Making Healthcare Safer IV

# Fatigue and Sleepiness of Clinicians Due to Hours of Service

*Rapid Response*

## Main Points

- Interventions to reduce clinician fatigue and sleepiness due to long work hours have had mixed effects on the incidence of medical errors, patient mortality, and patient morbidity.
- Recent research has focused primarily on resident physicians, and to a lesser extent, nurses and practicing physicians.
- Interventions have focused primarily on work schedules, including limiting the number of hours worked in a shift or total over a week and ensuring adequate time for recovery between shifts.
- Few studies have addressed fatigue risk management interventions beyond scheduling, but interventions have included lighting, breaks, and scheduled napping.
- Barriers have included concerns about continuity of care and increased faculty clinical responsibilities arising from changes in resident duty hour limitations.
- Facilitators have included handoff training and hiring mid-level providers.
- No toolkits were identified to support implementation of interventions for reducing clinician fatigue and sleepiness due to long duty hours.

Agency for Healthcare Research and Quality
PATIENT SAFETY

# 1. Background and Purpose

The Agency for Healthcare Research and Quality (AHRQ) Making Healthcare Safer (MHS) reports consolidate information for healthcare clinicians, health system administrators, researchers, and government agencies about patient safety practices (PSPs) that can improve patient safety across the healthcare system—from hospitals to primary care practices, long-term care facilities, and other healthcare settings. In Spring of 2023, AHRQ launched its fourth iteration of the MHS reports (MHS IV).

Fatigue and sleepiness of clinicians due to hours of service is a patient safety risk and associated PSPs were identified as high priority for inclusion in the MHS IV reports using a modified Delphi technique by a Technical Expert Panel (TEP) that met in December 2022. The TEP included 15 experts in patient safety with representatives of governmental agencies, healthcare stakeholders, clinical specialists, experts in patient safety issues, and a patient/consumer perspective. See the MHS IV Prioritization Report for additional details.[1]

Insufficient or disrupted sleep leads to a state of fatigue characterized by deficits in attention, memory, and cognitive speed.[2] This neurobehaviorally degraded state translates into poorer performance by clinicians[3] and ultimately can contribute to medical errors.[4] Thirty-six percent of healthcare practitioners and technicians and 45 percent of personnel in healthcare support occupations report chronic short sleep durations.[5] This is driven by long working hours, particularly for clinical trainees, and shift work schedules necessary to staff hospitals around the clock.

## 1.1 Overview of the Patient Safety Practice

Fatigue is a safety risk in the workplace across industries,[6] and consequently general principles and practices for fatigue risk management systems have been developed[7,8] and evaluated in different settings.[9] This PSP topic was addressed in the MHS I report, which provided a broad review of workplace fatigue including studies across industries, as very little research had been conducted within healthcare settings at the time.[10] The MHS I review covered interventions focused on hours of service (i.e., regulations limiting the maximum shift length or total hours worked, and comparisons of 8- versus 12-hour shift lengths), the direction and speed of rotation through shift work (i.e., shift rotation directions moving "forward" [day to evening to night] or "backward" [day to night to evening]; slow versus fast shift rotations), sleep hygiene education, work lighting, napping, and medical therapies (e.g., melatonin, sedatives, and stimulants). That report concluded that there was an insufficient evidence base within healthcare settings, but fatigue management interventions from other work domains had high face-validity, low likelihood of harm, and high ease of implementation. The hours of service and fatigue topic received a brief update in MHS II, focusing on evaluations of regulatory limitations on resident work hours.[11] Based on several systematic reviews of that literature, the MHS II review concluded that work hour limitations did not reduce mortality or improve safety; but there were fewer

objective and self-reported medical errors with 16-hour shift lengths than with traditional 30-hour shifts. Patient safety risks due to fatigue and sleepiness of healthcare workers were not addressed in MHS III.

In the decade since the MHS II report, the high levels of burnout among clinicians have come into focus.[12,13] While burnout is complex, sleep deprivation has been implicated in the development and sustainment of high levels of burnout.[14] The coronavirus disease of 2019 (COVID-19) pandemic may have amplified these issues in part due to atypical work schedules.[15]

In the prioritization process, the MHS IV TEP did not suggest alterations to past definitions of this patient safety risk or associated PSPs. However, due to the limited time and funding allocated for this rapid response, the report focuses on PSPs targeting clinicians rather than other healthcare workers because patient outcomes are more directly related to the performance of clinicians than to the performance of nonclinical healthcare workers. Clinicians are defined as any person providing healthcare to patients (e.g., physician, nurse, physician assistant, respiratory therapist, or pharmacist). The report also focuses on clinicians in acute care hospital settings because that is where interventions on shift schedules and fatigue risk management practices are most likely to have been conducted.

## 1.2 Purpose of the Rapid Response

The purpose of this rapid response is to summarize the most relevant and recent literature on PSPs focused on fatigue and sleepiness of clinicians related to hours of service and how these PSPs can be implemented. The report should be of interest to healthcare system and hospital leaders who are wrestling with concerns about clinician burnout.

