

APPENDIX C **SYSTEMATIC REVIEW OF THE LITERATURE** **ON THE IMPACT OF VARIATION IN RESIDENTS' DUTY** **HR SCHEDULES ON PATIENT SAFETY**

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Executive Summary

The review was conducted by a multidisciplinary group of 7 physicians (internal medicine, pediatrics, and surgery) and 3 nonphysicians. No member of the review group was affiliated with the Accreditation Council for Graduate Medical Education. The review focuses on duty hours and patient safety.

Important Concepts Identified in Previous Reviews

Veasey et al (2002) Literature Review

- Ascertain the impact of both acute and chronic sleep deprivation in any scheduling intervention or experiment.
- Evaluate interventions for control of additional factors, including circadian nadir, stimulant intake, and ambient conditions in testing environment.
- Napping and occasional low-dose caffeine may provide safe countermeasures for prolonged shifts.

Fletcher et al (2005) Systematic Review

- Noted variability in interventions, even within the same category (ie, differing models of “night float” rotations between programs).

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- Most studies analyzed did not adjust for differences outside of duty hour interventions, raising concern for unmeasured confounding.
- Different staffing models had different effects on patient continuity.

Philibert (2005) Meta-analysis of Sleep Loss and Performance

- Reduction in cognitive performance of approximately 1 standard deviation in subjects with sleep loss.
- The effect of sleep loss appeared to be greater in nonphysicians.
- Model proposed suggested that detrimental effects of fatigue are larger for vigilance and clinical performance than memory and cognitive function.
- Incremental effect showed sleep loss greater than 54 hours as having a larger effect than sleep loss of 30 hours.

Research Question

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

Methods

The group developed the protocol in June 2009, using their prior experience with this format for conducting systematic reviews. The review included a search of OvidSP MEDLINE, PubMed, Scopus, CINAHL, ERIC, PsycINFO, Campbell Collaboration Library, and Cochrane Database of

Systematic Reviews. One of the authors (M.G.) screened the title and abstract of citations identified in searches and classified these for further action. A total of 110 articles passed primary screening and secondary screening by a second member of the group.

Data Extraction

Data extraction used a 3-page structured coding form. Two members of the Review Group independently read each article and completed a coding form

Studies Included in the Analysis

A total of 48 studies were included in the final analysis. The remainder was excluded for a host of reasons, including the following:

- Twenty-four studies were excluded for small samples with no supporting analysis of statistical power, limited measurement of clinical outcomes or residents' performance, and data collection over a brief period.
- Twenty articles were excluded because they did not directly study duty hours and a variable related to patient safety.
- Five articles were excluded owing to the presence of confounding variables.
- Thirteen articles were excluded for miscellaneous reasons.

Study Design: Dependent Variables

The most important feature differentiating these studies was how the dependent variable was defined and selected. This process identified the following:

- Thirty-two studies that used clinical measures of patient care quality such as patient outcomes and clinical process indicators (*clinical studies*).
- Sixteen studies that examined residents' performance in laboratory settings as a proxy for safety measures using simulators or tests of cognitive and fine motor skills (*laboratory studies*).
- These 2 study types generally involved different units of analysis, with resulting

implications for sample size, study design, and findings.

- A consensus was reached that it would be valuable to differentiate the findings of the clinical and laboratory studies.

Thirty-two Clinical Studies Using Direct Measures of Patient Safety

Dependent/Outcome Variables

- Thirteen studies examined mortality and/or major indicators of morbidity.
- Seven studies analyzed mortality and morbidity and also other indicators, such as readmission, length of stay, or number of tests ordered.

Independent Variables

- Studies assessed the conditions before and after a major system change, such as implementation of 2003 ACGME duty hour regulations.
- Others analyzed scheduling option or set of options designed to reduce sleep deprivation, as compared to some conventional schedule.

Study Design

- More than 50% of the studies were time-series analyses in which the authors examined measures of patient safety at different time periods.
- Another group consisted of cohort studies in which the authors tracked details of hospitalization for samples of patients as they related to the duty hour schedule in effect for these patients' physicians.

Timing, Setting, and Duration

- The largest number of studies (21) involved data collected before and after the implementation of the 2003 ACGME duty hour regulations.
- Seven studies collected data on the effect of implementation of duty hour limits in New York State.

