinical simulations and performance on tests of cognitive and fine motor skills that have been used widely in laboratory studies of sleep deprivation and fatigue.

During July 2009 a sample of representative articles that had passed the screening was used to pre-test the coding form and instructions to reviewers. Although there were no changes to the overall structure of the form, the wording of many the items was edited for clarification, and several new options were added.

After screening, two members of the Review Group independently read each article and completed a coding form.

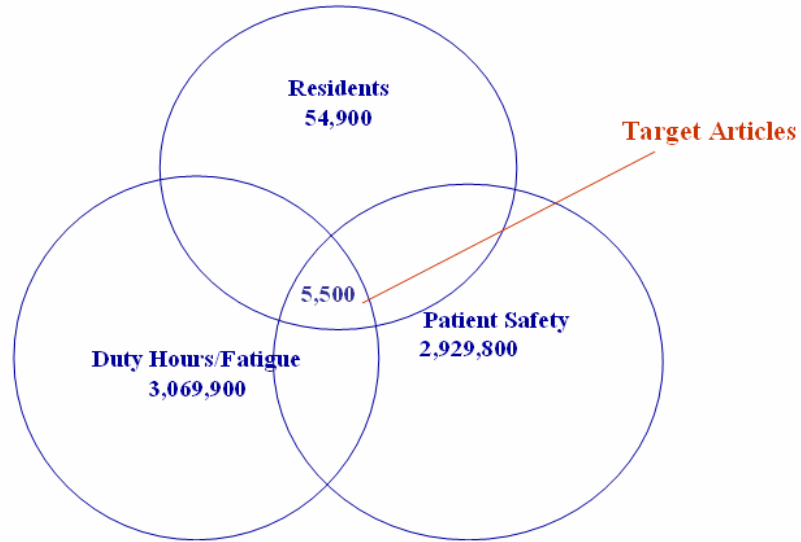
Data Analysis

The review forms data were entered into an Excel spreadsheet together with the data that had been collected in *RefWorksTM*. We used STATA version 10.0 (College Station, TX, USA) to compute descriptive statistics.

RESULTS

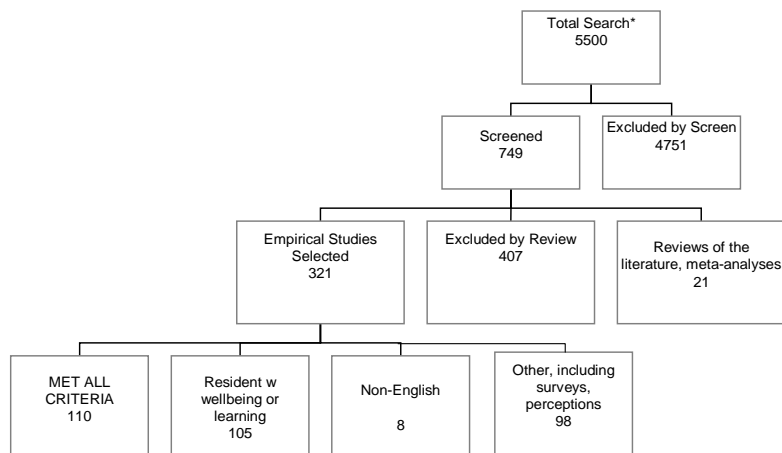
The OvidSP Medline search identified 5500 citations as shown in Figure 1.

Figure 1 OvidSP MEDLINE Search Strategy and Number of Articles



Screening of the titles and abstracts reduced this to 321 after excluding ineligible articles (Figure 2). Examples of the latter include commentaries, descriptive reviews of small, arbitrary samples, and non-empirical descriptive reports.

Figure 2. Disposition of Articles



*OvidSP MEDLINE database

Estimates of Inter-rater Reliability

A total of 110 articles passed primary screening by one of the authors (MG) and secondary screening by another member of the Review Group. Subsequently, these 110 studies were selected for review by two members of the Review Group using the data extraction form (Appendix A).

Values of Kappa based on the reviewers' coding were very high for the nations where studies were conducted (0.86), size of the residency programs (0.74), timing of data collection (0.72), scope of the samples (0.70) and duration of the studies (0.69). Values were also very good for level of residents studied (0.51), setting of the studies (0.49), quality rating of data collection/analysis (0.48), and the reviewers' interpretation of the effects documented in the studies (0.46).

Perhaps because of the heterogeneity of background in scientific methods among members of the Group, values of Kappa were lower for the reviewers' determination of the independent variable analyzed (i.e., the specific components of duty hour schedules studied) (0.34), the methods used to measure the dependent variable (0.30), and the types of study designs (0.28). Ideally, we would have preferred to reconvene the entire Group to refine and clarify the definitions of the categories of these three items, but the brevity of the project period required us to resolve these differences using an approach consistent with Cochrane, BEME and other systematic review protocols: resolution upon further review by two of the Group members (JWC and JJV).

There was very little agreement in the two reviewers' overall rating of the quality of the studies (0.06), which was provided on a 3-point scale of high, average and low. However, disagreements varied by only one point. There were no cases in which one reviewer rated a study as high while another rated it low. This item was excluded from the analysis. Time prevented us from re-convening the Group to clarify the criteria and re-reviewing the studies to establish a global rating of their quality.

Studies Included in the Analysis

There were 48 studies included in the final analysis as listed in Appendices B and C .

There were three major reasons for the reviewers' recommendations that 62 of the 110 studies be excluded from the final analysis. The most frequent included 24 articles with small samples of residents, limited measurement of clinical outcomes, limited measurements of residents' performance, and collection of data over a brief period of time. The studies with small samples of residents included no analysis of statistical power to support the sample size. For example, one study of the performance of 8 surgical residents using an endoscopic sinus surgery simulator reported no difference in performance before and after a 24-hour on-call period. The authors provided no power analysis to support the small sample size of 8. Furthermore, they did not provide information about the reliability of the scores obtained from the simulation device.¹¹

Another 20 articles mentioned duty hours, but were not direct studies of the impact of residents' duty hour schedules on a variable related to patient safety. Examples include a comparison of

resident staffing with staffing by hospitalists,¹² the impact of resident turnover on patient care,¹³ and the effect of team workload on care.¹⁴

There were 5 studies in which the reviewers identified confounding variables that were not controlled in the analysis and might have biased the findings. For example, one study concluded that implementation of the ACGME's 2003 duty hour regulations on a cardiology service was associated with improved quality of care. However, at the same time the authors cautioned readers in the Discussion section of the article that "The quality improvement program we have implemented previously may be the reason for this (improved quality of care, efficiency and adherence to evidence-based guidelines) ..."¹⁵

Finally, 13 articles were excluded for a variety of reasons such methods that were not clearly described, papers that were commentaries without empirical results, and studies that measured resident performance with instrumentation that did not have content validity in relation to patient safety (e.g., automobile driving simulator).

Study Design - Dependent Variables

Overall, the designs of the 48 studies were heterogeneous. They used a broad spectrum of dependent variables related to the construct of patient safety. The most important feature that differentiated the 48 studies was how the authors defined and selected the dependent variable for study.

There were two approaches that the investigators used to select dependent variables. The first group of 32 studies used widely-recognized clinical measures of patient care quality, such as patient outcomes and associated clinical process indicators. Measures of patient outcomes included mortality, morbidity, and complications. Measures of clinical processes included medical errors, readmissions, resource utilization and delays during hospitalization. The second group of 16 studies examined residents' performance in laboratory settings as a proxy for patient safety measures using clinical simulations, and tests of cognitive and fine motor skills.

As shown in Table 2 the two types of studies generally involved different units of analysis with resulting implications for sample size, study design and analysis. Nearly all of the clinical studies analyzed data on patients, patient admissions or patient-days in the hospital. There were two clinical studies that analyzed performance at the level of individual residents in clinical settings. These examined two types of medical errors made by residents. One was a study of residents' reports of their own accidental exposure to patients' body fluids.¹⁶ Another examined residents' self-inflicted injuries from sharp devices.¹⁷ All the laboratory studies consistently collected and analyzed data at the level of individual residents.

Table 2 Classification of 48 Studies of Residents' Duty Hours and Patient Safety According to Dependent Variable and Patients or Residents as Unit of Analysis

<u>Dependent Variable</u>	<u>Unit of Analysis</u>	
	<u>Patients</u>	<u>Residents</u>
Clinical studies of patient safety (n=32)		
Morbidity, mortality, errors and other indicators	1	
Morbidity, mortality, and other indicators	7	
Morbidity, mortality, and errors	4	
Morbidity and/or mortality	13	
Errors and other indicators	5	2
Laboratory studies of resident performance (n=16)		
Performance in clinical simulations		3
Cognitive/fine motor tests		13
Total Studies	30	18

Correspondingly, the clinical and laboratory studies each reported different types of findings and led to different patterns of conclusions. When we presented our preliminary findings on September 11 to the representatives of the ACGME in Chicago there was a consensus that it would be valuable to differentiate the findings of clinical studies based on patient outcomes and professional performance in applied settings from the findings of laboratory studies of resident performance on tests and simulations. Therefore, the key features of the clinical and laboratory studies were analyzed independently and are reported separately in the next two parts of the Results section.

Key Features: 32 Clinical Studies Using Direct Measures of Patient Safety

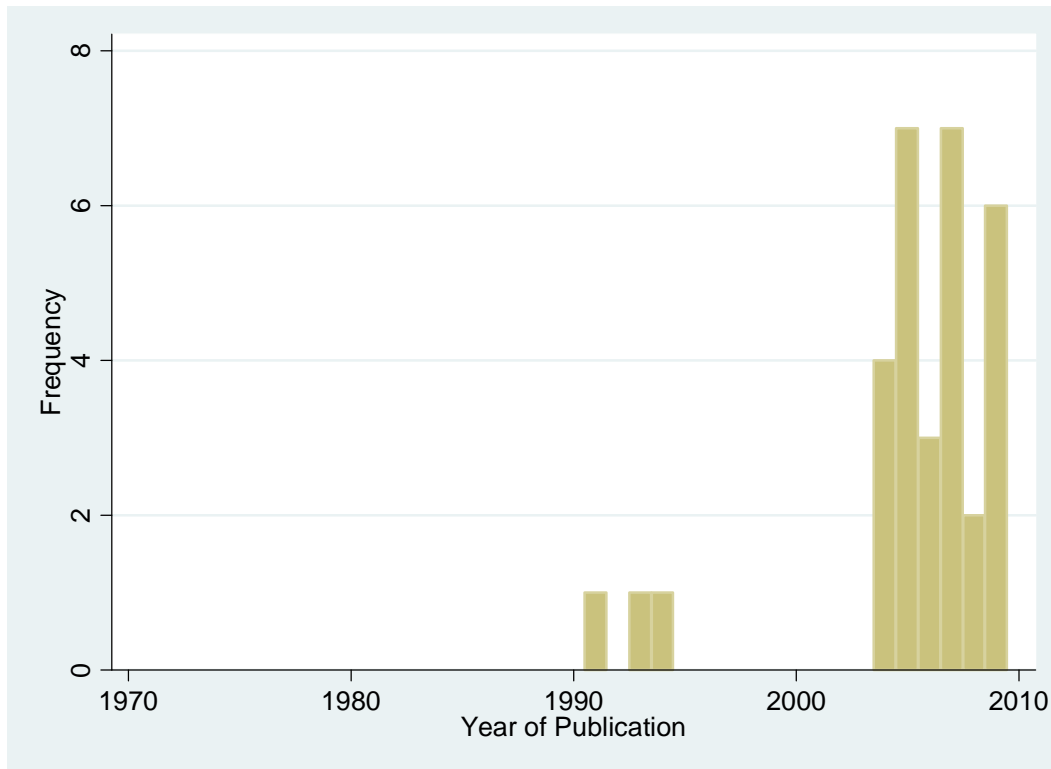
Dependent/Outcome Variables A large fraction (13) of the 32 studies examined only mortality and/or major indicators of morbidity. The next largest group of 7 studies analyzed mortality and morbidity, and also examined other indicators related to patient safety such as hospital readmissions, length of stay and number of tests ordered. Some studies used measures of medical errors, which were based on chart review, electronic medical records, or local targeted data systems that tracked these types of events. One study¹⁸ examined the widest array of clinical measures of patient safety including mortality, morbidity, errors, and other indicators of quality of patient care.

Independent Variable The independent variable in the studies was defined either as conditions before and after a major system change, such as implementation of the 2003 ACGME duty hours regulations (23), or a scheduling option or set of options designed to reduce sleep deprivation that was compared to some conventional schedule (9).

Study Design Over half (19) of the 32 studies were time series analyses in which the authors examined measures of patient safety in different time periods associated with, for example, a change in duty-hour schedules, or in cross-over designs in which the same residents were rotated to different schedules. Another group of 7 studies were designated as cohort studies in which the authors tracked details in the hospitalization of samples of patients and related these outcomes to the duty hour schedule in effect during the patients' hospital stay.

Timing, Setting and Duration The largest number of studies (21) involved data that had been collected before and after the implementation of the 2003 ACGME duty hour regulations. A large number (7) reported data that had been collected before and after the 1989 New York regulations. Nearly all have been published since 2004 (Figure 3). Nearly all (31) were conducted in the US. The majority (18) involved the inpatient setting, 3 involved only patients in intensive care and 11 involved other settings. The majority (18) involved data from medical schools, but about one-fourth (8) involved both medical school and non-medical school settings. There were 5 studies from VA and military hospitals. Over three-fourths (25) of the clinical studies involved a year or more of data collection.

Figure 3 Year of Publication of 32 Clinical Studies



Sampling About half (17) of the 32 clinical studies reported data from a single residency program. However, there were 9 large studies based on data for national samples of patients involving residents in one or more specialties and data collected for one year or more.

About one-third (11) were from general surgery or subspecialties, 7 were from Internal Medicine and the remainder involved Family Medicine, Neurology, Obstetrics/Gynecology, Pediatrics and 10 studies involving multiple specialties, within one or more institutions.