## 1.3 Review Questions

1. What are the frequency and severity of harms associated with fatigue and sleepiness of clinicians due to hours of service?
2. What patient safety measures or indicators have been used to examine the harm associated with fatigue and sleepiness of clinicians?
3. What PSPs have been used to prevent or mitigate the harms associated with fatigue and sleepiness of clinicians due to hours of service and in what settings have they been used?
4. What is the rationale for the PSPs used to prevent or mitigate the harms associated with fatigue and sleepiness of clinicians due to hours of service?
5. What studies have assessed the effectiveness and unintended effects of the PSPs and what new evidence has been published since the search was done for the MHS II report in 2013?
6. What are common barriers and facilitators to implementing the PSPs?
7. What resources (e.g., cost, staff, time) are required for implementation?
8. What toolkits are available to support implementation of the PSPs?

# 2. Methods

We followed processes proposed by the AHRQ Evidence-based Practice Center Program.[16] The rapid response is intended to present the end-user with an answer based on the best available evidence, but does not attempt to formally synthesize the evidence into conclusions. While the steps are similar to those of a typical systematic review, the methods are different (i.e., streamlined systematic review methods).[17]

For this rapid response, strategic adjustments were made to streamline traditional systematic review processes and deliver an evidence product in the allotted time. Adjustments included being as specific as possible about the questions, limiting the number of databases searched, modifying search strategies to focus on finding the most valuable studies (i.e., being flexible on sensitivity to increase the specificity of the search), and restricting the search to studies published recently (i.e., since 2013 when the search was performed for the MHS II report) in English and performed in the United States. Additionally, it was deemed out of scope for this rapid response to refer back to primary studies when included systematic reviews failed to provide sufficient clarification. For this report, we used the artificial intelligence (AI) feature of DistillerSR (AI Classifier Manager) as a second reviewer at the title and abstract screening stage.

We asked our content experts to answer Review Questions 1 and 2 by citing selected references that best answer the questions without conducting a systematic search for all evidence on the targeted harms and related patient safety measures or indicators. We focused on the harms and patient safety measures or indicators that are addressed in the studies we identified for Review Question 5. For Review Question 2, we focused on identifying relevant measures that are included in the Centers for Medicare & Medicaid Services (CMS) patient safety measures, AHRQ's Patient Safety Indicators, or the National Committee for Quality Assurance (NCQA) patient safety related measures. We asked our content experts to answer Review Questions 3 and 4 by citing selected references, including patient safety practices (PSPs) used and explanations of the rationale presented in the studies we identified for Review Question 5. For Review Questions 6 and 7, we focused on the barriers, facilitators, and required resources reported in the studies we identified for Review Question 5. For Review Question 8, we identified publicly available patient safety toolkits developed by AHRQ or other organizations that could help to support implementation of the PSPs. To accomplish that task, we reviewed AHRQ's Patient Safety Network (PSNet)[18] and AHRQ's listing of patient safety–related toolkits[19] and we included any toolkits mentioned in the studies we find for Review Question 5. We identified toolkits without assessing or endorsing them.

## 2.1 Eligibility Criteria for Studies of Effectiveness

We searched for original studies and systematic reviews on Review Question 5 according to the inclusion and exclusion criteria presented in Table 1. As this review

focuses on patient safety, we searched for studies and systematic reviews that report on clinical and patient safety outcomes. Work hours and fatigue risk management interventions also have intermediate outcomes for workers (e.g., well-being) and organizations (e.g., turnover and absenteeism), but these are out of scope for the current rapid response.

**Table 1. Inclusion and exclusion criteria**

| Study Parameter | Inclusion Criteria | Exclusion Criteria |
|---|---|---|
| **Population** | Clinicians in acute care hospital settings | Non-clinician healthcare workers;<br>Clinicians in settings other than an acute care hospital |
| **Intervention** | *Modifications to work schedules* (duration and structure of hours worked) including:<br>• Limitations to total hours worked<br>• Limitations to maximum shift duration<br>• Shift patterns including changes to speed and direction of shift rotations, and recovery time between shifts<br><br>*Fatigue risk management practices*, including:<br>• Sleep hygiene education<br>• Napping<br>• Workplace lighting<br>• Fatigue monitoring, reporting, and incident analysis systems<br>• Pharmacological agents (e.g., caffeine, melatonin, sleep medications) | No intervention of interest |
| **Comparator** | Defined time periods (such as historically controlled "before-after" trials) or cohort group(s) of clinicians without work schedule or fatigue risk management intervention. | No defined historical or contemporaneous cohort comparison group |
| **Outcome** | *Clinical outcomes*:<br>• Mortality<br>• Complications<br>*Specific patient safety outcomes*:<br>• Incidence of medical errors or adverse events | No outcome of interest |
| **Timing** | Original studies and systematic reviews published January 2013 through September 2023 | Published before 2013 |
| **Setting** | Acute care hospital setting in the United States | Healthcare settings other than acute care hospitals;<br>For multi-site studies, no site in the United States |
| **Type of studies** | Systematic reviews;<br>Randomized controlled trials, non-randomized trials, and observational studies with a comparison group. | Study design not specified, or no control described;<br>Qualitative studies with no quantitative component |

## 2.2 Literature Searches for Studies of Effectiveness

We searched PubMed and the Cochrane Library for systematic reviews and original studies published since the MHS II report in 2013 that address the review questions (Appendix Table A-1).