- Nearly all had been published since 2004.

Sampling

- Seventeen of the clinical studies reported data from a single residency program.
- Nine were large studies based on data for national samples of patients and involving residents in 1 or more specialty, and lasting 1 year or more.
- Most studies involved sample sizes of 30 to 100.

Sixteen Laboratory Studies of Proxy Measures of Resident Performance

Dependent/Outcome Variables

- More than three-fourths of these studies analyzed measures of cognitive and fine motor skills.
- Only 3 studies involved resident performance in clinical simulations. The 3 studies with clinical simulations used 1 device, the minimally invasive surgery trainer (MIST-VR).

Independent Variables

- Sleep status defined either by self-report or before and after a scheduled overnight call.

Study Design

- Three-fourths were cross-over studies in which authors measured residents rotating under different schedules.

Timing, Setting, and Duration

- More than three-fourths involved data collected before the 2003 ACGME duty hour restrictions.
- The median year of publication (2002) was earlier ($P < .01$) than that for the clinical studies (2006).
- Nearly all studies were based on data from a single residency program.

- Most of these studies lasted less than 1 year.

Sampling

- Fourteen of 16 studies reported data from a single residency program.
- The median number of residents studied was 30.

Effect of Duty Hour Schedules on Patient Safety

- Most of the 48 studies reported either a positive effect (27) or no clear effect (17) of duty hour limits on patient safety.
- Only 4 studies reported negative effects.
- Of the clinical studies, approximately one-third reported positive effects.
- Positive effects were more likely found in smaller studies in narrow, tightly controlled settings, or limited measurements of patient safety. The median number of subjects in studies demonstrating positive effects was 11 402.
- Sixteen studies reported no effect or mixed effects of duty hour limits on patient care. The median number of subjects in these studies was more than 4 million patients.
- Four clinical studies concluded that limits on duty hours have had a negative impact on patient safety.
- There were no reports of negative effects among laboratory studies, and nearly all of the laboratory studies (94%) reported positive effects of duty hour limits on patient safety.

Comments

- There is little evidence in the literature indicating that duty hour restrictions have compromised patient safety.
- There is a significant contribution to the overall pattern of positive results by the laboratory studies.
- If the laboratory studies are removed from the review, the trend is changed from one of

significantly positive results to one where mixed or neutral results predominate.

- There are 2 potentially offsetting weaknesses of the laboratory designs:
 - The question surrounding the acceptability of the proxies that authors have substituted for patient care outcomes;
 - 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 design of most of the laboratory investigations presented little support for using a blinded approach with the subjects.
- A concern raised by this review group regards the external validity of studies using cognitive and fine motor skill tests and medical simulators.
 - There are many “layers” between tasks being assayed 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.
- While the strength of the clinical studies rested on the fact that they measured actual metrics of patient safety, their perspective tended to be from a “higher altitude,” where many confounders common in such investigations were typically in play.
- The review group proposed potential explanations for the difference between smaller positive trials and large trials with neutral or ambiguous results. These included the fact that competing influences address the consequences of reductions in the duty hours of a particular resident, such as:
 - Decrease in continuity of care (or increase in patient “handoffs”);
 - Increase in work intensity of residents remaining on duty.
- Studies that are sufficiently large to provide statistical power to make conclusions

about meaningful patient care events cannot prove individual compliance with the duty hour reduction under study or the actual amount of sleep obtained by the residents in the study.

- Layered supervision and increasing use of “care teams” may have adapted to and become more protective of fatigue-induced errors, as this issue has gained national prominence.
- It is difficult to isolate the individual components of the duty hour limits, and most large studies analyzed the sum of changes implemented under the standards or state regulations.
- The highest proportion of studies, where an individual component was able to be isolated, researched modifications of overnight call shift duration.

The review identified several important gaps.

- There were no studies of napping as a fatigue-mitigating process for prolonged duty periods.
- There was a lack of depth of studies involving long duty periods and probable fatigue in some specialties (obstetrics and gynecology, pediatrics).
- Few studies compared differential methods of complying with duty hour requirements.
- The timing of this review in relation to the ACGME 2003 regulations does not permit analysis of any long-term data.

Studies Included in the Review

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