As far as we could determine only one study involved as sample of fewer than 30 residents. The majority of studies involved either 30 to 100 residents (10) or more than 100 residents (12). However, in 8 studies it was impossible to determine the number of residents involved. This was not surprising because as reported earlier the unit of analysis of the data reported in all but 2 of the clinical studies was patients, not residents. The median number of patients analyzed in the 32 studies was 8,195 with an interquartile range 1,562 to 313,669 patients

Key Features: 16 Laboratory Studies of Proxy Measures of Resident Performance

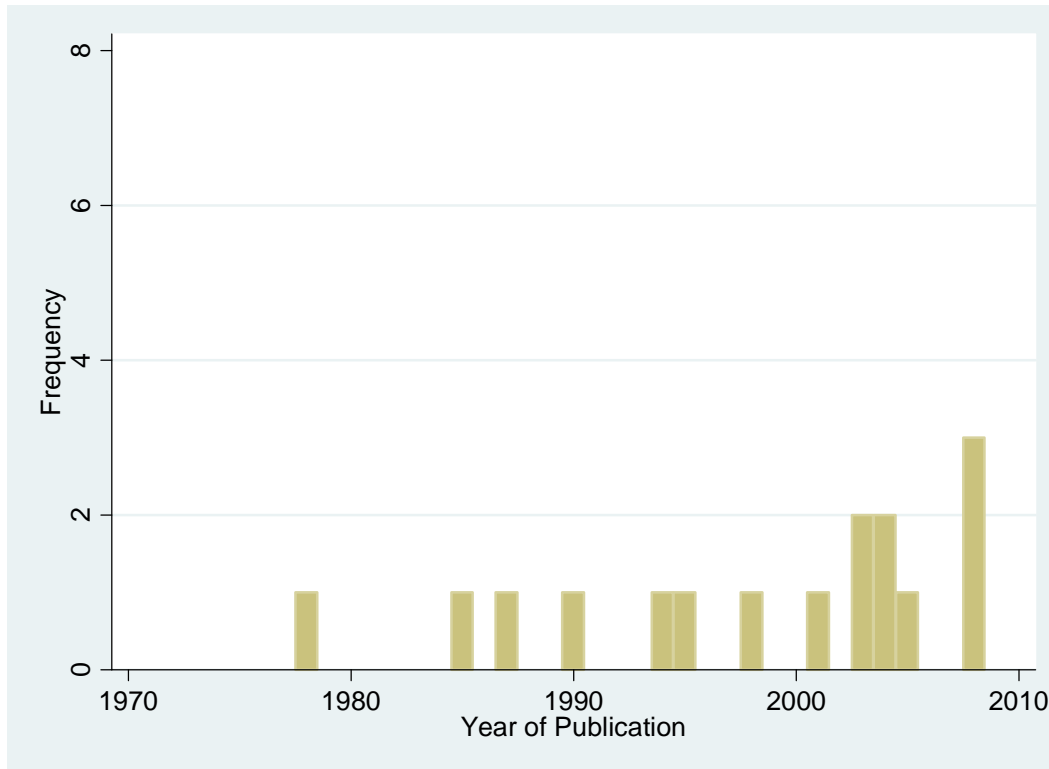
Dependent/Outcome Variables Over three-fourths (13) of the 16 studies that analyzed measures of resident performance used performance on tests of cognitive and fine motor skills. Examples of these tests include a paper-and-pencil number connection test as a measure of vigilance, a memory recall test, and a colored word test to simulate distraction.¹⁹ Only 3 involved resident performance in clinical simulations.

Independent Variable The laboratory studies examined the effect of sleep deprivation on residents' performance. The residents' status was defined either by self-report (for example a questionnaire on recent sleep patterns,²⁰ or before and after scheduled overnight call.²¹

Study Design Three-fourths (12) of the 16 studies were based on cross-over studies in which the authors measured the performance of samples of residents rotating under different schedules. Only 2 studies involved parallel controls in which the performance of different groups of residents on different schedules was compared. Only 1 study randomized residents to different schedules.

Timing, Setting and Duration Over three-fourths (13) of the 16 laboratory studies involved data that had been collected before the 2003 ACGME duty hour restrictions. Their publication dates are shown in Figure 4, and their median year of publication (2002) was earlier ($p < .01$) than the average of 2006 for the publication dates of the clinical studies shown previously in Figure 3. A little over half were conducted in the US, 3 in the United Kingdom, and 3 in other nations. Over three-fourths were from medical schools, and the remaining 4 were conducted in affiliates, Veterans Affairs Hospitals and other settings. About three-fourths (11) of the studies collected data for less than 6 months, sometimes less than a month.

Figure 4 Year of Publication of 16 Laboratory Studies



Sampling Nearly all (14) of the 16 studies reported data from a single residency program. However, one study analyzed residents from multiple programs in the same organization and another analyzed multiple organizations. There were no national studies.

Internal Medicine was the most frequent specialty (5), followed by General Surgery or subspecialties (2), Obstetrics/Gynecology (2), Anesthesiology (2), Pediatrics (1), and multiple specialties (4).

The median number of residents studied was 30 with an interquartile range of 21 to 34. The smallest study involved 14 residents and the largest, 68. Almost three-fourths (11) of the studies involved multiple levels of residents, 2 involved first year-residents only and 3 involved combinations of levels.

Effect of Duty Hour Schedules on Patient Safety

Our review revealed that the studies reported in the literature on the relationship between duty hour schedules and patient safety have used two distinct approaches. One, referred to as clinical studies, involved the use of widely-recognized clinical measures of patient outcomes and associated clinical processes. Examples of these measure included mortality, morbidity, complications, medical errors, readmissions and resource utilization.

The other approach, referred to as laboratory studies, used measures of residents' performance in laboratory settings as proxies for patient safety. These measures included residents' performance

on clinical simulations such as laparoscopic simulators, and tests of cognitive and fine motor skills.

Table 3 summarizes the reviewers' assessment of the effects reported by the clinical and laboratory studies.

Table 3 Classification of 48 Studies According to Type of Study and Findings of Effect of Duty Hour Limits on Patient Safety

<u>Findings of Effect on Patient Safety</u>	<u>Type of Study</u>	
	<u>Clinical</u>	<u>Laboratory</u>
Positive effect	12	15
Negative effect	4	0
No effect, mixed, unclear, ambiguous	16	1
Total Studies	32	16

Overall, the vast majority of the 48 studies reported either a positive effect (27) or no clear effect (17) of duty hour limits on patient safety. Only 4 reported negative effects.

Clinical Studies About a third of the clinical studies reported positive effects. However, these positive effects were more likely to be based on smaller studies in narrow, tightly-controlled settings, or limited measurements of patient safety. Examples include cardiac care,²² trauma,²³ and intensive care units.²⁴ The median number of subjects in the clinical studies demonstrating positive effects was 11,402 patients. One of the studies reporting positive effects examined residents' accidental exposure to patients' body fluids over a two-year period in a large hospital with 6,000 employees, but the authors did not specify the total number of residents and patients involved.

On the other hand, 16 clinical studies reported no effect or mixed effects of duty hour limits on patient care. The median number of subjects in these studies was over 4 million patients. Examples include a study of over 14 million patients admitted to VA and Medicare acute-care hospitals from July, 2000 to June, 2005,²⁵ and two studies, each reporting data on over 8 million Medicare patients^{26, 27}

Four clinical studies concluded that limits on duty hours have had a negative impact on patient safety. Laine et al (1993) studied the care of approximately 500 patients in an urban teaching hospital immediately before and after the implementation of duty hour limits in New York.²⁸ They found delayed test ordering and increases in in-hospital complication rates. Poulouse et al

(2005) also studied the care of 2.6 million patients in New York hospitals around the same time and reported worsening trends of accidental punctures and lacerations, and postoperative pulmonary emboli and deep vein thromboses.²⁹ Frankel et al (2005) studied 4900 patients and reported an increase in one hospital's intensive care readmission rate after implementation of the ACGME 2003 regulations,³⁰ and Salim et al (2007) studied approximately 17,000 patients and reported a significant increase in total preventable and non-preventable complications after 2003.³¹

Laboratory Studies Nearly all (94%) of the laboratory studies reported positive effects of duty hour limits on patient safety. The median number of residents studied was 30, ranging from 14 to 68. As would be expected from the distribution of sample size, nearly all studies (14) were based on data from a single residency program. The vast majority (14) of the laboratory studies lasted less than one year, but the duration of one study was unclear.

Only 3 of the laboratory studies examined residents' performance on clinical simulations. All used one device -- the minimally invasive surgery trainer, virtual reality (MIST-VR) surgical simulator.^{20, 21, 32} The remaining studies reported positive results based on neurological, cognitive and fine motor skill tests such as continuous electrooculography to measure visual attention,³³ a paper test of short-term recall and electrocardiogram interpretation,¹⁹ a locally-developed array of virtual reality tasks using special equipment to test psychomotor skills,³⁴ tests of response time and memory,³⁵ tests of lab report interpretation³⁶ and manual dexterity measured by the Purdue pegboard test.³⁷

There were no reports of negative effects among the laboratory studies. One study reported mixed effects of duty hour limits on patient safety for senior residents in anesthesiology using the Torrence Test of Creative Thinking (TTCT), a standardized test of creative and divergent thinking. Although the authors did not find differences between the mean scores for rested and sleep deprived residents on the Verbal and Figural scores of the test, they found differences in scores of Originality and Flexibility, which they interpreted as being related to divergent thinking and creativity.³⁸

Comment

The results of this review revealed several findings that should be commented on in more detail. First among these is that there is little evidence in the literature that duty hour restrictions have compromised patient safety. Only four of the forty-eight studies reviewed presented sufficient evidence to suggest this possibility. This is an important and reassuring finding as the ACGME's policies are being evaluated.

Three of the four negative studies represent data from single programs, and should therefore be interpreted with caution given the variable methods programs have utilized to comply with duty hour restrictions. For example one of these studies collected data surrounding New York State Section 405 regulations, and the impact on these changes in one teaching hospital.²⁸ The timing of the data collection for this study coincided with the period of implementation of the new regulations within the institution, allowing little time for "best practices" to emerge. While more recent study designs surrounding the ACGME replicate this pre/post design, their timing follows a decade of experience applying systems to limit resident duty hours. These systems are now

well described in the literature and have been refined in many instances over that time period. Thus, the negative findings of this early study must be considered in that context.

Of significant import is the contribution that the laboratory studies have made to the overall pattern of positive results. As noted previously, over half of the total studies suggesting improvement in patient safety with duty hour reductions present data collected by testing trainees' cognitive and fine motor skills, or in simulated clinical environments. As shown in Table 3 if these studies are removed from the review, the trend is changed from one of significantly positive results, to one where mixed or neutral results predominate. It is very clear that the evidence presented by laboratory studies is heavily weighted in the positive direction. Fifteen of sixteen laboratory studies analyzed by our Group concluded that fatigue and or acute sleep loss impacted clinicians in a variety of ways suggesting a decrease in their performance, and thus a potential increase in medical errors.

The reader should not be surprised at differences in findings between the two types of studies which we have labeled 'clinical' and 'laboratory.' This is particularly true in the larger proportion of clinical studies whose findings are more ambiguous than their laboratory counterparts. While the strength of the clinical studies was that they examined actual measures of patient safety, their perspective tended to be from a 'higher altitude' than the laboratory studies, and from such heights the view of details is blurred. These studies, in which patients or patients' clinical conditions were the outcome measures, tended to be large, retrospective, real-world studies where the many confounders common in such investigation were typically in play, weakening their quasi-experimental methodological validity, making causality more difficult to establish, and leading to more ambiguity of results.

The studies of residents' performance on tests which were proxies for patient outcomes, on the other hand, showed less ambiguity for the reason that they were designed from the outset to do so. By establishing laboratory-like conditions prospectively the authors of these studies were able to more closely model classical experimental design which admitted fewer potential confounders. This is the strength of these designs. There are two potentially offsetting weaknesses of these 'laboratory' designs. The first of these is the question of acceptability of the proxies their authors have substituted for patient care outcomes (how closely the outcome measures of these studies approximate the outcome measures of the clinical studies). The second potential weakness is that, despite their relative lack of ambiguity, the evidence they produce can only lead to inferential, rather than deductive, decisions about how their results apply to the real world of patient safety.

The validity of these findings and their implication for patient safety in real clinical settings has not been demonstrated. The design of the majority of these investigations presented little support for "blinding" of trainees. The residents were aware that their performance was being observed and analyzed. The prominence of this discussion within both the literature and in the milieu of medical training would also imply that the subjects were also aware of the hypotheses under investigation.

A concern raised by our Review Group is the external validity of studies using cognitive and fine motor skills tests, and medical simulators. The strongest concern lies with the 13 reports that used non-simulator based testing. There are many "layers" between the cognitive tasks being

assayed in these laboratory studies and the final and complex process of provision of care to patients. A review of this nature cannot quantify this difference, or extrapolate the meaning of such data to actual patient care. High fidelity medical simulators can shorten this gap. The studies using this modality are therefore more compelling. However, the immediacy of patient care, and the high-stakes of that environment are still not perfectly replicated, and thus the findings of such trials must also be carefully weighed when compared with those that evaluate effects of fatigue or mitigation of fatigue in a true clinical system.

As noted in our Results, many of the “positive” clinical studies were tests conducted in single institutions, or single clinical settings, such as intensive care units. In contrast, the larger, multi-institution or national trials more often yielded neutral or ambiguous results. This paradox is compelling, and to date, there is no evidence for a unifying explanation for this phenomenon. However, the Review Group will propose several potential explanations suggested by the body of literature as a whole.

One of the most discussed concepts has been that of competing influences. These essentially represent necessary consequences of reductions in duty hours. The most frequently discussed is the decrease in continuity of care attendant with the scheduling changes required to comply with duty hour regulations. The number of patient “hand-offs” or “sign-outs” are typically used to quantify this effect. This continues to be a compelling argument. However, there is not enough evidence available to implicate this as the cause of the neutral results of most large trials. Another competing influence implicated has been increase in work intensity. In many programs, the work hour reductions have created larger panels of patients and more tasks for the clinicians remaining on duty. This is obviously another attractive theory, but again, little was found in our review to strongly implicate it as a dominant effect.

Another concern has been that larger trials, necessary to provide the statistical power to make conclusions about meaningful patient care events, cannot prove program compliance with the actual duty hour reductions under study. Similarly, the authors of these trials have no ability to control for actual sleep of the groups under study. It has been illustrated that residents working under duty hour regulations do not always increase their sleep time.³⁹ Again, while compelling, this is not supported by our analysis of the large trials reviewed. In our opinion, even incomplete compliance might be expected to yield some positive benefit. Moreover, if safety improvement was a “dose-effect” of decrease in duty hours and increase in sleep, we would have expected that the literature assessing impact of regulations on specialties with historically longer duty periods (General Surgery) show more effect than specialties where the effect of the reductions in time at work were more modest (Internal Medicine). There is no evidence of such a differential effect.

There are other possibilities that could explain this paradox. One is that the “system” of care in teaching hospitals has partially adapted to fatigue and its risks as this issue gained national attention. In other words, layered supervision, and increasing use of care teams may have become increasingly more protective of fatigue induced errors as well. This would have likely impacted the “controls” used in the pre-post analyses recently conducted since this issue was clearly under discussion prior to the implementation of the ACGME 2003 regulations. This would have decreased the overall burden of fatigue related errors, and thus made it difficult to show effect with even the largest trial. While no evidence reviewed directly proves this theory, it should be noted as an example that the trials conducted by the Harvard Work Hours, Health and

Safety Group eloquently show that errors are often intercepted by other members of the care team.²⁴

It is difficult to isolate individual phases of resident work. Indeed, most studies overall looked at regulations as a whole, studying impact of large system changes such as those introduced by the ACGME duty hour requirements of 2003. However, overnight call is more feasibly isolated for study, and it is therefore no surprise that the highest proportion of studies looking at a single component of work examined the impact of these longer shifts and/or modifications of these longer duty periods. In total, the results of these studies suggest that overnight duty, especially that of greater than 24 hours will require further evaluation. A well done trial has shown that these shifts induce physiologic effects strongly correlated with acute sleep deprivation.³³ A companion trial has shown the clinical impact of these extended shifts.²⁴ It is important to note that studying the call process thoroughly, and controlling its subjects well, necessitates very small samples. Typically, one residency is utilized for these investigations. Moreover, these trials were often conducted in very specific care environments, such as the intensive care units utilized in the Harvard studies referenced above. How these micro-systems studies translate to the multiple specialty systems conducting training and providing patient care in varying environments must be considered. This is very important as these works are traditionally interpreted in the context of recommending large system changes.