## 2.3 Selection of Studies

We used the AI Classifier Manager as a semi-automated screening tool to conduct this review efficiently at the title and abstract screening stage. The title and abstract of each citation were screened by a team member based on predefined eligibility criteria (Table 1), and then the AI Classifier Manager served as a second reviewer of each citation. The AI Classifier Manager generated a ranking score for each citation, based upon a training set of titles and abstracts screened first by team members. The threshold for the AI Classifier Manager to include citations was set at a ranking score of 0.5 or above (scale 0 to 1.0). The full text of each remaining potentially eligible article was reviewed by two team members to confirm eligibility. The data from eligible articles were extracted by a single team member who prepared a summary of the study, including author, year, study design, number of study participants, and main findings relevant to each of the review questions.

## 2.4 Risk of Bias (Quality) Assessment

For studies that addressed Review Question 5 about the effectiveness of PSPs, we used the Cochrane Collaboration's tool for assessing the risk of bias of randomized controlled trials (RCTs) or the ROBINS-I tool for assessing the Risk Of Bias In Non-randomized Studies – of Interventions.[20-23]

For RCTs, we used the items in the Cochrane Collaboration's tool that cover the domains of selection bias, performance bias, detection bias, attrition bias, reporting bias, and other bias.[20,22] For nonrandomized studies, we used specific items in the ROBINS-I tool that assess bias due to confounding, bias in selection of participants into the study, bias in classification of interventions, bias due to deviations from intended interventions, bias due to missing data, bias in measurement of outcomes, and bias in selection of the reported results.[21,23] The risk of bias assessments focused on the main outcome of interest in each study.

For recent eligible systematic reviews, the primary reviewer used the criteria developed by the United States Preventive Services Task Force Methods Workgroup for assessing the quality of systematic reviews.[24]

- **Good –** Recent relevant review with comprehensive sources and search strategies; explicit and relevant selection criteria; standard appraisal of included studies; and valid conclusions.

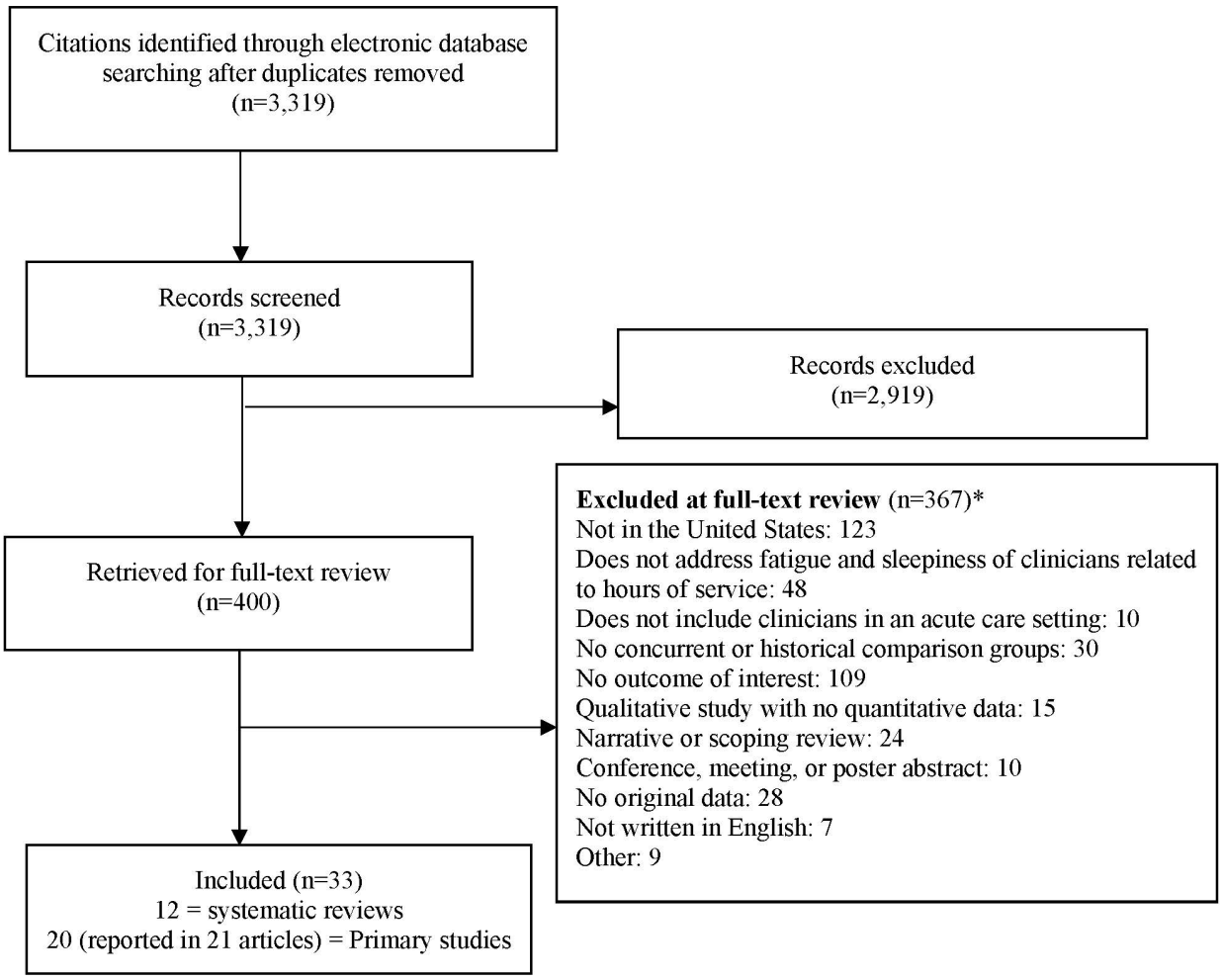
- **Fair –** Recent relevant review that is not clearly biased but lacks comprehensive sources and search strategies.
- **Poor –** Outdated, irrelevant, or biased review without systematic search for studies, explicit selection criteria, or standard appraisal of studies.

# 3. Evidence Base

## 3.1 Number of Studies

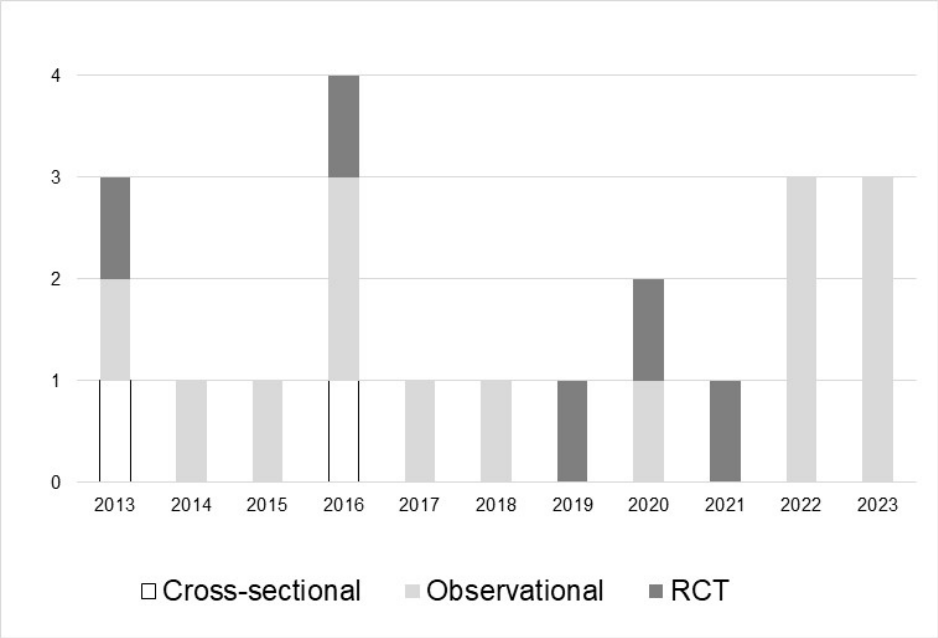
Our search retrieved 3,319 unique titles and abstracts from which we reviewed 400 full-text articles for eligibility. We found 12 systematic reviews and 20 primary studies (reported in 21 articles) that met the inclusion criteria (Figure 1).

**Figure 1. Results of the search and screening**




*Total exceeds the number of citations in the exclusion box because citations could be excluded for more than one reason (i.e., both reviewers did not need to agree on reason for exclusion).

**Figure 2. Number of included primary studies by year of publication and design**




RCT = randomized controlled trial

## 3.2 Findings for Review Questions

### 3.2.1 Question 1. What Are the Frequency and Severity of Harms Associated With Fatigue and Sleepiness of Clinicians Due to Hours of Service?

The exact prevalence of fatigue and sleepiness of clinicians due to long hours of service and the effects on patient safety and patient outcomes is challenging to estimate. However, the Centers for Disease Control and Prevention (CDC) found that 36 percent of healthcare clinicians and technical workers reported short sleep durations in 2018, a 15 percent increase since 2010.[5] Further, meta-analysis of studies evaluating sleep disturbances during the coronavirus disease of 2019 (COVID-19) pandemic estimated that 34.8 percent of nurses and 41.6 percent of physicians experienced sleep disturbances.[25] Safety is a distal outcome for occupational fatigue, which is influenced by many factors including the hours worked, workload, and sleep amount and quality.[26] Long work hours are common among healthcare industry workers, as is poor quality sleep.[25] While work demands vary by clinical specialty and setting, between 2001 and 2021, average physician work hours per week decreased by 7.6 percent, from 52.6 to 48.6 hours per week, with rapid growth in total hours contributed to the workforce by advanced practice professionals.[27] An estimated 17 percent of healthcare workers work 48 hours or more per week, and 6 percent work 60 or more hours per week,[28] with over 100,000 resident physicians working 80 hours per week including shifts of 24 hours or longer in duration.[29] Work-hour duration and shift structure can increase worker fatigue, which may decrease cognitive and psycho-motor performance, and increase the likelihood of adverse events and preventable patient harm including medication errors,[30] and errors in clinical performance of physicians[31] and nurses.[32] The diversity of outcomes and studies prohibits a precise estimate of the magnitude of harm attributable to healthcare worker fatigue.

### 3.2.2 Question 2. What Patient Safety Measures or Indicators Have Been Used To Examine the Harm Associated With Fatigue and Sleepiness of Clinicians?