This review has revealed important gaps that remain in our knowledge. Our Group found no trials looking at resident napping as a fatigue mitigating process for prolonged duty periods. We were disappointed by the depth of study in specific specialties that involve long duty periods and fatigue, such as pediatrics and obstetrics and gynecology. Few trials looked at differential methods of complying with duty hour requirements, for example comparing night float models. Finally, the timing of the current review in relation to the ACGME 2003 regulations does not permit analysis of any long term data. Indeed, the specialty training programs of longest duration had not yet graduated their first class of residents who trained fully under these guidelines when even the most recent studies found had been completed.

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Appendix A Data Extraction Form

Systematic Review of the Literature:

Duty Hours and Patient Safety

A7a. **Unit of analysis** 1 Residents 2 Patients 8 Other

A7b. **Number of subjects** _____

A8. **Reviewer's Notes** (brief and legible, please)

A. CITATION, REVIEW TRACKING

A1. **Ref Works ID #** _____

A2. **1st Author**, last name _____

A3. Primary reviewer

- 1 JRBoex
- 2 JWCaruso
- 3 MGGraham
- 4 MGrasberger
- 5 JKairys
- 6 NMartin
- 7 DLPaskin
- 8 JSalt
- 9 GStryjewski
- 10 JJVeloski
- 80 Other _____

A4. **Date of review** ____/____/2009

A5. **Status**

- 1 Include in review
- 2 Uncertain (*STOP explain in notes*)
- 3 Exclude (*STOP explain in notes*)

A6. **Global rating of study's quality**

- 1 **Low.** Biased or confounded Explain in Notes
- 2 **Average.**
- 3 **High.** Few, or no threats to validity.

A7. **Effect of duty hour limits on patient safety**

- 1 **Negative** (Duty hour limits **reduce** patient safety)
- 3 **No effect, no impact.**
- 5 **Positive** (Duty hour limits **increase** safety)
- 9 **Unclear, unable to determine, mixed, ambiguous**

For Office Use Only-----
Date data entry ____/____/2009
Initials data entry

B. DESIGN and ANALYSIS

C. SAMPLE

B1. Type of Study (check one)

*(page nos. refer to definition in Dawson & Trapp)

Observational (no intervention)

- 11 Descriptive, case series, case study p8*
- 12 Cross-sectional (studies, surveys) p9
- 13 Case-control (retrospective) p9
- 14 Cohort (prospective or retrospective) p11

Experimental (intervention)

- 21 Randomized (parallel controls) p15
- 22 Parallel controls (not randomized) p16
- 23 Sequential, self (x-over, time series) p16
- 24 External controls (incl historical) p17

- 80 Other design or mixture in one study, describe:

- 90 Unclear (explain in notes)

B2. Data Collection and Analysis

- 1 Unacceptable (serious gaps in documentation or fatal flaws in data or analysis)
(STOP explain in Notes)
- 2 Acceptable, meets standards
- 3 Exceeds professional standards

B3. Timing of Data Collection

- 1 Pre 1984 (Zion case)
- 2 1985-1989 (before NY 405 Regulation)
- 3 Pre/post NY 405 Regulation
- 4 1990-2003 (before ACGME duty hour restr.)
- 5 Pre/post ACGME duty hour restr.
- 6 2004-2008 (before 2008 IOM report)
- 7 2009
- 8 Other _____

C1. Scope (check one)

- 1 One program, limited sample
- 2 One organization, multi-prog
- 3 Multiple organizations
- 4 National/international, limited
- 5 National/interntl, multi-site
- 8 Other _____

C2. Size

- 1 Less than 30 residents
- 2 30 to 100
- 3 More than 100
- 9 Unclear (explain in notes)

C3. Duration

- 1 Less than 6 months
- 2 6 to 12 months
- 3 Year or more
- 9 Unclear (explain in notes)

C4. Level (check one)

- 1 PGY 1 only
- 2 All level residents
- 8 Other _____

C5. Residency/specialty (describe in box)

C6. **Clinical site** (check one)

- 1 ICU
- 2 Inpatient
- 3 Ambulatory/outpatient
- 4 Procedure area
- 8 Other, including multiple _____

C7. **Nation** (check one)

- 1 USA
- 2 Canada
- 3 UK
- 4 Australia/New Zealand
- 8 Other _____

D. DEPENDENT VARIABLE(S)
DEFINITION OF PERFORMANCE AND
MEASUREMENT/INSTRUMENTATION

D1. **Outcomes** (check all that apply)

- a Medical errors (incl needle sticks)
- b Morbidity, complications, adverse events
- c Mortality
- d Other quality indicators (re-adm, tests ordered, delays....)
- e Clinical simulation
- f Cognitive/fine motor skills, general
- x Other _____

D2. **Measurement** (check one)

- 1 Chart review
- 2 Electronic medical records
- 3 Claims/discharge abstracts
- 4 Clinical simulation
- 5 Neurobehavioral/psychomotor
- 8 Other _____

E. INDEPENDENT VARIABLE(S)
CHARACTERISTICS OF DUTY HOUR SCHEDULE
STUDIED, AND OTHER VARIABLES

E1. **Duty hour component studied** (check one)

- 1 Work week duration (e.g., 80 hrs)
- 2 Over night call duration (e.g., 30 hrs)
- 3 Over night call freq (e.g., 1/3 days)
- 4 Shift duration
- 5 Rest period duration
- 6 ACGME 2003 Dty Hrs Regs
- 8 Other, including multiple _____

E2. **Setting** (check one)

- 1 University/Medical School
- 2 Major affiliate
- 3 VA hospital
- 4 Private (e.g., Kaiser-Permanente)
- 5 Non-teaching
- 8 Other, including multiple _____

E3. **Other Interventions/
Moderating Variables
Studied and Controlled**

- NONE

Yes (check all that apply)

- a Level of supervision
- b Hand-offs
- c Night float
- d Staffing solutions, alternative providers
- x Other _____

Appendix B - Reference List

48 Studies Included in Review

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Appendix C

Abstracts of 48 Articles Reviewed - ACGME Duty Hours Study

Updated Sep 2009

B. Afessa, C. C. Kennedy, K. W. Klarich, T. R. Aksamit, J. C. Kolars and R. D. Hubmayr.	4
Introduction of a 14-hour work shift model for housestaff in the medical ICU.....	4
A. Alshekhlee, T. Walbert, M. DeGeorgia, D. C. Preston and A. J. Furlan.....	4
The impact of Accreditation Council for Graduate Medical Education duty hours, the July phenomenon, and hospital teaching status on stroke outcomes	4
J. T. Arnedt, J. Owens, M. Crouch, J. Stahl and M. A. Carskadon.....	5
Neurobehavioral performance of residents after heavy night call vs after alcohol ingestion	5
R. D. Ayalon and F. Friedman Jr.	6
The effect of sleep deprivation on fine motor coordination in obstetrics and gynecology residents	6
J. L. Bailit and M. H. Blanchard.	6
The effect of house staff working hours on the quality of obstetric and gynecologic care.....	6
P. Bartel, W. Offermeier, F. Smith and P. Becker.	7
Attention and working memory in resident anaesthetists after night duty: group and individual effects.....	7
L. Davydov, G. Caliendo, B. Mehl and L. G. Smith.....	7
Investigation of correlation between house-staff work hours and prescribing errors.	7
C. de Virgilio, A. Yaghoubian, R. J. Lewis, B. E. Stabile and B. A. Putnam.....	8
The 80-Hour Resident Workweek Does Not Adversely Affect Patient Outcomes or Resident Education	8
B. J. Eastridge, E. C. Hamilton, G. E. O'Keefe, et al.	8
Effect of sleep deprivation on the performance of simulated laparoscopic surgical skill.....	8
P. I. Ellman, I. L. Kron, J. S. Alvis, et al.....	9
Acute sleep deprivation in the thoracic surgical resident does not affect operative outcomes	9
D. N. Fisman, A. D. Harris, M. Rubin, G. S. Sorock and M. A. Mittleman.	9
Fatigue increases the risk of injury from sharp devices in medical trainees: results from a case-crossover study.....	9
H. L. Frankel, A. Foley, C. Norway and L. Kaplan.....	10
Amelioration of increased intensive care unit service readmission rate after implementation of work-hour restrictions.....	10
R. R. Gopaldas, J. Huh, F. G. Bakaeen, et al.	11
The Impact of Resident Work-Hour Restrictions on Outcomes of Cardiac Operations 1	11
D. J. Gottlieb, C. M. Parenti, C. A. Peterson and R. P. Lofgren.....	11
Effect of a change in house staff work schedule on resource utilization and patient care.	11
T. P. Grantcharov, L. Bardram, P. Funch-Jensen and J. Rosenberg.	11
Laparoscopic performance after one night on call in a surgical department: Prospective study	11
J. Green-McKenzie and F. S. Shofer.....	12
Duration of time on shift before accidental blood or body fluid exposure for housestaff, nurses, and technicians.....	12

M. M. Halbach, C. O. Spann and G. Egan.....	12
Effect of sleep deprivation on medical resident and student cognitive function: A prospective study.....	12
R. P. Hart, D. G. Buchsbaum, J. B. Wade, R. M. Hamer and J. A. Kwentus.....	13
Effect of sleep deprivation on first-year residents' response times, memory, and mood.....	13
M. R. Hawkins, D. A. Vichick and H. D. Silsby.....	13
Sleep and nutritional deprivation and performance of house officers.....	13
G. W. Hendey, B. E. Barth and T. Soliz.....	13
Overnight and postcall errors in medication orders.....	13
L. I. Horwitz, M. Kosiborod, Z. Lin and H. M. Krumholz.....	14
Changes in outcomes for internal medicine inpatients after work-hour regulations.....	14
D. L. Howard, J. H. Silber and D. R. Jobes.....	14
Do regulations limiting residents' work hours affect patient mortality?.....	14
M. M. Hutter, K. C. Kellogg, C. M. Ferguson, W. M. Abbott and A. L. Warshaw.....	15
The impact of the 80-hour resident workweek on surgical residents and attending surgeons.....	15
H. M. A. Kaafarani, K. M. F. Itani, L. A. Petersen, J. Thornby and D. H. Berger.....	16
Does resident hours reduction have an impact on surgical outcomes?.....	16
K. Kahol, M. J. Leyba, M. Deka, et al.....	16
Effect of fatigue on psychomotor and cognitive skills.....	16
C. Laine, L. Goldman, J. R. Soukup and J. G. Hayes.....	16
The impact of a regulation restricting medical house staff working hours on the quality of patient care.....	16
C. P. Landrigan, A. M. Fahrenkopf, D. Lewin, et al.....	17
Effects of the accreditation council for graduate medical education duty hour limits on sleep, work Hours, and safety.....	17
C. P. Landrigan, J. M. Rothschild, J. W. Cronin, et al.....	18
Effect of reducing interns' work hours on serious medical errors in intensive care units.....	18
D. R. Leff, R. Aggarwal, M. Rana, et al.....	18
Laparoscopic skills suffer on the first shift of sequential night shifts: program directors beware and residents prepare.....	18
C. Leonard, N. Fanning, J. Attwood and M. Buckley.....	19
The effect of fatigue, sleep deprivation and onerous working hours on the physical and mental wellbeing of pre-registration house officers.....	19
Lingenfelter Th., R. Kaschel, A. Weber, H. Zaiser-Kaschel, B. Jakober and J. Kuper.....	19
Young hospital doctors after night duty: Their task-specific cognitive status and emotional condition.....	19
S. W. Lockley, J. W. Cronin, E. E. Evans, et al.....	20
Effect of reducing interns' weekly work hours on sleep and attentional failures.....	20
C. A. Morrison, M. M. Wyatt and M. M. Carrick.....	21
Impact of the 80-hour work week on mortality and morbidity in trauma patients: an analysis of the National Trauma Data Bank.....	21
M. B. Mycyk, M. R. McDaniel, M. A. Fotis and J. Regalado.....	21
Hospitalwide adverse drug events before and after limiting weekly work hours of medical residents to 80.....	21
C. S. Nelson, K. Dell'Angela, W. S. Jellish, I. E. Brown and M. Skaredoff.....	21
Residents' performance before and after night call as evaluated by an indicator of creative thought.....	21
L. A. Petersen, T. A. Brennan, A. C. O'Neil, E. F. Cook and T. H. Lee.....	22
Does housestaff discontinuity of care increase the risk for preventable adverse events?.....	22
B. K. Poulouse, W. A. Ray, P. G. Arbogast, et al.....	22
Resident work hour limits and patient safety.....	22
E. C. Poulton, G. M. Hunt, A. Carpenter and R. S. Edwards.....	23
The performance of junior hospital doctors following reduced sleep and long hours of work.....	23
A. R. Privette, S. R. Shackford, T. Osler, J. Ratliff, K. Sartorelli and J. C. Hebert.....	24
Implementation of resident work hour restrictions is associated with a reduction in mortality and provider-related complications on the surgical service: a concurrent analysis of 14,610 patients.....	24

J. Robbins and F. Gottlieb.....	24
Sleep deprivation and cognitive testing in internal medicine house staff	24
A. K. Rosen, S. A. Loveland, P. S. Romano, et al.	25
Effects of resident duty hour reform on surgical and procedural patient safety indicators among hospitalized Veterans Health Administration and Medicare patients.....	25
A. Salim, P. G. R. Teixeira, L. Chan, et al.	25
Impact of the 80-hour workweek on patient care at a level I trauma center	25
P. Schenarts, J. Bowen, M. Bard, et al.	26
The effect of a rotating night-float coverage scheme on preventable and potentially preventable morbidity at a level 1 trauma center.	26
K. D. Shetty and J. Bhattacharya.	26
Changes in hospital mortality associated with residency work-hour regulations	26
K. G. Volpp, A. K. Rosen, P. R. Rosenbaum, et al.....	27
Mortality among patients in VA hospitals in the first 2 years following ACGME resident duty hour reform.....	27
K. G. Volpp, A. K. Rosen, P. R. Rosenbaum, et al.....	28
Mortality among hospitalized medicare beneficiaries in the first 2 years following ACGME resident duty hour reform	28
K. G. Volpp, A. K. Rosen, P. R. Rosenbaum, et al.....	29
Did Duty Hour Reform Lead to Better Outcomes Among the Highest Risk Patients?	29
A. Yaghoubian, G. Saltmarsh, D. K. Rosing, R. J. Lewis, B. E. Stabile and C. De Virgilio.....	29
Decreased bile duct injury rate during laparoscopic cholecystectomy in the era of the 80-hour resident workweek	29

B. Afessa, C. C. Kennedy, K. W. Klarich, T. R. Aksamit, J. C. Kolars and R. D. Hubmayr.
Introduction of a 14-hour work shift model for housestaff in the medical ICU
Chest,2005,128,3910-3915

STUDY OBJECTIVE: To describe the outcomes of switching housestaff from a traditional model of "long-call" every 4 days to a 14-h work-shift model in a medical ICU (MICU) over a 5-week pilot period. **DESIGN:** Retrospective comparison of a 5-week pilot period for a 14-h work-shift model vs a 4-month period for the traditional model.

SETTING: The MICU of a tertiary medical center.

PARTICIPANTS: A total of 626 patients admitted to the MICU and 34 internal medicine residents taking care of them.

INTERVENTIONS: None.

MEASUREMENTS: Severity-adjusted patient outcomes, housestaff performance on end-of-rotation examinations, and scheduled duty hours during the 5-week 14-h work-shift pilot period compared to a 16-week traditional nonpilot work period.

RESULTS: There were no statistically significant differences in patients' adjusted mortality rates, hospital lengths of stay, or housestaff performance on end-of-rotation knowledge assessment examinations between the pilot and nonpilot periods. During the pilot period, each resident was scheduled to work for an average of 61.3 h weekly, and each fellow for 65.3 h weekly. In comparison, each resident and fellow was scheduled to work for an average of 73.3 h weekly during the nonpilot period.