Patient safety outcomes reported in studies included in this review varied widely. The included systematic reviews focused on medication safety, surgical outcomes, patient injuries, errors made or detected by others, mortality, morbidity, readmission, infection, and length of stay. Primary studies included mortality, clinical complications, 30-day readmissions, self-reported and observed medical errors and adverse events, and medication errors.

### 3.2.3 Question 3. What Patient Safety Practices (PSPs) Have Been Used To Prevent or Mitigate the Harms Associated With Fatigue and Sleepiness of Clinicians due to Hours of Service and in What Settings Have They Been Used?

PSPs to mitigate the harms associated with fatigue and sleepiness of clinicians focus primarily on the total amount of hours worked or the structure of shifts. Primary studies included in this rapid response were conducted across emergency department, surgical ward, medical ward, and hospital-wide settings. Studies investigated aspects of the quantity and quality of sleep prior to a work shift on safety, the impact of completing an overnight call shift and amount of sleep during a call shift on safety the subsequent day, the total hours worked per shift or per week, and changes in duty hour regulations, including: (1) the 2011 policy limiting work to no more than 80 hours per week and no more than 30 hours worked per individual shift; (2) the 2011 policy restricting shifts to less than 16 hours during the first year of residents and 24 hours afterwards, requiring at least one day off per week, requiring at least 8 hours between duty periods, and requiring 14 hours free after 24-hour shifts; and (3) the 2017 policy, which eased restrictions on the maximum shift duration for first-year residents from 16 to 24 hours.

### 3.2.4 Question 4. What Is the Rationale for the PSPs Used To Prevent or Mitigate the Harms Associated With Fatigue and Sleepiness of Clinicians due to Hours of Service?

Interventions targeting maximum hours worked or maximum shift duration seek to minimize cognitive and physical performance decrements observed after long durations of focus at work.[7,9] Interventions modifying shift schedules in terms of timing seek to maximize recovery between shifts or minimize circadian rhythm disruption.[33] The three risk management interventions discussed in included reviews sought to reduce fatigue with lighting conditions designed to promote alertness, or with break or napping interventions designed to provide rest within a shift to decrease fatigue.

### 3.2.5 Question 5. What Studies Have Assessed the Effectiveness and Unintended Effects of the PSPs and What New Evidence Has Been Published Since the Search Was Done for the MHS II Report in 2013?

A total of 12 systematic reviews met the criteria for inclusion. Of those 12 reviews, 11 reported the effects of work shift modifications or interventions on specific patient

safety outcomes (incidence of medical errors or adverse events) [34-44] and 6 reported the effects on other clinical outcomes.[38,40-42,44,45] Article types in reviews included, but were not limited to, randomized control trials (RCTs), non-randomized controlled trials, survey studies, observational studies, and meta-analyses. The clinician population in these SRs consisted of nurses, military and nonmilitary surgical teams, physicians, and residents. Of the 12 reviews, 5 reported findings for risk management practices and all 12 reviews investigated some type of work schedule modification. Reviews reported on outcomes including clinical and patient safety outcomes such as mortality, readmission, complications, or adverse events. Acute care settings included surgery, radiology, pediatrics, intensive care unit (ICU), and neonatal ICU, among others.

We also identified 20 primary studies in 21 articles. Eight of these studies (reported in 9 articles) prospectively assessed the impact of shift structure modifications on outcomes of interest, and a further 12 were cross-sectional studies evaluating differences in total hours or shift structure on outcomes of interest.

An overview of the included systematic reviews and primary studies is presented in Tables 2a and 2b.

**Table 2a. Overview of the systematic reviews**

| Author, Year<br><br>Setting | Objective | Literature Search -End Date<br><br># Included Studies<br><br>Study Design | Work Schedule or Mitigation Comparisons Description | Main Outcome Findings [as reported in the review] |
|---|---|---|---|---|
| Weaver, 2023[44]<br><br>Hospital | To evaluate the impact of work hour policies (i.e., the ACGME's 2003 and 2011 resident physicians work hour guidelines) and work schedules on patient safety | 2019<br><br>N=68<br><br>RCT: 4<br>Observational: 6 | Limit all resident physicians to 80-hour work weeks and 28-hour shifts in 2003. | **Incidence of medical errors or adverse events:** Limited shift durations and shorter work weeks were associated with improved patient safety in clinical trials, as well as in observational studies on work shift duration differences not specifically tied to policy changes.<br><br>**Mortality:** Limiting all resident physicians to 80-hour work weeks and 28-hour shifts in 2003 was associated with an 11% reduction in patient mortality ($p < 0.001$).<br><br>The overall quality of evidence was moderate. |
| Di Muzio, 2019[34]<br><br>Hospital | To analyze the correlation between clinical risk management and the occurrence of medication errors and the effects of shift work on inpatient nurses. | 2017<br><br>N=19<br><br>Cross-sectional survey: 7<br>Prospective study: 1<br>Descriptive study: 4<br>Web-based study:1<br>Survey: 2<br>Case study: 1<br>Longitudinal study: 1<br>Observational study: 2 | Nursing shift work (night shifts, reduced staffed shifts (i.e., number of nursing staff is limited), 12-hour shifts, and working greater than 40 hours a week) | **Incidence of medical errors or adverse events:** The main reasons behind medication errors are stress, fatigue, increased workload, night shifts, nurse staffing ratio, and workflow interruptions.<br><br>Strength of evidence: NR |