CONCLUSIONS: The 14-h work shift is a feasible option for housestaff rotation in the MICU. Although the power of our study to detect significant differences in mortality, length of stay, and educational outcomes was low, there was no evidence of compromised patient care or housestaff education associated with the 14-h shift model over the course of this 5-week pilot study.

A. Alsheklee, T. Walbert, M. DeGeorgia, D. C. Preston and A. J. Furlan.

The impact of Accreditation Council for Graduate Medical Education duty hours, the July phenomenon, and hospital teaching status on stroke outcomes
J.Stroke Cerebrovasc Dis.,2009,18,232-238

BACKGROUND: Acute ischemic stroke (AIS) is common cause of hospital admission. The objective of this study was to determine the impact of the new Accreditation Council for Graduate Medical Education (ACGME) duty hour regulations on AIS outcomes including inhospital mortality.

METHODS: Hospitalized patients with AIS were selected from the National Inpatient Sample database. Patients with AIS with a known mortality and hospital teaching status were included for the years 2000 through 2005. Inhospital mortality and predictors of mortality were stratified by the hospital teaching status. To determine the variability of mortality around the month of July (July phenomenon) the trend of mortality was determined in teaching hospitals stratified by the calendar month of each year.

RESULTS: In all, 377,266 patients were included in this analysis; 43.0% were admitted to teaching hospitals. Overall inhospital mortality was 10.8%, slightly higher in teaching hospitals (11.4% v 10.3%, $P < .0001$). The trend in AIS mortality showed a decline during the 6 years included in this study in both hospital types ($P < .0001$). Adjusted analysis showed decline in mortality in both hospital types after July 1, 2003: odds ratio (OR) 0.91 (95% confidence interval [CI] 0.87, 0.94) in

teaching hospitals and OR 0.81 (95% CI 0.78, 0.84) in nonteaching hospitals. Predictors of AIS-associated hospital mortality were similar in both hospital types except for sepsis, which was another independent predictor of death in nonteaching hospitals (OR 1.58, 95% CI 1.30, 1.94). There was no significant change in AIS mortality when stratified by each calendar month within the years included in this study (P value = .25-.93).

CONCLUSION: There was no difference in AIS mortality after the implementation of the new ACGME duty hour standards. In addition, data support the lack of July phenomenon in neurology residency programs in regard to AIS mortality.

J. T. Arnedt, J. Owens, M. Crouch, J. Stahl and M. A. Carskadon.

Neurobehavioral performance of residents after heavy night call vs after alcohol ingestion
JAMA,2005,294,1025-1033

CONTEXT: Concern exists about the effect of extended resident work hours; however, no study has evaluated training-related performance impairments against an accepted standard of functional impairment.

OBJECTIVES: To compare post-call performance during a heavy call rotation (every fourth or fifth night) to performance with a blood alcohol concentration of 0.04 to 0.05 g% (per 100 mL of blood) during a light call rotation, and to evaluate the association between self-assessed and actual performance.

DESIGN, SETTING, AND PARTICIPANTS: A prospective 2-session within-subject study of 34 pediatric residents (18 women and 16 men; mean age, 28.7 years) in an academic medical center conducted between October 2001 and August 2003, who were tested under 4 conditions: light call, light call with alcohol, heavy call, and heavy call with placebo.

INTERVENTIONS: Residents attended a test session during the final week of a light call rotation (non-post-call) and during the final week of a heavy call rotation (post-call). At each session, they underwent a 60-minute test battery (light and heavy call conditions), ingested either alcohol (light call with alcohol condition) or placebo (heavy call with placebo condition), and repeated the test battery. Performance self-evaluations followed each test.

MAIN OUTCOME MEASURES: Sustained attention, vigilance, and simulated driving performance measures; and self-report sleepiness, performance, and effort measures. **RESULTS:** Participants achieved the target blood alcohol concentration. Compared with light call, heavy call reaction times were 7% slower (242.5 vs 225.9 milliseconds, $P < .001$); commission errors were 40% higher (38.2% vs 27.2%, $P < .001$); and lane variability (7.0 vs 5.5 ft, $P < .001$) and speed variability (4.1 vs 2.4 mph, $P < .001$) on the driving simulator were 27% and 71% greater, respectively. Speed variability was 29% greater in heavy call with placebo than light call with alcohol (4.2 vs 3.2 mph, $P = .01$), and reaction time, lapses, omission errors, and off-roads were not different. Correlation between self-assessed and actual performance under heavy call was significant for commission errors ($r = -0.45$, $P = .01$), lane variability ($r = -0.76$, $P < .001$), and speed variability ($r = -0.71$, $P < .001$), but not for reaction time.

CONCLUSIONS: Post-call performance impairment during a heavy call rotation is comparable with impairment associated with a 0.04 to 0.05 g% blood alcohol concentration during a light call rotation, as measured by sustained attention, vigilance, and simulated driving tasks. Residents' ability to judge this impairment may be limited and task-specific.

R. D. Ayalon and F. Friedman Jr.

The effect of sleep deprivation on fine motor coordination in obstetrics and gynecology residents
Am.J.Obstet.Gynecol.,2008,199,576.e1-576.e5

Objective: The purpose of this study was to evaluate the effect of acute sleep deprivation on the fine motor coordination in obstetrics and gynecology residents.

Study Design: Twenty-eight obstetrics and gynecology residents completed a series of tasks using the Purdue pegboard standardized protocol for testing fine motor coordination both before and after a 24-hour call.

Results: Twenty-three participants were women and 5 were men. There was a learning curve demonstrated for performance of the tasks. There was a statistically significant decline in performance of residents after overnight call. When adjusting for the learning curve, effects of sleep deprivation were magnified for all tasks: right (dominant) hand ($P = .0005$), left hand ($P = .0020$), both hands ($P < .0001$), and assembly ($P < .0001$). There were significant differences in performance when segregated by year of training and sex; female residents appeared to tolerate better lack of sleep.

Conclusion: Acute sleep deprivation has a deleterious effect on fine motor coordination in this group of obstetrics and gynecology residents.

J. L. Bailit and M. H. Blanchard.

The effect of house staff working hours on the quality of obstetric and gynecologic care.
Obstet.Gynecol.,2004,103,613-616

OBJECTIVE: To measure the effect of house staff working hours reforms on the quality of obstetric and gynecologic care.

METHODS: Sentinel events, medication errors, maternal and neonatal outcomes, and decision making were measured before and after the Accreditation Council of Graduate Medical Education work-hour reforms. Data sources consisted of the perinatal database at MetroHealth Medical Center (Case Western Reserve University, Cleveland, OH), incident reports filed in the hospital department of risk management, the patient-satisfaction database at MetroHealth Medical Center, and the pharmacy medication error database. Two reviewers examined all incident reports separately, and discrepancies were resolved by mutual agreement.

RESULTS: Patient demographics did not change across the 2 time periods. Obstetric outcomes were the same for third- and fourth-degree lacerations, umbilical arterial pH less than 7, fever, and the need for general anesthesia. Postpartum hemorrhage and neonatal resuscitations were significantly decreased over time (2% before versus 1% after work-hour restrictions [$P = .008$], and 30% before versus 26% after work-hour restrictions [$P < .001$], respectively). The rate of primary cesarean delivery rose from 14% to 16%, a nonsignificant difference ($P < .06$). There were no differences in rates of cesarean delivery for nonreassuring fetal status, failed induction, labor abnormality, or repeat cesarean delivery. Reported medication errors associated with resident performance were too rare for comparison across time periods. The number of incident reports directly involving residents before and after work-hour restrictions were 3 and 10, respectively-too few to reach statistical significance.

CONCLUSIONS: Although problems in physician performance may be underreported, resident work-hour restrictions show minimal evidence of improvement in quality of care.

LEVEL OF EVIDENCE: II-3

P. Bartel, W. Offermeier, F. Smith and P. Becker.

Attention and working memory in resident anaesthetists after night duty: group and individual effects.

Occup.Environ.Med.,2004,61,167-170

AIMS: To investigate the effects of a single period of night duty on measures of attention and working memory in a group of residents (registrars) in anaesthesiology. Emphasis was placed on individual deficits using a reference point of the equivalent effect of a blood alcohol concentration (BAC) >0.05% determined by other researchers.

METHODS: There were 33 subjects aged 26-42 years. Night duty was performed on a weekly basis. Baseline assessments were conducted at either 08 15 or 08 55 preceding night duty and repeated 24-25 hours later, just after the completion of duty. Questionnaires included items regarding duration of sleep and the Stanford Sleepiness Scale. A battery of four reaction time (RT) tasks of increasing difficulty, lasting approximately 35 minutes, was administered on a personal computer. These ranged from simple RT to progressively more complex RT tasks incorporating working memory. A significant change was regarded as >15% deterioration in respect of speed or accuracy.

RESULTS: The mean duration of sleep preceding night duty was 7.04 hours and 1.66 hours during the period of night duty. Intergroup comparisons revealed significant prolongation in mean response speed in the first three tests. Mean accuracy was significantly reduced only in respect of the two more complex tests. A >15% deterioration in response speed occurred in up to 30% of subjects on a single task, rising to 52% (17/33) overall. Deterioration occurred in a patchy distribution in most subjects, involving no more than one or two of the four tasks. As regards accuracy, the prevalence of deterioration increased with task complexity.

CONCLUSIONS: Results are in general agreement with previous group analyses. A new dimension was added by the analysis of a broad spectrum of individual response to sleep deprivation. The effects of sleep loss in residents cannot be overlooked, even in a relatively benign work schedule.

L. Davydov, G. Caliendo, B. Mehl and L. G. Smith.

Investigation of correlation between house-staff work hours and prescribing errors.

Am.J.Health-Syst Pharm.,2004,61,1130-1134

PURPOSE: The possible correlation between the frequency and significance of prescribing errors and the number of hours worked during a 24-hour shift by hospital house staff was studied.

METHODS: A prospective observational trial was conducted in two internal medicine units at an academic medical center. Orders written by medical house staff covering the study units between January 8 and March 10, 2001, were collected daily and evaluated for obvious prescribing errors, the type and significance of the errors, and the number of hours the resident had worked during a 24-hour shift at the time of the prescribing error.

RESULTS: A total of 45,366 orders (including orders for medications, laboratory tests, diagnostic procedures, and nursing care) were entered on the study units during the study period. A total of 498 erroneous prescribing orders were identified. A majority of the erroneous orders (77%) could have resulted in significant morbidity or mortality had they reached the patient. The most common errors involved the wrong dose (18%), the wrong dosage frequency (15%), and duplicate orders

(15%). There was no statistically significant correlation between the number of hours worked and the frequency or significance of the errors.

CONCLUSION: The number of hours worked by medical house staff during a 24-hour shift did not appear to affect the frequency or significance of their prescribing errors.

C. de Virgilio, A. Yaghoubian, R. J. Lewis, B. E. Stabile and B. A. Putnam.

The 80-Hour Resident Workweek Does Not Adversely Affect Patient Outcomes or Resident Education

Curr.Surg.,2006,63,435-439

Purpose: To determine whether the 80-hour resident workweek adversely affects patient outcomes or resident education.

Methods: To assess patient outcomes, the authors reviewed trauma patient morbidity and mortality at the second busiest level I trauma center in Los Angeles County before (July 1998-June 2003, Period 1) and after (July 2003-June 2005, Period 2) implementation of the duty hour limitation via a retrospective review of a prospective database. All patients were operated and managed by residents under faculty supervision. Patient characteristics included the injury severity score (ISS), mechanism of injury, complications, and death. To assess resident education, the authors compared ABSITE percentile scores, first-time pass rates on the American Board of Surgery Qualifying and Certifying Examinations, and total and chief resident operative case volumes. In addition, they estimated institutional costs incurred to comply with the new duty hour rules.

Results: Patient outcomes. Over the entire 7-year study period, 11,518 trauma patients were transported to Harbor-UCLA Medical Center. Compared with Period 1, Period 2 experienced an increase in average yearly patient volume from 1510 to 1981 ($p < 0.01$). The average ISS also increased, from 7.9 to 9.6 ($p < 0.0001$), as did the proportion of penetrating trauma from 14.8% to 17.6% ($p < 0.0001$). Morbidity and mortality rates remained unchanged. Resident education. Mean ABSITE scores and first-time Qualifying and Certifying Exam pass rates were unchanged. Mean resident total major case volumes increased significantly in Period 2 from 831 to 1156 ($p < 0.0001$), whereas chief resident year case volumes were unchanged. The estimated cost incurred by this institution to conform to the new work hour standards was approximately \$359,000 per year.

Conclusions: Despite concerns that the 80-hour workweek might threaten patient care and resident education, the morbidity and mortality rates at a busy level I trauma center remained unchanged.

The quality of surgical resident education, as measured by operative volumes, ABSITE scores, and written and oral board examination pass rates were likewise unchanged. The reorganization of the authors' general surgery residency program to comply with the duty hour restrictions was achieved within reasonable cost. © 2006 Association of Program Directors in Surgery.

B. J. Eastridge, E. C. Hamilton, G. E. O'Keefe, et al.

Effect of sleep deprivation on the performance of simulated laparoscopic surgical skill

Am.J.Surg.,2003,186,169-174

Background: Resident work hours may impact patient care. We hypothesized that "call-associated" acute sleep deprivation has no effect on technical dexterity as measured on a minimally invasive surgery trainer, virtual reality (MIST VR) surgical simulator.

Methods: Thirty-five surgical residents were prospectively evaluated pre-call (rested), on-call (rested), and post-call (acutely sleep deprived). Participants completed questionnaires regarding sleep hours and level of fatigue. Technical skill was assessed using the MIST VR. Speed, errors,

and economy of motion were automatically recorded by the MIST VR computer simulator. Data were analyzed by paired Student t test and analysis of variance.

Results: Estimated hours of sleep and subjective indicators of fatigue were different between rested and sleep-deprived residents. The number of errors and time to complete all tasks increased at the post-call assessment.

Conclusions: Resident work schedules lead to sleep deprivation and fatigue. Call-associated sleep deprivation and fatigue are associated with increased technical errors in the performance of simulated laparoscopic surgical skills. © 2003 Excerpta Medica, Inc. All rights reserved.

P. I. Ellman, I. L. Kron, J. S. Alvis, et al.

Acute sleep deprivation in the thoracic surgical resident does not affect operative outcomes

Ann.Thorac.Surg.,2005,80,60-65

Background. There is an increasing trend toward work hour restrictions for doctors world wide. These reforms have been inspired, in part, by the assertion by some that the fatigued physician is more prone to making errors. Interestingly, there is very little in the way of objective data with regard to the effects of sleep deprivation on patient outcomes. We have recently studied this in attending surgeons. The present study focused on thoracic surgical residents. Our hypothesis was that acute sleep deprivation would not lead to an increase in operative times or complications.

Methods. A retrospective review of all cases performed by thoracic surgical residents at the University of Virginia from January 1994 to March of 2004 was done. Complication rates of cases performed by "sleep deprived" (SD) residents were compared with cases done when the residents were "not sleep deprived" (NSD). A resident was deemed sleep deprived if he or she performed a case the previous evening that started between 10 pm and 5 am or ended between the hours of 11 pm and 7:30 am.