| Author, Year<br><br>Setting | Objective | Literature Search -End Date<br><br># Included Studies<br><br>Study Design | Work Schedule or Mitigation Comparisons Description | Main Outcome Findings [as reported in the review] |
|---|---|---|---|---|
| Gates, 2018[40]<br><br>Independent practices | To synthesize evidence on the (1) impact of insufficient sleep and fatigue on health, performance, and patient safety; and (2) effectiveness of interventions targeting insufficient sleep and fatigue. | 2017<br><br>N=47<br><br>RCT: 2<br>Observational: 45 | Shift work schedule (e.g., 24-hour shift versus standard workday, overnight work, 17-hour night shift and usual day, long on-call shifts) | **Incidence of medical errors or adverse events:** Results showed no association between fatigue or insufficient sleep with surgical performance, and mixed findings for psychomotor performance, work performance, and medical errors.<br><br>**Mortality or complications:** For sleep deprived versus non-sleep deprived surgeons, no difference was found in patient mortality or postoperative complications. The findings for intraoperative complications and length of stay were mixed.<br><br>**Strength of evidence:**<br>The overall quality of the body of research was poor based upon generally unclear or high risk of bias (62% of studies). All cohort studies were at low risk of bias. |
| Harris,2015[45]<br><br>Surgical units | To assess the impact of work-hour restrictions on clinician quality-of-life, skill development, resident education, patient care outcomes, and resident attitudes. | 2012<br><br>N=11<br><br>Prospective analysis: 1<br>Surgical case logs and survey results: 10 | Reduction in resident work hours (i.e., resident duty hour restrictions, limiting number of hours worked). | **Incidence of medical errors or adverse events:** Found inconclusive results on patient outcomes.<br><br>**Strength of evidence:** NR |
| Leroyer, 2014[38]<br><br>Surgical units | To determine association between extended medical shifts and consequences for patients. | 2009<br><br>N=6<br><br>RCT: 1<br>Observational: 5 | Extended duration shifts worked by medical interns (e.g., number worked in the last month, comparing extended shifts to regular shifts), day procedures following emergency night procedures versus not following a night procedure, and duty hour restrictions | **Incidence of medical errors or adverse events:** Extended-duration shifts are weakly associated with an increased occurrence of serious medical errors.<br><br>**Mortality:** Extended-duration shifts are weakly associated with increased mortality among patients.<br><br>**Strength of evidence**: Selected studies meet the high methodological quality criteria based off of the Consort 2010 checklist.[46] |

| Author, Year<br><br>Setting | Objective | Literature Search -End Date<br><br># Included Studies<br><br>Study Design | Work Schedule or Mitigation Comparisons Description | Main Outcome Findings [as reported in the review] |
|---|---|---|---|---|
| Lawrence,2014[39]<br><br>Not specified | To evaluate extended-duty shifts to develop evidence-based recommendations for student nurse-midwives/student midwives. | 2012<br><br>N=40<br><br>RCT: 13<br>Correlational: 9<br>Descriptive: 17<br>Meta-analysis: 1 | Extended-duty shifts, or work schedules having a longer than normal workday; (e.g., time worked in excess of 8 hours, shifts longer than 12 hours) | **Incidence of medical errors or adverse events:** Extended-duty shifts may cause cognitive errors (e.g., attention lapses, visual tracking errors, worsened recall) and physical errors (e.g., decreased motor skills, increased time to react to changes) by clinicians, leading to safety concerns.<br><br>**Strength of evidence: NR** |
| Smith-Miller, 2014[36]<br><br>Acute care setting | To examine current research related to nurse fatigue and identify effective prevention strategies. | 2013<br><br>N=22<br><br>Does not give specific breakdown of study types | 1. Limiting the frequency of day-night rotations, having minimum interval of 48 hours after a night shift before scheduling a day shift, restricting the number of consecutive 12-hour shifts and curbing shift duration to 12 hours. Unit procedures that limit involuntary overtime, on-call status, and the practice of calling nonscheduled nurses.<br><br>2. Duty-free breaks giving nurses responsibility-free work breaks (quiet & nap time). | **Incidence of medical errors or adverse events:** Shifts longer than 12 hours contribute to increased fatigue and errors. The number of hours of sleep in the preceding 24 hours is predictive of individuals' propensity to make errors and their alertness to detect errors made by others.<br><br>**Strength of evidence:**<br>The quality of the evidence was assessed using the GRADE guidelines process.<br>The included studies were reviewed by the authors and ranked as low (N = 3), moderate (N = 11), or high (N = 9). |