Results. A total of 7,323 cases were recorded in the STS database over the 10-year period examined. Two hundred and twenty-nine of these cases (3%) were performed by SD residents. Mortality rates for coronary artery bypass operations showed no significant differences (2.1% [SD = 3 of 141 patients] vs 3.1% (NSD = 143 of 4452 patients), $p = 0.63$). A comparison of operative, neurologic, renal, infectious, and pulmonary complications as well as cardiopulmonary bypass times, cross-clamp times, the use of blood products, and length of stay also demonstrated no significant differences between groups.

Conclusions. Acute sleep deprivation in thoracic surgical residents does not affect operative efficiency, morbidity, or mortality in cardiac surgical operations. © 2005 by The Society of Thoracic Surgeons.

D. N. Fisman, A. D. Harris, M. Rubin, G. S. Sorock and M. A. Mittleman.

Fatigue increases the risk of injury from sharp devices in medical trainees: results from a case-crossover study.

Infect.Control Hosp.Epidemiol.,2007,28,10-17

BACKGROUND: Extreme fatigue in medical trainees likely compromises patient safety, but regulations that limit trainee work hours have been controversial. It is not known whether extreme fatigue compromises trainee safety in the healthcare workplace, but evidence of such a relationship would inform the current debate on trainee work practices. Our objective was to evaluate the

relationship between fatigue and workplace injury risk among medical trainees and nontrainee healthcare workers.

DESIGN: Case-crossover study. **SETTING:** Five academic medical centers in the United States and Canada. **PARTICIPANTS:** Healthcare workers reporting to employee healthcare clinics for evaluation of needlestick injuries and other injuries related to sharp instruments and devices (sharps injuries). Consenting workers completed a structured interview about work patterns, time at risk of injury, and frequency of fatigue. **RESULTS:** Of 350 interviewed subjects, 109 (31%) were medical trainees. Trainees worked more hours per week ($P < .001$) and slept less the night before an injury ($P < .001$) than did other healthcare workers. Fatigue increased injury risk in the study population as a whole (incidence rate ratio [IRR], 1.40 [95% confidence interval {CI}, 1.03-1.90]), but this effect was limited to medical trainees (IRR, 2.94 [95% CI, 1.71-5.07]) and was absent for other healthcare workers (IRR, 0.97 [95% CI, 0.66-1.42]) ($P = .001$).

Conclusions. Long work hours and sleep deprivation among medical trainees result in fatigue, which is associated with a 3-fold increase in the risk of sharps injury. Efforts to reduce trainee work hours may result in reduced risk of sharps-related injuries among this group.

H. L. Frankel, A. Foley, C. Norway and L. Kaplan.

Amelioration of increased intensive care unit service readmission rate after implementation of work-hour restrictions.

J. Trauma, 2006, 61, 116-121

In July 2003, we reallocated our resident workforce to address mandated duty-hour restrictions. In the subsequent academic year (AY), surgical intensive care unit (SICU) service readmission rates (RR) doubled. We hypothesized that a targeted intervention could reduce SICU service RR in academic year (AY) 2004-05.

METHODS: This study was conducted at an urban teaching hospital before (AY02-03, period 1), during (AY03-04, period 2), and after (AY04-05, period 3) implementation of the Accreditation Council for Graduate Medical Education guidelines. Demographics, RR, and reason were culled from Project Impact and a complications database. SICU staff (dedicated intensivist, two or three fellows, and six residents) remained constant. In periods 2 and 3 (versus 1), ward residents cross-covered ≥ 3 services every 5 to 6 nights (versus every 3 in period 1) with physician assistant support (versus none in period 1). During period 3, a focused transfer phone call, charted care summary, and discharge checkup defined the intervention. Interperiod comparisons were by chi² and t test analysis; $p < 0.05$ (versus period 1) defined significance.

RESULTS: In all, 1,570, 1,705 and 1,681 patients were treated in periods 1, 2, and 3, respectively. There were no demographic or APACHE score differences. RRs were 1.4%, 3.0% and 1.2% in periods 1, 2, and 3, respectively. The percentages of readmissions as a result of ward care were 16.7, 41, and 10%, respectively. The most common readmission indication was respiratory (46% in period 1; 51% in period 2, and 80% in period 3) and was associated with an increased proportion of readmission as a result of patient disease (46% in period 1; 41% in period 2; 80% in period 3). Intervention noncompliance preceded 30% of period 3 readmissions.

CONCLUSION: A targeted intervention can reduce the rate of SICU readmission caused by care inadequacies stemming from a resident reallocation strategy.

R. R. Gopaldas, J. Huh, F. G. Bakaeen, et al.

The Impact of Resident Work-Hour Restrictions on Outcomes of Cardiac Operations 1
J.Surg.Res.,2009,2,1-7

Background: The Accreditation Council of Graduate Medical Education mandated an 80-h/wk resident physician work-hour restriction on July 1, 2003. The objective of this study was to evaluate the impact of the resident work-hour restriction on outcomes of cardiac operations.

Materials and Method: We reviewed records of 1562 patients who underwent cardiac operations at our institution between 1997 and 2007, and we compared outcomes of operations performed before July 1, 2003 (pre-reform, n = 777) and those performed after July 1, 2003 (post-reform, n = 785).

Multivariate analysis with logistic regression was used to test for the independent effects of the resident work-hour reform by controlling for patient-specific confounding factors.

Results: Post-reform patients had a significantly lower 30-d mortality rate (1.8% versus 3.9%; P = 0.01) and a slightly lower 6-month mortality rate (4.5% versus 6.3%; P = 0.12) than pre-reform patients. Multivariate analysis revealed that the post-reform patients had significantly lower adjusted 30-d mortality (odds ratio, 0.37; 95% CI, 0.18-0.75; P = 0.006) and 6-mo mortality (odds ratio, 0.56; 95% CI, 0.34-0.91; P = 0.02) than the pre-reform patients.

Conclusions: Cardiac operations performed after the resident work-hour restriction went into effect were associated with significantly lower adjusted 30-d and 6-mo mortality rates than were operations performed before the work-hour restriction became effective. © 2009 Elsevier Inc. All rights reserved.

D. J. Gottlieb, C. M. Parenti, C. A. Peterson and R. P. Lofgren.

Effect of a change in house staff work schedule on resource utilization and patient care.
Arch.Intern.Med.,1991,151,2065-2070

Concern is frequently expressed by health care providers and consumers that the work environment of physicians-in-training may adversely affect their performance. This article documents the effects of changing from a traditional rotational overnight call schedule for house staff to a schedule designed to reduce sleep deprivation, distribute admissions more evenly throughout the week, and improve continuity of inpatient care on the internal medicine service of a large, university-affiliated Veterans Affairs Medical Center. In a prospective, time-series study, the hypothesis that this change would improve the efficiency and quality of medical care was evaluated by comparing the hospital course of the patients admitted during 4-week periods prior to and following the change in work schedule. The patients in the preintervention group do not differ significantly from those in the postintervention group in any identifiable clinical characteristics. The length of stay was shorter (10.9 vs 9.3 days) and the number of laboratory tests ordered per patient was smaller (24.0 vs 19.0) for patients cared for under the new work schedule compared with those cared for under the traditional work schedule. Resident physicians also committed fewer medication errors under the new work schedule (16.9 vs 12.0 per 100 patients discharged). We conclude that altering the house staff work schedule affects patient care and can lead to a decrease in utilization of health care resources.

T. P. Grantcharov, L. Bardram, P. Funch-Jensen and J. Rosenberg.

Laparoscopic performance after one night on call in a surgical department: Prospective study
Br.Med.J.,2001,323,1222-1223

Surgeons often operate during the night, and often after disturbed sleep or total lack of sleep. Impairment of surgical dexterity due to fatigue could lead to mistakes that are life threatening for the patient. Our study investigated the hypothesis that one night on call in a surgical department would adversely affect the surgeon's performance on simulated laparoscopic tasks.

J. Green-McKenzie and F. S. Shofer.

Duration of time on shift before accidental blood or body fluid exposure for housestaff, nurses, and technicians.

Infect.Control Hosp.Epidemiol.,2007,28,5-9

BACKGROUND: Shift work has been found to be associated with an increased rate of errors and accidents among healthcare workers (HCWs), but the effect of shift work on accidental blood and body fluid exposure sustained by HCWs has not been well characterized.

OBJECTIVES: To determine the duration of time on shift before accidental blood and body fluid exposure in housestaff, nurses, and technicians and the proportion of housestaff who sustain a blood and body fluid exposure after 12 hours on duty.

METHODS: This retrospective, descriptive study was conducted during a 24-month period at a large urban teaching hospital. Participants were HCWs who sustained an accidental blood and body fluid exposure.

RESULTS: Housestaff were on duty significantly longer than both nursing staff ($P=.02$) and technicians ($P<.0001$) before accidental blood and body fluid exposure. Half of the blood and body fluid exposures sustained by housestaff occurred after being on duty 8 hours or more, and 24% were sustained after being on duty 12 hours or more. Of all HCWs, 3% reported an accidental blood and body fluid exposure, with specific rates of 7.9% among nurses, 9.4% among housestaff, and 3% among phlebotomists.

CONCLUSIONS: Housestaff were significantly more likely to have longer duration of time on shift before blood and body fluid exposure than were the other groups. Almost one-quarter of accidental blood and body fluid exposures to housestaff were incurred after they had been on duty for 12 hours or more. Housestaff sustained a higher rate of accidental blood and body fluid exposures than did nursing staff and technicians.

M. M. Halbach, C. O. Spann and G. Egan.

Effect of sleep deprivation on medical resident and student cognitive function: A prospective study. Am.J.Obstet.Gynecol.,2003,188,1198-1201

OBJECTIVE: The purpose of this study was to determine whether cognitive function test results decrease after a typical night of on-call duty, on the basis of the amount of sleep that is obtained.

STUDY DESIGN: Two standard cognitive functions tests (the Grooved Pegboard and California Verbal Learning Test II) were administered to the 30 participants who were members of the obstetrics and gynecology house staff and to medical students at Emory University School of Medicine. Each test was administered twice, before and after on-call duty. The data were analyzed with a paired two-tailed Student t test.

RESULTS: For the California Verbal Learning Test II, trial 5 showed a decrease in score of 0.8 ($P=.05$) after on-call duty. Trials 1 through 5 showed a decrease in score of 3.5 ($P=.01$).

CONCLUSION: This finding suggests that cognitive function test scores do decrease after on-call duty. Scrutiny of this issue by the Accreditation Council of Graduate Medical Education is justified, and the issue should continue to be evaluated. Our finding suggests that a change in our current educational structure is warranted.

R. P. Hart, D. G. Buchsbaum, J. B. Wade, R. M. Hamer and J. A. Kwentus.
Effect of sleep deprivation on first-year residents' response times, memory, and mood
J.Med.Educ.,1987,62,940-941

In the study reported here, the authors examined residents who were sleep-deprived and those who were not sleep-deprived, using tasks designed to assess the residents' speed of information-processing and decision-making and their recent memory and mood.

M. R. Hawkins, D. A. Vichick and H. D. Silsby.
Sleep and nutritional deprivation and performance of house officers
J.Med.Educ.,1985,60,530-535

A study was conducted by the authors to compare cognitive functioning in acutely and chronically sleep-deprived house officers. A multivariate analysis of variance revealed significant deficits in primary mental tasks involving basic rote memory, language, and numeric skills as well as in tasks requiring high-order cognitive functioning and traditional intellectual abilities. These deficits existed only for the acutely sleep-deprived group. The finding of deficits in individuals who reported five hours or less of sleep in a 24-hour period suggests that the minimum standard of four hours that has been considered by some to be adequate for satisfactory performance may be insufficient for more complex cognitive functioning.

G. W. Hendey, B. E. Barth and T. Soliz.
Overnight and postcall errors in medication orders.
Acad.Emerg.Med.,2005,12,629-634

OBJECTIVE: To compare the error rates in medication orders by physicians who were off call, on overnight call, and postcall.

METHODS: This was a retrospective review of inpatient medication orders, pharmacy records, and resident physician work schedules in a university-affiliated community teaching hospital with residency programs in emergency medicine, family practice, internal medicine, obstetrics, pediatrics, and surgery. The authors calculated error rates, odds ratios (ORs), and 95% confidence intervals (95% CIs) for physicians during April 2000.

RESULTS: In 8,195 medication orders, there were 177 errors (2.16% overall error rate). There was an increased error rate for overnight and postcall orders (2.71%, OR 1.44, 95% CI = 1.06 to 1.95) in comparison to orders written by off-call physicians (1.90%). Error rates were significantly higher on the medical/surgical wards during the overnight (3.91%, OR 1.89, 95% CI = 1.22 to 2.92) and postcall (3.41%, OR 1.64, 95% CI = 1.10 to 2.43) periods compared with the off-call (2.11%) period, and postgraduate year 1 (PGY1) physicians had a higher overnight error rate (4.23%, OR 2.28, 95% CI = 1.44 to 3.61). Error rates were also higher on the medical/surgical wards compared with critical care units (2.62% vs. 1.22%, OR 2.17, 95% CI = 1.48 to 3.18). The PGY1 physicians had error rates similar to those of the PGY2-5 physicians when off call, but were significantly higher on overnight call (4.23% vs. 0.52%, OR 8.47, 95% CI = 2.00 to 35.82).

CONCLUSIONS: Medication-ordering error rates were higher for overnight and postcall physicians, particularly on the general medical/surgical wards, and in PGY1 physicians during the overnight period.

L. I. Horwitz, M. Kosiborod, Z. Lin and H. M. Krumholz.

Changes in outcomes for internal medicine inpatients after work-hour regulations

Ann.Intern.Med.,2007,147,97-103

Background: Limits on resident work hours are intended to reduce fatigue-related errors, but may raise risk by increasing transfers of responsibility for patients.

Objective: To examine changes in outcomes for internal medicine patients after the implementation of work-hour regulations.

Design: Retrospective cohort study. **Setting:** Urban, academic medical center. **Patients:** 14 260 consecutive patients discharged from the teaching (housestaff) service and 6664 consecutive patients discharged from the nonteaching (hospitalist) service between 1 July 2002 and 30 June 2004.

Measurements: Outcomes included intensive care unit utilization, length of stay, discharge disposition, 30-day readmission rate to the study institution, pharmacist interventions to prevent error, drug-drug interactions and in-hospital death.

Results: The teaching service had net improvements in 3 outcomes. Relative to changes experienced by the nonteaching service, the rate of intensive care unit utilization decreased by 2.1% (95% CI, -3.3% to -0.7%; $P = 0.002$), the rate of discharge to home or rehabilitation facility versus elsewhere improved by 5.3% (CI, 2.6% to 7.6%; $P < 0.001$), and pharmacist interventions to prevent error were reduced by 1.92 interventions per 100 patient-days (CI, -2.74 to -1.03 interventions per 100 patient-days; $P < 0.001$). Teaching and nonteaching services had similar changes over time in length of stay, 30-day readmission rate, and adverse drug-drug interactions.

In-hospital death was uncommon in both groups, and change over time was similar in the 2 groups.

Limitations: The study was a retrospective, nonrandomized design that assessed a limited number of outcomes. Teaching and non-teaching cohorts may not have been affected similarly by secular trends in patient care.

Conclusions: After the implementation of work-hour regulations, 3 of 7 outcomes improved for patients in the teaching service relative to those in the nonteaching service. The authors found no evidence of adverse unintended consequences after the institution of workhour regulations. © 2007 American College of Physicians.

D. L. Howard, J. H. Silber and D. R. Jobes.

Do regulations limiting residents' work hours affect patient mortality?