| Author, Year<br><br>Setting | Objective | Literature Search -End Date<br><br># Included Studies<br><br>Study Design | Work Schedule or Mitigation Comparisons Description | Main Outcome Findings [as reported in the review] |
|---|---|---|---|---|
| Stec, 2018[37]<br>Radiology | To review current literature regarding radiologist fatigue. | 2017<br><br>N=27<br><br>Reviews: 14<br>Primary research studies: 10<br>Other: 3 | 1. Radiologist work hours changes and lengths.<br><br>2. Ergonomic design of reading workstations, such as adjusting ambient lighting, brightness difference between monitor and surroundings, reducing screen flickers, reducing daily readings, increasing breaks, reading while sitting versus standing up, and adjusting technology specific to user work habits and preferences. | **Incidence of medical errors or adverse events:** Radiologists are more prone to errors after 10 hours of clinical interpretation.<br>A controlled increase in ambient lighting and maintaining a significant difference between brightness of the monitor and surroundings could increase radiologist's detection and identification capacity of low-contrast objects. Additionally, they found that ocular fatigue can be reduced by taking breaks, reducing daily readings, and eliminating screen flickers.<br><br>**Strength of evidence:** NR |
| Bolster,2015[41]<br><br>Patient care settings (various settings including radiology, surgery, pediatrics, internal medicine) | To determine Impact of duty hour restrictions conducted 1 year prior to the implementation of the ACGME's 2011 regulations. | 2013<br><br>N=27<br><br>RCT: 14<br>Non-RCT: 3<br>Observational: 10 | 1. Duty hour restrictions included night float, shortened shifts, and number of consecutive night shifts<br><br>2. Protected time for sleep (a period during a work shift in which residents transfer all of their responsibilities to another individual, so that they can obtain uninterrupted sleep). | **Incidence of medical errors or adverse events:** The impact of duty hour restrictions most frequently had no impact on patient care. When analyzed by intervention type, the most frequent result of shift length changes was no impact, and that of night float was an unfavorable impact. For protected time for sleep, one study reported no impact on patient care.<br><br>**Strength of evidence**: NR |
| Parker, 2016[35]<br><br>ICU | To examine the impact of sleep deprivation on cognitive performance in military surgical teams. | 2016<br><br>N=14<br><br>Does not give specific breakdown of study types | 1. Strategic scheduling of work hours and improved working conditions<br><br>2. Prophylactic sleep, activity breaks, stimulants, and hypnotics | **Incidence of medical errors or adverse events:** Recommends implementing on-call periods of no more than 12 hours in duration, with adequate rest periods every 24 hours, as sleep deprivation after 24 hours on-call duty affects cognitive performance, increasing the number of errors and omissions.<br><br>**Strength of evidence:** NR |

| Author, Year<br><br>Setting | Objective | Literature Search -End Date<br><br># Included Studies<br><br>Study Design | Work Schedule or Mitigation Comparisons Description | Main Outcome Findings [as reported in the review] |
|---|---|---|---|---|
| Bae,2021[42]<br><br>Various settings | To review the comprehensive characteristics of adverse nurse work schedules and to synthesize the evidence of their relationships with adverse patient outcomes. | 2019<br><br>N=22<br><br>Cross-sectional: 18<br>Retrospective cohort study: 2<br>Longitudinal: 2 | 1. Nurse work schedule characteristics, including long work hours, overtime, and consecutive shift work.<br><br>2. Nurse break time, including breaks, lack of time away, and insufficient work breaks. | **Incidence of medical errors or adverse events or mortality:**<br>Nurses' breaks were indirectly related to patient safety.<br>Found a conclusive relationship between excessive nurse work hours and adverse patient outcomes.<br>Working more than 12 hours in a day had an adverse effect on patient outcomes, as did working more than 40 hours per week.<br>There were mixed findings in the relationship between nurse overtime and adverse patient outcomes. Insufficient time away between shifts was related to increased patient mortality.<br>Nurses' insufficient breaks were indirectly related to adverse patient outcomes.<br><br>**Strength of evidence**: NR |
| Sephien,2023[43]<br><br>Hospital | To synthesize the evidence associated with resident duty hour restrictions and its impact on resident- and patient-based outcomes. | 2020<br><br>N = 9<br><br>RCT: 9 | 1. Longer resident physician work hours compared to shorter resident physician work hours.<br><br>2. Sleep interventions included promoting sleep before night shift and protected nap/sleep time. | **Incidence of medical errors or adverse events:** There was no significant association between reduced shift length and length of stay, and the odds of serious medical errors, or preventable adverse events per 1000 events.<br><br>**Strength of evidence:**<br>The overall certainty of evidence of included RCTs ranged from very low to low. |

ACGME = Accreditation Council for Graduate Medical Education; GRADE = Grading of Recommendations, Assessment; N = number; NR = not reported; RCT = randomized controlled trial;