[see comment][erratum appears in J Gen Intern Med. 2004 Feb;19(2):204 Note: Silber, Jeffrey H [corrected to Silber, Jeffrey H]].

J.Gen.Intern.Med.,2004,19,1-7

OBJECTIVE: To conduct a statewide analysis of the effect of New York's regulations, limiting internal medicine and family practice residents' work hours, on patient mortality.

DESIGN: Retrospective study of inpatient discharge files for 1988 (before the regulations) and 1991 (after the regulations).

SETTING AND PATIENTS: Adult patients discharged from New York teaching hospitals (170214) and nonteaching hospitals (143,455) with a principal diagnosis of congestive heart failure, acute myocardial infarction, or pneumonia, for the years 1988 and 1991 (periods before and after Code 405 regulations went into law). Patients from nonteaching hospitals served as controls.

MEASUREMENT: In-hospital mortality.

RESULTS: Combined unadjusted mortality for congestive heart failure, acute myocardial infarction, and pneumonia patients declined between 1988 and 1991 in both teaching (14.1% to 13.0%; $P = .0001$) and nonteaching hospitals (14.0% to 12.5%; $P = .0001$). Adjusted mortality also declined between 1988 and 1991 in both teaching (odds ratio [OR], death 1991/1988, 0.868; 95% confidence interval [CI], 0.843 to 0.894; $P = .0001$) and nonteaching hospitals (OR, death 1991/1988, 0.853; 95% CI, 0.826 to 0.881; $P = .0001$). This beneficial trend toward lower mortality over time was nearly identical between teaching and nonteaching hospitals ($P = .4348$).

CONCLUSION: New York's mandated limitations on residents' work hours do not appear to have positively or negatively affected in-hospital mortality from congestive heart failure, acute myocardial infarction, or pneumonia in teaching hospitals.

M. M. Hutter, K. C. Kellogg, C. M. Ferguson, W. M. Abbott and A. L. Warshaw.
The impact of the 80-hour resident workweek on surgical residents and attending surgeons.
Ann.Surg.,2006,243,864-871

OBJECTIVE: To assess the impact of the 80-hour resident workweek restrictions on surgical residents and attending surgeons.

SUMMARY BACKGROUND DATA: The ACGME mandated resident duty hour restrictions have required a major workforce restructuring. The impact of these changes needs to be critically evaluated for both the resident and attending surgeons, specifically with regards to the impact on motivation, job satisfaction, the quality of surgeon training, the quality of the surgeon's life, and the quality of patient care.

METHODS: Four prospective studies were performed at a single academic surgical program with data collected both before the necessary workforce restructuring and 1 year after, including: 1) time cards to assess changes in components of daily activity; 2) Web-based surveys using validated instruments to assess burnout and motivation to work; 3) structured, taped, one-on-one interviews with an external PhD investigator; and 4) statistical analyses of objective, quantitative data.

RESULTS: After the work-hour changes, surgical residents have decreased "burnout" scores, with significantly less "emotional exhaustion" (Maslach Burnout Inventory: 29.1 "high" vs. 23.1 "medium," $P = 0.02$). Residents have better quality of life both in and out of the hospital. They felt they got more sleep, have a lighter workload, and have increased motivation to work (Herzberg Motivation Dimensions). We found no measurable, statistically significant difference in the quality of patient care (NSQIP data). Resident training and education objectively were not statistically diminished (ACGME case logs, ABSITE scores). Attending surgeons perceived that their quality of their life inside and outside of the hospital was "somewhat worse" because of the work-hour changes, as they had anticipated. Many concerns were identified with regards to the professional development of future surgeons, including a change toward a shift-worker mentality that is not patient-focused, less continuity of care with a loss of critical information with each handoff, and a decrease in the patient/doctor relationship.

CONCLUSION: Although the mandated restriction of resident duty hours has had no measurable impact on the quality of patient care and has led to improvements for the current quality of life of residents, there are many concerns with regards to the training of professional, responsible surgeons for the future.

H. M. A. Kaafarani, K. M. F. Itani, L. A. Petersen, J. Thornby and D. H. Berger.
Does resident hours reduction have an impact on surgical outcomes?
J.Surg.Res.,2005,126,167-171

Background. We assessed the impact of restricting surgical resident work hours as required by the Accreditation Council for Graduate Medical Education (ACGME), on postoperative outcomes.
Materials and methods. The divisions of General and Vascular Surgery at the Michael E. DeBakey Houston Veteran Affairs Medical Center implemented a limited work hours schedule effective October 1, 2002. We compared the rate of postoperative morbidity and mortality before and after the new schedule. Clinical data were collected by the VA National Surgical Quality Improvement Program (NSQIP) for the periods of October 1, 2001 to September 30, 2002 (preintervention), and October 1, 2002 to September 30, 2003 (postintervention). We assessed risk-adjusted observed to expected (O/E) ratios of mortality and prespecified postoperative morbidity for each study period.
Results. In the preintervention period, there were 405 general surgery and 202 vascular surgery cases as compared to 382 and 208 cases, respectively in the postintervention period. There were no significant differences in mortality O/E ratios between the pre- and postintervention periods (0.63 versus 0.60 in general surgery; 0.78 versus 0.81 in vascular surgery; $P = 0.90$ and 0.94 , respectively) or in morbidity O/E ratios (1.06 versus 1.27 in general surgery; 1.47 versus 1.50 in vascular surgery; $P = 0.20$ and 0.90 , respectively).
Conclusion. The restricted resident work hour schedule in general and vascular surgery in our facility did not significantly affect postoperative outcomes. © 2005 Elsevier Inc. All rights reserved.

K. Kahol, M. J. Leyba, M. Deka, et al.
Effect of fatigue on psychomotor and cognitive skills
Am.J.Surg.,2008,195,195-204

Background: Previous studies have explored the effect of fatigue on general psychomotor proficiency. However, studies specifically addressing the effect of fatigue on surgical residents' cognitive skills during simulated surgical exercises are lacking.
Methods: Thirty-seven surgical residents in both the precall and the postcall condition were tested for psychomotor and cognitive skill evaluation on a virtual-reality simulator with haptic feedback and hand-motion recording. To evaluate surgical skills, hand- and tool-movement smoothness, cognitive errors, and time to completion for specific tasks were analyzed.
Results: In addition increased cognitive errors, a significant decrease ($P < .01$) was recorded in the proficiency variables of memory, attention, and intermodal coordination tasks when residents were in the postcall condition.
Conclusions: Fatigue and sleep deprivation cause a significant deterioration in the surgical residents' cognitive skills as measured by virtual reality simulation. Psychomotor skills are also negatively impacted during tasks that require a combination of psychomotor and cognitive skills. © 2008 Excerpta Medica Inc. All rights reserved.

C. Laine, L. Goldman, J. R. Soukup and J. G. Hayes.
The impact of a regulation restricting medical house staff working hours on the quality of patient care
J.Am.Med.Assoc.,1993,269,374-378

Objective. - To examine the impact on patient care of a New York State regulation that restricted house staff working hours.

Design. - Retrospective cohort study.

Setting. - General medical service of an urban teaching hospital.

Patients. - A total of 263 (94%) of 281 patients discharged from the study service during October 1988 and 263 (93%) of 283 patients discharged from the same service during October 1989.

Interventions. - On July 1, 1989, New York State enacted a new regulation, Code 405, which limited residents' working hours and specified levels of supervision and ancillary support.

Main Outcome Measures. - In-hospital mortality, transfers to intensive care units, cardiopulmonary resuscitation attempts, discharge disposition, length of stay, medical complications, and house staff delays in ordering tests and procedures.

Results. - Although the cohorts were comparable in severity of illness measures, more patients in 1989 suffered at least one medical complication (91 [35%] vs 59 [22%]; $P=.002$) and experienced at least one diagnostic test delay because of house staff (44 [17%] vs 4 [2%]; $P<.001$). These significant differences persisted after controlling for potential confounders in multivariate analyses. However, we found no significant differences in more serious outcomes: in-hospital mortality, transfer to intensive care unit, discharge disposition, or length of stay.

Conclusions. - These results suggest that restricted house staff working hours were associated with delayed test ordering by house staff and increased in-hospital complications. While these potentially deleterious effects on the quality of care did not result in statistically significant differences in more serious outcomes, further study at other hospitals is warranted to determine staffing strategies that optimize quality of care for patients, as well as medical education and quality of life for house officers.

C. P. Landrigan, A. M. Fahrenkopf, D. Lewin, et al.

Effects of the accreditation council for graduate medical education duty hour limits on sleep, work Hours, and safety

Pediatrics,2008,122,250-258

OBJECTIVE. To mitigate the risks of fatigue-related medical errors, the Accreditation Council for Graduate Medical Education introduced work hour limits for resident physicians in 2003. Our goal was to determine whether work hours, sleep, and safety changed after implementation of the Accreditation Council for Graduate Medical Education standards.

METHODS. We conducted a prospective cohort study in which residents from 3 large pediatric training programs provided daily reports of work hours and sleep. In addition, they completed reports of near-miss and actual motor vehicle crashes, occupational exposures, self-reported medical errors, and ratings of educational experience. They were screened for depression and burnout. Concurrently, at 2 of the centers, data on medication errors were collected prospectively by using an established active surveillance method.

RESULTS. A total of 220 residents provided 6007 daily reports of their work hours and sleep, and 16 158 medication orders were reviewed. Although scheduling changes were made in each program to accommodate the standards, 24-to 30-hour shifts remained common, and the frequency of residents' call remained largely unchanged. There was no change in residents' measured total work hours or sleep hours. There was no change in the overall rate of medication errors, and there was a borderline increase in the rate of resident physician ordering errors, from 1.06 to 1.38 errors per

100 patient-days. Rates of motor vehicle crashes, occupational exposures, depression, and self-reported medical errors and overall ratings of work and educational experiences did not change. The mean length of extended-duration (on-call) shifts decreased 2.7% to 28.5 hours, and rates of resident burnout decreased significantly (from 75.4% to 57.0%).

CONCLUSIONS: Total hours of work and sleep did not change after implementation of the duty hour standards. Although fewer residents were burned out, rates of medication errors, resident depression, and resident injuries and educational ratings did not improve. Copyright © 2008 by the American Academy of Pediatrics.

C. P. Landrigan, J. M. Rothschild, J. W. Cronin, et al.

Effect of reducing interns' work hours on serious medical errors in intensive care units

N.Engl.J.Med.,2004,351,1838-1848

BACKGROUND: Although sleep deprivation has been shown to impair neurobehavioral performance, few studies have measured its effects on medical errors.

METHODS: We conducted a prospective, randomized study comparing the rates of serious medical errors made by interns while they were working according to a traditional schedule with extended (24 hours or more) work shifts every other shift (an "every third night" call schedule) and while they were working according to an intervention schedule that eliminated extended work shifts and reduced the number of hours worked per week. Incidents were identified by means of a multidisciplinary, four-pronged approach that included direct, continuous observation. Two physicians who were unaware of the interns' schedule assignments independently rated each incident.

RESULTS: During a total of 2203 patient-days involving 634 admissions, interns made 35.9 percent more serious medical errors during the traditional schedule than during the intervention schedule (136.0 vs. 100.1 per 1000 patient-days, $P<0.001$), including 56.6 percent more nonintercepted serious errors ($P<0.001$). The total rate of serious errors on the critical care units was 22.0 percent higher during the traditional schedule than during the intervention schedule (193.2 vs. 158.4 per 1000 patient-days, $P<0.001$). Interns made 20.8 percent more serious medication errors during the traditional schedule than during the intervention schedule (99.7 vs. 82.5 per 1000 patient-days, $P=0.03$). Interns also made 5.6 times as many serious diagnostic errors during the traditional schedule as during the intervention schedule (18.6 vs. 3.3 per 1000 patient-days, $P<0.001$).

CONCLUSIONS: Interns made substantially more serious medical errors when they worked frequent shifts of 24 hours or more than when they worked shorter shifts. Eliminating extended work shifts and reducing the number of hours interns work per week can reduce serious medical errors in the intensive care unit.

D. R. Leff, R. Aggarwal, M. Rana, et al.

Laparoscopic skills suffer on the first shift of sequential night shifts: program directors beware and residents prepare.

Ann.Surg.,2008,247,530-539

OBJECTIVE: Research evaluating fatigue-induced skills decline has focused on acute sleep deprivation rather than the effects of circadian desynchronization associated with multiple shifts. As a result, the number of consecutive night shifts that residents can safely be on duty without

detrimental effects to their technical skills remains unknown. A prospective observational cohort study was conducted to assess the impact of 7 successive night shifts on the technical surgical performance of junior residents.

METHODS: The interventional strategy included training 21 residents from surgery and allied disciplines on a virtual reality surgical simulator, towards the achievement of preset benchmark scores, followed by 294 technical skills assessments conducted over 1764 manpower night shift hours. Primary outcomes comprised serial technical skills assessments on 2 tasks of a virtual reality surgical simulator. Secondary outcomes included assessments of introspective fatigue, duration of sleep, and prospective recordings of activity (number of "calls" received, steps walked, and patients evaluated).

RESULTS: Maximal deterioration in performance was observed following the first night shift. Residents took significantly longer to complete the first ($P = 0.002$) and second tasks ($P = 0.005$) compared with baseline. They also committed significantly greater numbers of errors ($P = 0.025$) on the first task assessed. Improved performance was observed across subsequent shifts towards baseline levels.

CONCLUSIONS: Newly acquired technical surgical skills deteriorate maximally after the first night shift, emphasizing the importance of adequate preparation for night rotas. Performance improvements across successive shifts may be due to ongoing learning or adaptation to chronic fatigue. Further research should focus on assessments of both technical procedural skills and cognitive abilities to determine the rotas that best minimize errors and maximize patient safety.

C. Leonard, N. Fanning, J. Attwood and M. Buckley.

The effect of fatigue, sleep deprivation and onerous working hours on the physical and mental wellbeing of pre-registration house officers

Ir.J.Med.Sci.,1998,167,22-25

The potential deleterious effects of doctors' long and arduous shifts have received relatively scant attention. This study addressed the effect of a 32 h on-call shift on 16 pre-registration medical house officers in St. James's Hospital, Dublin. We assessed 5 psychological parameters (Tension-Anxiety, Depression-Dejection, Vigour-Activity, Fatigue-Inertia and Confusion-Bewilderment) as well as 5 simple tests of alertness and concentration both pre- and post-call. The doctors were randomly assigned to be tested either pre- or post-call. On average the doctors got 4.5 hours sleep during a 32 h shift. This long shift had an adverse effect on all the psychological parameters ($p < 0.05$) except Depression-Dejection. The total mood disturbance score, which has been shown to correlate well with general psychological well-being, deteriorated significantly after the 32 h shift, $p < 0.005$. Two of the simple tests of alertness and concentration (Trail-making test and Stroop Color-Word test) also showed a significant fall-off in performance with sleep deprivation, $p < 0.05$, although the remaining tests (Delayed Story Recall, Critical Flicker Fusion and Three Minute Grammatical Reasoning Test) were not significantly impaired by the 32 h shift. This study shows that prolonged periods of duty without sleep adversely affect junior doctors, both in their psychological well-being and in their ability to carry out simple tasks.

Lingenfelter Th., R. Kaschel, A. Weber, H. Zaiser-Kaschel, B. Jakober and J. Kuper.

Young hospital doctors after night duty: Their task-specific cognitive status and emotional condition

Med.Educ.,1994,28,566-572

Sleep deprivation is an unpleasant burden of young hospital doctors during their medical training. It may disrupt the balance between coping strategies available to them and the professional demands encountered. Impaired medical care offered by sleep-deprived juniors may be a consequence. Valid research work on this subject is rare and surprisingly contradictory. Therefore, we evaluated the task-specific cognitive status and emotional condition of 40 young hospital doctors (27 men and 13 women, 29.9 ± 2.9 years of age) at the University of Tuebingen, all of whom were in the beginning of their academic career. Subjects were tested twice acting as their own control, once at 8.00 am after a night off duty (OD) (at least 6 hours of uninterrupted sleep), and once at a similar time after a night on call (OC) being in the hospital for 24 hours. Standardized and reliable psychometric tests thought to represent daily routine medical function were performed. On-call activities were recorded by means of a sleep diary, whereas a questionnaire interrogated aspects of private and professional life. Neuropsychological function deteriorated significantly: number connection test (per cent of norms \pm SD, 103.2 ± 9.8 OC vs 107.8 ± 10.5 OD, $F = 27.7$, $P < 0.001$), things-to-do list (correct items \pm SD, 6.7 ± 1.2 OC vs 7.4 ± 1.5 OD, $F = 12.7$, $P < 0.01$), Vienna reaction timer (per cent of norms \pm SD, 95.6 ± 9.0 OC vs 97.7 ± 10.4 OD, $F = 4.8$, $P < 0.05$), Stroop test (T-values \pm SD, 59.7 ± 6.3 OC vs 64.6 ± 7.1 OD, $F = 37.1$; $P < 0.001$), ECG test (correct responses \pm SD, 38.3 ± 7.3 OC vs 43.4 ± 6.5 OD, $F = 45.2$, $P < 0.001$) and status of mood (T-value \pm SD, 60.3 ± 9.0 OC vs 54.0 ± 6.6 OD, $F = 19.6$, $P < 0.001$). Cognitive function and mood status of young hospital doctors after a night on call decrease considerably. In view of the special vulnerability of medical trainees to occupational stress all efforts are warranted to reduce sleep deprivation in the medical profession.

S. W. Lockley, J. W. Cronin, E. E. Evans, et al.

Effect of reducing interns' weekly work hours on sleep and attentional failures

N.Engl.J.Med.,2004,351,1829-1837

BACKGROUND: Knowledge of the physiological effects of extended (24 hours or more) work shifts in postgraduate medical training is limited. We aimed to quantify work hours, sleep, and attentional failures among first-year residents (postgraduate year 1) during a traditional rotation schedule that included extended work shifts and during an intervention schedule that limited scheduled work hours to 16 or fewer consecutive hours.

METHODS: Twenty interns were studied during two three-week rotations in intensive care units, each during both the traditional and the intervention schedule. Subjects completed daily sleep logs that were validated with regular weekly episodes (72 to 96 hours) of continuous polysomnography ($r=0.94$) and work logs that were validated by means of direct observation by study staff ($r=0.98$).

RESULTS: Seventeen of 20 interns worked more than 80 hours per week during the traditional schedule (mean, 84.9; range, 74.2 to 92.1). All interns worked less than 80 hours per week during the intervention schedule (mean, 65.4; range, 57.6 to 76.3). On average, interns worked 19.5 hours per week less ($P<0.001$), slept 5.8 hours per week more ($P<0.001$), slept more in the 24 hours preceding each working hour ($P<0.001$), and had less than half the rate of attentional failures while working during on-call nights ($P=0.02$) on the intervention schedule as compared with the traditional schedule.

CONCLUSIONS: Eliminating interns' extended work shifts in an intensive care unit significantly increased sleep and decreased attentional failures during night work hours.

C. A. Morrison, M. M. Wyatt and M. M. Carrick.

Impact of the 80-hour work week on mortality and morbidity in trauma patients: an analysis of the National Trauma Data Bank

J.Surg.Res.,2009,154,157-162

INTRODUCTION: The implementation of the 80-h work week restrictions implemented by the Accreditation Council for Graduate Medical Education (ACGME) in July 2003 were intended, in part, to improve patient outcomes by reducing fatigue-related resident errors. Although concerns were raised regarding the possibility for increased error due to decreased continuity of patient care, recent studies have shown no significant change in mortality or complication rates since the onset of these new restrictions. This study is the first to examine the effects of the 80-h work week on mortality in trauma patients on a national level.

METHODS: Data were obtained from the National Trauma Data Bank (NTDB) version 6.2 from 1994 to 2005. Data were then divided into two groups: "pre-80-h work week" (2001-2002) and "post-80-h work week" (2004-2005). Because the ACGME's guidelines were implemented mid-year in 2003, and because the NTDB classifies admission date only by year, all patients admitted during 2003 were excluded from the analysis. Information regarding patient demographics and hospital type (teaching versus nonteaching) was collected. Our primary outcome measure was mortality. Secondary outcomes included length of mechanical ventilation, length of ICU stay, and length of hospitalization.

RESULTS: The overall mortality rate decreased from 4.64% in the pre-80-h work week to 4.46% in the post-80-h work week (P

M. B. Mycyk, M. R. McDaniel, M. A. Fotis and J. Regalado.

Hospitalwide adverse drug events before and after limiting weekly work hours of medical residents to 80

Am.J.Health-Syst.Pharm.,2005,62,1592-1595

Purpose. Adverse drug events (ADEs) at a hospital before and after the weekly work hours of medical residents were limited to 80 were studied.

Methods. The study population included all adults admitted to a 750-bed academic tertiary care hospital where resident physicians provide direct care under the supervision of faculty attending physicians. The six-month period after implementation of the 80-hour work limit (July 1 to December 31, 2003) was compared with the same six-month period one year before implementation (July 1 to December 31, 2002).

Results. There were no significant differences between study periods in any measured variables, including number of confirmed ADEs (194 before, 172 after), number of ADEs per 1000 patient days (1.3 before, 1.1 after), and number of preventable ADEs (21 before, 22 after).

Conclusion. Hospitalwide ADEs remained constant despite limiting of resident physician weekly work hours to 80. Copyright © 2005, American Society of Health-System Pharmacists, Inc. All rights reserved.

C. S. Nelson, K. Dell'Angela, W. S. Jellish, I. E. Brown and M. Skaredoff.

Residents' performance before and after night call as evaluated by an indicator of creative thought

J.Am.Osteopath.Assoc.,1995,95,600-603

The effects of sleep deprivation on medical personnel have received much attention. This study evaluates the effects of sleep loss on divergent-thinking (creative or innovative) processes as measured by the Torrance Test of Creative Thinking (TTCT). Anesthesia residents who had approximately 30 minutes sleep while being on-call were evaluated. These physicians had similar caffeine and nicotine consumption before and after the test. The results reported here demonstrate that postcall residents had TTCT scores that were appreciably below those scores of rested residents. Postcall verbal fluency was less among the on-call group than among the rested group (94.0 +/- 9.7 vs 101.8 +/- 9.8) as was figural originality (89.9 +/- 22.1 vs 113.3 +/- 20.3). These study results suggest that sleep deprivation affects divergent, or creative, thinking. Divergent-thinking processes are usually innovative and are used during complex problem-solving tasks. Further studies are needed on the effects of sleep deprivation. This information can then be used to help improve residents' working conditions and patient care.

L. A. Petersen, T. A. Brennan, A. C. O'Neil, E. F. Cook and T. H. Lee.

Does housestaff discontinuity of care increase the risk for preventable adverse events?

Ann.Intern.Med.,1994,121,866-872

Objective: To study the relation between housestaff coverage schedules and the occurrence of preventable adverse events.

Design: Case-control study. Setting: Urban teaching hospital. Patients: All 3146 patients admitted to the medical service during a 4-month period.

Measurements: A previously tested confidential self-report system to identify adverse events, which were defined as unexpected complications of medical therapy that resulted in increased length of stay or disability at discharge. A panel of three board-certified internists confirmed events and evaluated preventability based on case summaries. Housestaff coverage was coded according to the day in the usual intern's schedule and to cross-coverage status. Cross-coverage was defined as care by a house officer who was not the patient's usual intern and not a member of the usual intern's patient care team. Coverage for an adverse event was assigned according to who was covering during the proximate cause of that event. Clinical data were collected for each patient and two matched controls.

Results: Of the 124 adverse events reported and confirmed, 54 (44%) were judged potentially preventable. In the univariate analysis, patients with potentially preventable adverse events were more likely than their controls to be covered by a physician from another team at the time of the event (26% compared with 12% [odds ratio, 3.5; P=0.01]). In the multivariate analysis, three factors were significant independent correlates of potentially preventable adverse events: cross-coverage (odds ratio, 6.1; 95% CI, 1.4 to 26.7), Acute Physiology and Chronic Health Evaluation II score (odds ratio per point, 1.2; CI, 1.1 to 1.4), and history of gastrointestinal bleeding (odds ratio, 4.7; CI, 1.2 to 19.0).

Conclusion: Potentially preventable adverse events were strongly associated with coverage by a physician from another team, which may reflect management by housestaff unfamiliar with the patient. The results emphasize the need for careful attention to the outcome of work-hour reforms for housestaff.

B. K. Poulouse, W. A. Ray, P. G. Arbogast, et al.

Resident work hour limits and patient safety

Ann.Surg.,2005,241,847-860

Objective: This study evaluates the effect of resident physician work hour limits on surgical patient safety.

Background: Resident work hour limits have been enforced in New York State since 1998 and nationwide from 2003. A primary assumption of these limits is that these changes will improve patient safety. We examined effects of this policy in New York on standardized surgical Patient Safety Indicators (PSIs).

Methods: An interrupted time series analysis was performed using 1995 to 2001 Nationwide Inpatient Sample data. The intervention studied was resident work hour limit enforcement in New York teaching hospitals. PSIs included rates of accidental puncture or laceration (APL), postoperative pulmonary embolus or deep venous thrombosis (PEDVT), foreign body left during procedure (FB), iatrogenic pneumothorax (PTX), and postoperative wound dehiscence (WD). PSI trends were compared pre- versus postintervention in New York teaching hospitals and in 2 control groups: New York nonteaching hospitals and California teaching hospitals.

Results: A mean of 2.6 million New York discharges per year were analyzed with cumulative events of 33,756 (APL), 36,970 (PEDVT), 1,447 (FB), 10,727 (PTX), and 2,520 (WD). Increased rates over time (expressed per 1000 discharges each quarter) were observed in both APL (0.15, 95% confidence interval, 0.09-0.20, $P < 0.05$) and PEDVT (0.43, 95% confidence interval, 0.03-0.83, $P < 0.05$) after policy enforcement in New York teaching hospitals. No changes were observed in either control group for these events or New York teaching hospital rates of FB, PTX, or WD.

Conclusions: Resident work hour limits in New York teaching hospitals were not associated with improvements in surgical patient safety measures, with worsening trends observed in APL and PEDVT corresponding with enforcement. Copyright © 2005 by Lippincott Williams & Wilkins.

E. C. Poulton, G. M. Hunt, A. Carpenter and R. S. Edwards.

The performance of junior hospital doctors following reduced sleep and long hours of work
Ergonomics, 1978, 21, 279-295

Thirty junior hospital doctors were studied for one month each during 1974. A 3 min version of the Baddeley test of grammatical reasoning was given eight times during the month. It was regarded as a routine; no special emphasis was placed upon performing well. A sleep debt of 3 h or greater reliably reduced the efficiency of the first group of doctors on this test. The fall in efficiency was still reliable when corrected for the times of day of the tests. Working 18 h or longer during the last 24 h also reduced efficiency, but this could have been due to the associated loss of sleep which the long hours of work entailed. The second group of doctors always performed a 3 min laboratory forms test after each test of grammatical reasoning. Before the laboratory forms test their errors on the previous test were checked with them, and they had the sheets showing the normal ranges. On this more challenging test a sleep debt of 3 h or greater the previous night made the doctors reliably more variable in their rate of work. However a reliable deterioration in efficiency occurred only with the largest cumulative sleep debt of 8 h. The increase in variability without a change in efficiency suggests that although the doctors were tired, they were able to compensate for it during the 3 min test. The successful compensation carried over to the test of grammatical reasoning, although it was always performed first. Thirty junior hospital doctors were studied for one month each during 1974. A 3 min version of the Baddeley test of grammatical reasoning was given eight times during the month. It was regarded as a routine; no special emphasis was placed upon

performing well. A sleep debt of 3 h or greater reliably reduced the efficiency of the first group of doctors on this test. The fall in efficiency was still reliable when corrected for the times of day of the tests. Working 18 h or longer during the last 24 h also reduced efficiency, but this could have been due to the associated loss of sleep which the long hours of work entailed. The second group of doctors always performed a 3 min laboratory forms test after each test of grammatical reasoning. Before the laboratory forms test their errors on the previous test were checked with them, and they had the sheets showing the normal ranges. On this more challenging test a sleep debt of 3 h or greater the previous night made the doctors reliably more variable in their rate of work. However a reliable deterioration in efficiency occurred only with the largest cumulative sleep debt of 8 h.

A. R. Privette, S. R. Shackford, T. Osler, J. Ratliff, K. Sartorelli and J. C. Hebert.

Implementation of resident work hour restrictions is associated with a reduction in mortality and provider-related complications on the surgical service: a concurrent analysis of 14,610 patients
Ann.Surg.,2009,250,316-321

OBJECTIVE: To determine the effect of implementation of work hour restrictions on the rates of morbidity, mortality, and provider-related complications in surgical patients and to determine the incremental personnel costs associated with implementation.

SUMMARY BACKGROUND DATA: In 2003, the Accreditation Council for Graduate Medical Education enacted resident work hour restrictions (RWHR) to improve patient safety by decreasing errors attributed to resident fatigue. There are no quantitative data on surgical patients to validate whether this objective has been achieved and, if so, at what cost.

METHODS: Retrospective observational cohort analysis of data gathered concurrently with patient care for 30 days after admission or surgical intervention before implementation (prerestriction: July 2001-June 2003) and after (postrestriction: July 2005-June 2007). Main outcome measures: mortality, surgical complications, percentage of complications judged to be provider-related, and incremental personnel costs (salary and fringe of providers).

RESULTS: A total of 14,610 patients were admitted during the 2 periods. Compared with the prerestriction period, there was a significant reduction in the percentage of complications attributed to providers (pre: 48.3%; post: 38.6%, $P < 0.001$) and a significant reduction in mortality rate (pre: 1.9%; post: 1.1%, $P = 0.002$) in the postrestriction period. Postrestriction the clinical care hours provided by attending surgeons increased significantly and was associated with a 1250% increase in the RVU-82 billing modifier ("no qualified resident available") from 523 RVUs pre-RWHR to 6542 post-RWHR. There was an increase in annual personnel costs postrestriction of \$1.466 million.

CONCLUSIONS: Implementation of RWHR was associated with reduced provider-related complications and mortality suggesting improved patient safety. This was likely due to several factors including reduced resident fatigue and greater attending involvement in clinical care.

J. Robbins and F. Gottlieb.

Sleep deprivation and cognitive testing in internal medicine house staff
West.J.Med.,1990,152,82-86

There is increased concern about the effects of sleep deprivation on physician performance. We administered four standard tests of cognitive function to 23 university hospital house staff. Each physician served as his or her own control, and the tests were administered at rest, after a night on

call, and after a night of sleep for recovery. The study was designed so that normal learning would minimize any deterioration in the post-on-call test performance. Statistically significant deterioration occurred in 3 of the 4 tests after a night on call. Even physicians acclimated to sleep deprivation on a regular, every-third-or-fourth-night basis showed functional impairment. The results have implications for patient care under conditions where house staff are stressed by sleep deprivation and prolonged fatigue.

A. K. Rosen, S. A. Loveland, P. S. Romano, et al.

Effects of resident duty hour reform on surgical and procedural patient safety indicators among hospitalized Veterans Health Administration and Medicare patients
Med.Care,2009,47,723-731

OBJECTIVE: Improving patient safety was a strong motivation behind duty hour regulations implemented by Accreditation Council for Graduate Medical Education on July 1, 2003. We investigated whether rates of patient safety indicators (PSIs) changed after these reforms.

RESEARCH DESIGN: Observational study of patients admitted to Veterans Health Administration (VA) (N = 826,047) and Medicare (N = 13,367,273) acute-care hospitals from July 1, 2000 to June 30, 2005. We examined changes in patient safety events in more versus less teaching-intensive hospitals before (2000-2003) and after (2003-2005) duty hour reform, using conditional logistic regression, adjusting for patient age, gender, comorbidities, secular trends, baseline severity, and hospital site.

MEASURES: Ten PSIs were aggregated into 3 composite measures based on factor analyses: "Continuity of Care," "Technical Care," and "Other" composites.

RESULTS: Continuity of Care composite rates showed no significant changes postreform in hospitals of different teaching intensity in either VA or Medicare. In the VA, there were no significant changes postreform for the technical care composite. In Medicare, the odds of a Technical Care PSI event in more versus less teaching-intensive hospitals in postreform year 1 were 1.12 (95% CI; 1.01-1.25); there were no significant relative changes in postreform year 2.

Other composite rates increased in VA in postreform year 2 in more versus less teaching-intensive hospitals (odds ratio, 1.63; 95% CI; 1.10-2.41), but not in Medicare in either postreform year.

CONCLUSIONS: Duty hour reform had no systematic impact on PSI rates. In the few cases where there were statistically significant increases in the relative odds of developing a PSI, the magnitude of the absolute increases were too small to be clinically meaningful.

A. Salim, P. G. R. Teixeira, L. Chan, et al.

Impact of the 80-hour workweek on patient care at a level I trauma center
Arch.Surg.,2007,142,708-712

Hypothesis: The 80-hour workweek limitation for surgical residents is associated with an increase in mortality and complication rates among adult trauma surgical patients.

Design: Retrospective cohort study. **Setting:** Academic level I trauma center. **Patients:** Trauma patients admitted before and after the 80-hour workweek limitation.

Methods: We compared death and complication rates for adult trauma patients admitted during a 24-month period before (2001-2003) and a 24-month period after (2004-2006) implementation of the 80-hour workweek at our institution. Relative risk and its 95% confidence intervals were examined.

Main Outcome Measures: Patient care outcomes included preventable and nonpreventable complications and deaths.

Results: The patient populations from the 2 time periods were clinically similar. No significant differences were found in the total and the preventable death rates. The time period after the 80-hour workweek mandate had a significantly higher total complication rate (5.64% vs 7.28%; relative risk, 1.29; 95% confidence interval, 1.15-1.45; $P < .001$), preventable complication rate (0.89% vs 1.28%; relative risk, 1.43; 95% confidence interval, 1.06-1.91; $P = .02$), and nonpreventable complication rate (4.75% vs 5.81%; relative risk, 1.22; 95% confidence interval, 1.08-1.39; $P = .002$).

Conclusion: Although there was no difference in deaths between the 2 time periods, there was a significant increase in total, preventable, and nonpreventable complications. This increase in complication rate may be due, in part, to the new 80-hour workweek policy. ©2007 American Medical Association. All rights reserved.

P. Schenarts, J. Bowen, M. Bard, et al.

The effect of a rotating night-float coverage scheme on preventable and potentially preventable morbidity at a level 1 trauma center.

Am.J.Surg.,2005,190,147-152

BACKGROUND: The effect of resident work-hour restriction on patient outcome remains controversial.

METHODS: Demographic data, mechanism of injury, length of hospital stay length of intensive care unit (ICU) stay, ventilator days, mortality, and complication data were prospectively collected for 11 months before and 11 months after institution of a rotating night-float system. Seven attending surgeons reviewed all complications and categorized each as preventable, potentially preventable, or nonpreventable.

RESULTS: Both study periods were comparable with respect to demographic data, mean Injury Severity Score, mechanism of injury, and admissions. Limitation of resident work hours had no effect on length of hospital or ICU stay, ventilator days, or mortality. Work-hour restrictions did not increase or decrease the total number of complications nor did it alter the distribution of those determined to be preventable or potentially preventable.

CONCLUSIONS: Resident work-hour restrictions were not associated with significant improvement or deterioration in patient outcome.

K. D. Shetty and J. Bhattacharya.

Changes in hospital mortality associated with residency work-hour regulations

Ann.Intern.Med.,2007,147,73-80

BACKGROUND: In 2002, the Accreditation Council on Graduate Medical Education enacted regulations, effective 1 July 2003, that limited work hours for all residency programs in the United States.

OBJECTIVE: To determine whether work-hour regulations were associated with changes in mortality in hospitalized patients.

DESIGN: Comparison of mortality rates in high-risk teaching service patients hospitalized before and after July 2003, with nonteaching service patients used as a control group. **SETTING:** 551 U.S.

community hospitals included in the Healthcare Cost and Utilization Project's Nationwide Inpatient Survey between January 2001 and December 2004.

PATIENTS: 1,511,945 adult patients admitted for 20 medical and 15 surgical diagnoses.

Measurement: Inpatient mortality.

RESULTS: In 1,268,738 medical patients examined, the regulations were associated with a 0.25% reduction in the absolute mortality rate ($P = 0.043$) and a 3.75% reduction in the relative risk for death. In subgroup analyses, particularly large improvements in mortality were observed among patients admitted for infectious diseases (change, -0.66% ; $P = 0.007$) and in medical patients older than 80 years of age (change, -0.71% ; $P = 0.005$). By contrast, in 243,207 surgical patients, regulations were not associated with statistically significant changes (change, 0.13% ; $P = 0.54$).

LIMITATIONS: Teaching status was assigned according to hospital characteristics because direct information on each patient's provider was not available. Results reflect changes associated with the sum of regulations, not specifically with caps on work hours.

CONCLUSIONS: The work-hour regulations were associated with decreased short-term mortality among high-risk medical patients in teaching hospitals but were not associated with statistically significant changes among surgical patients in teaching hospitals.

K. G. Volpp, A. K. Rosen, P. R. Rosenbaum, et al.

Mortality among patients in VA hospitals in the first 2 years following ACGME resident duty hour reform

JAMA,2007,298,984-992

CONTEXT: Limitations in duty hours for physicians-in-training in the United States were established by the Accreditation Council for Graduate Medical Education (ACGME) and implemented on July 1, 2003. The association of these changes with mortality among hospitalized patients has not been well established.

OBJECTIVE: To determine whether the change in duty hour regulations was associated with relative changes in mortality in hospitals of different teaching intensity within the US Veterans Affairs (VA) system.

DESIGN, SETTING, AND PATIENTS: An observational study of all unique patients ($N = 318$ 636) admitted to acute-care VA hospitals ($N = 131$) using interrupted time series analysis with data from July 1, 2000, to June 30, 2005. All patients had principal diagnoses of acute myocardial infarction (AMI), congestive heart failure, gastrointestinal bleeding, or stroke or a diagnosis related group classification of general, orthopedic, or vascular surgery. Logistic regression was used to examine the change in mortality for patients in more vs less teaching-intensive hospitals before (academic years 2000-2003) and after (academic years 2003-2005) duty hour reform, adjusting for patient comorbidities, common time trends, and hospital site.

MAIN OUTCOME MEASURE: All-location mortality within 30 days of hospital admission.

RESULTS: In postreform year 1, no significant relative changes in mortality were observed for either medical or surgical patients. In postreform year 2, the odds of mortality decreased significantly in more teaching-intensive hospitals for medical patients only. Comparing a hospital having a resident-to-bed ratio of 1 with a hospital having a resident-to-bed ratio of 0, the odds of mortality were reduced for patients with AMI (odds ratio [OR], 0.48; 95% confidence interval [CI], 0.33-0.71), for the 4 medical conditions together (OR, 0.74; 95% CI, 0.61-0.89), and for the 3 medical conditions excluding AMI (OR, 0.79; 95% CI, 0.63-0.98). Compared with hospitals in the 25th percentile of teaching intensity, there was an absolute improvement in mortality from

prereform year 1 to postreform year 2 of 0.70 percentage points (11.1% relative decrease) and 0.88 percentage points (13.9% relative decrease) in hospitals in the 75th and 90th percentile of teaching intensity, respectively, for the combined medical conditions.

CONCLUSIONS: The ACGME duty hour reform was associated with significant relative improvement in mortality for patients with 4 common medical conditions in more teaching-intensive VA hospitals in postreform year 2. No associations were identified for surgical patients.

K. G. Volpp, A. K. Rosen, P. R. Rosenbaum, et al.

Mortality among hospitalized medicare beneficiaries in the first 2 years following ACGME resident duty hour reform

J.Am.Med.Assoc.,2007,298,975-983

Context: The Accreditation Council for Graduate Medical Education (ACGME) implemented duty hour regulations for physicians-in-training throughout the United States on July 1, 2003. The association of duty hour reform with mortality among patients in teaching hospitals nationally has not been well established.

Objective: To determine whether the change in duty hour regulations was associated with relative changes in mortality among Medicare patients in hospitals of different teaching intensity.

Design, Setting, and Patients: An observational study of all unique Medicare patients (N=8 529 595) admitted to short-term, acute-care, general US nonfederal hospitals (N=3321) using interrupted time series analysis with data from July 1, 2000, to June 30, 2005. All Medicare patients had principal diagnoses of acute myocardial infarction, congestive heart failure, gastrointestinal bleeding, or stroke or a diagnosis related group classification of general, orthopedic, or vascular surgery. Logistic regression was used to examine the change in mortality for patients in more vs less teaching-intensive hospitals before (academic years 2000-2003) and after (academic years 2003-2005) duty hour reform, adjusting for patient comorbidities, common time trends, and hospital site.

Main Outcome Measure: All-location mortality within 30 days of hospital admission.

Results: In medical and surgical patients, no significant relative increases or decreases in the odds of mortality for more vs less teaching-intensive hospitals were observed in either postreform year 1 (combined medical conditions group: odds ratio [OR], 1.03; 95% confidence interval [CI], 0.98-1.07; and combined surgical categories group: OR, 1.05; 95% CI, 0.98-1.12) or postreform year 2 (combined medical conditions group: OR, 1.03; 95% CI, 0.99-1.08; and combined surgical categories group: OR, 1.01; 95% CI, 0.95-1.08) compared with the prereform years. The only condition for which there was a relative increase in mortality in more teaching-intensive hospitals postreform was stroke, but this association preceded the onset of duty hour reform. Compared with nonteaching hospitals, the most teaching-intensive hospitals had an absolute change in mortality from prereform year 1 to postreform year 2 of 0.42 percentage points (4.4% relative increase) for patients in the combined medical conditions group and 0.05 percentage points (2.3% relative increase) for patients in the combined surgical categories group, neither of which were statistically significant.

Conclusion: The ACGME duty hour reform was not associated with either significant worsening or improvement in mortality for Medicare patients in the first 2 years after implementation. ©2007 American Medical Association. All rights reserved.

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Did Duty Hour Reform Lead to Better Outcomes Among the Highest Risk Patients?

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BACKGROUND: Earlier work demonstrated that ACGME duty hour reform did not adversely affect mortality, with slight improvement noted among specific subgroups.

OBJECTIVE: To determine whether resident duty hour reform differentially affected the mortality risk of high severity patients or patients who experienced post-operative complications (failure-to-rescue).

DESIGN: Observational study using interrupted time series analysis with data from July 1, 2000 - June 30, 2005. Fixed effects logistic regression was used to examine the change in the odds of mortality or failure-to-rescue (FTR) in more versus less teaching-intensive hospitals before and after duty hour reform.

PARTICIPANTS: All unique Medicare patients (n = 8,529,595) admitted to short-term acute care non-federal hospitals and all unique VA patients (n = 318,636 patients) with principal diagnoses of acute myocardial infarction, congestive heart failure, gastrointestinal bleeding, stroke or a DRG classification of general, orthopedic or vascular surgery.

MEASUREMENTS AND MAIN RESULTS: We measured mortality within 30 days of hospital admission and FTR, measured by death among patients who experienced a surgical complication. The odds of mortality and FTR generally changed at similar rates for higher and lower risk patients in more vs. less teaching intensive hospitals. For example, comparing the mortality risk for the 10% of Medicare patients with highest risk to the other 90% of patients in post-reform year 1 for combined medical an OR of 1.01 [95% CI 0.90, 1.13], for combined surgical an OR of 0.91 [95% CI 0.80, 1.04], and for FTR an OR of 0.94 [95% CI 0.80, 1.09]. Findings were similar in year 2 for both Medicare and VA. The two exceptions were a relative increase in mortality for the highest risk medical (OR 1.63 [95% CI 1.08, 2.46]) and a relative decrease in the high risk surgical patients within VA in post-reform year 1 (OR 0.52 [95% CI 0.29, 0.96]).

CONCLUSIONS: ACGME duty hour reform was not associated with any consistent improvements or worsening in mortality or failure-to-rescue rates for high risk medical or surgical patients.

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Decreased bile duct injury rate during laparoscopic cholecystectomy in the era of the 80-hour resident workweek

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Background: Considerable concern has been raised about the effects of restricted duty hours on surgical training. However, to our knowledge, the effect of the 80-hour resident workweek on operative outcomes after laparoscopic cholecystectomy has not been well studied.

Objective: To compare the rates of bile duct injury and overall complications after laparoscopic cholecystectomy before and after the institution of the duty-hour restriction.

Design: Retrospective review of patient medical records to determine morbidity and mortality before (January 1, 2000, to June 30, 2003; period 1) and after (July 1, 2003, to June 30, 2006; period 2) implementation of duty hour limitations.

Setting: Major public teaching hospital. **Patients:** A total of 2470 patients who had undergone laparoscopic cholecystectomy.

Main Outcome Measures: Bile duct injury and overall complication rates as determined using multivariate analysis.

Results: Overall, 2470 laparoscopic cholecystectomy procedures were performed, including 353 in period 1 and 1117 in period 2. In period 2, more patients had acute cholecystitis as the indication for surgery (49% vs 35% in period 1, $P < .001$), and a higher percentage of patients were male (22% vs 18%, $P = .01$). The incidence of bile duct injury and total complications decreased in period 2 from 1% to 0.4% ($P = .04$) and from 5% to 2% ($P < .001$), respectively. Mortality was unchanged. Multivariate analysis revealed that period 2 was protective for bile duct injury (odds ratio, 0.31; 95% confidence interval, 0.1-0.96; $P = .04$). For complications, both female sex (odds ratio, 0.62; 95% confidence interval, 0.38-0.9) and surgery during period 2 (odds ratio, 0.46; 95% confidence interval, 0.28-0.75) were protective, whereas older age (odds ratio, 1.03; 95% confidence interval, 1.02-1.05) was associated with complications.

Conclusion: At a major public teaching hospital, the bile duct injury rate and the overall complication rate decreased after implementation of the 80-hour workweek. ©2008 American Medical Association. All rights reserved.