**Table 2b. Overview of the included primary studies**

| Author, Year | Study Design<br><br>Setting<br><br>Population (as stated by the study) | Work Schedule Comparison | Outcome Findings |
|---|---|---|---|
| Weaver, 2016[47] | Cross-sectional study<br><br>Setting: ED<br><br>Population: Registered nurses | The quality and quantity of sleep using the Pittsburgh Sleep Quality Index and wrist actigraphy. The study compared nurses on day shift (7:00 am to 7:00 pm, 9:00 am to 9:00 pm, 11:00 am to 11:00 pm) and night shifts (1:00 pm to 1:00 am, 3:00 pm to 3:00 am, and 7:00 pm to 7:00 am). | **Incidence of medical errors or adverse events**<br>Sleep quantity was not associated with minor, moderate or severe perceived errors |
| Iverson, 2018[48] | Observational study<br><br>Setting: Cardiac surgery unit<br><br>Population: Patients undergoing PCI performed by clinicians | Compared clinical outcomes of percutaneous coronary interventions performed by sleep and non-sleep deprived operators. Non-sleep deprived defined as operators performing a case between 7 am and 11:59 pm as well as a case the preceding night, between 12 am and 6:59 am. | **Complications**<br>Major procedural complication: no statistically significant difference (p = 0.42)<br>Bleeding event: no statistically significant difference (p = 0.29)<br><br>**Mortality**<br>In-hospital mortality: no statistically significant difference (p=1.0) |
| Abdalla, 2022[49] | Observational study<br><br>Setting: Neurointerventional surgery societies<br><br>Population: Neuro-interventional surgeons | Neurointerventional surgery calls and sleep deprivation with physician burnout, physical and driving safety, and fatigue-related medical errors. Compared the total hours of sleep while on call: 6-8 hours, 4-6 hours, less than four hours of total sleep. | **Incidence of medical errors or adverse events**<br>Risk of medical errors showed strong association in respondents reporting < 4 hours of uninterrupted sleep (45.7% versus 25.5%, p = 0.008)<br>Statistically significant association of sleeping < 6 hours and fatigue related medical errors (38.9% vs. 18.4%, p = 0.02) |
| Quan, 2023[50] | Observational study<br><br>Setting: Surgical units<br><br>Population: Surgeons | Impact of sleep deficiency on surgical outcomes (particularly among attending surgeons), comparing surgeons who were non-post call status versus those on post-call (defined as > 2 hours of nighttime clinical duties). | **Incidence of medical errors or adverse events**<br>No statistically significant difference in incidence of medical errors: IRR 3.16 comparing non-post call and post call error rate, p = 0.165 |
| Kalmbach, 2017[51] | Observational study<br><br>Setting: Hospital<br><br>Population: First year medical residents | Internship-related sleep duration, and duty hours. The study compared sleep time (<6 hours vs. > 6 hours) and weekly work hours (70 hours vs. ≥ 70 hours). | **Incidence of medical errors or adverse events**<br>Residents with less than 6 hours of sleep more likely to make medical errors (relative risk 1.3, p = 0.03).<br><br>Error rates higher for residents who work more than 70 hours per week (relative risk 1.5, p < 0.01) |
| Bae, 2013[52] | Observational study<br><br>Setting: Hospital<br><br>Population: Registered nurses | Regulations on nurse overtime, nurse injuries, and adverse patient events. Secondary analysis on the effect of nurse overtime vs. no overtime and total work hours (≤40 hours per week vs. ≥ 40 hours per week) on | **Complications**<br>No significant difference in number of any adverse events between comparisons of overtime vs. no overtime, and nurses with overtime regulation vs. without. There were significantly higher adverse events comparing nurses working ≥ 40 hours per |

| Author, Year | Study Design<br><br>Setting<br><br>Population (as stated by the study) | Work Schedule Comparison | Outcome Findings |
|---|---|---|---|
| | | nurse injuries and adverse patient events. | week compared to nurses working ≤ 40 hours per week (OR 14.36 [95% CI: 1.20 to 171.9]).<br>Rates of patient falls were significantly higher among nurses with overtime regulations, and among voluntary overtime nurses. Rates of patient pressure ulcers were significantly higher among nurses with overtime regulations, voluntary overtime nurses, and nurses working ≥ 40 hours per week. Rates of patient nosocomial infections were significantly higher among nurses with overtime regulations, on-call nurses, and nurses working ≥ 40 hours per week. There were no statistically significant differences among comparison groups for failure to rescue.<br><br>**Incidence of medical errors or adverse events**<br>No significant difference in medication errors between comparisons of overtime vs. no overtime, and nurses with overtime regulation vs. without regulations. There was a significant increase in medication errors for nurses working ≥ 40 hours per week compared to nurses working ≤ 40 hours per week (OR 3.71 [95% CI: 1.16-11.84]) |
| Stimpfel, 2013[53] | Cross-sectional study<br><br>Setting: Hospital<br><br>Population: Registered nurses | Shift length (8 hours, 12 hours, ≥13 hours) with nurse job outcomes, nurse-reported patient outcomes, and nurse-assessed safety and quality of care in hospitals. | **Incidence of medical errors or adverse events**<br>The likelihood of a nurse reporting poor quality or a poor safety grade on their unit was greater for nurses working > 13 hours compared to nurses working 8 hours shifts (adjusted OR 2.76 and 3.14, respectively). |
| Westley, 2020[54] | Observational study<br><br>Setting: Hospital<br><br>Population: Bedside and clinic registered nurses | Nurses' work hours on near-miss medication error alerts.<br><br>Nurses' work hours:<br>• 60 hours or more work within 7 days<br>• Less than 60 hours work within 7 days | **Incidence of medical errors or adverse events**<br>Nurses working 60 hours or more in a week had an average near-miss rate of 4% compared to 3% ($p < 0.001$) for nurses who did not. Nurses working extended hours had a significantly increased risk of triggering a near-miss alert compared to those not working extended hours. |
| Ouyang, 2016[55] | Observational study<br><br>Setting: In-patient general medicine unit<br><br>Population: General medicine patients | Impact on patient care when house staff work more than 80 hours per week compared to working less than 80 hours per week. | **Mortality**<br>No statistical difference for rate of in-hospital mortality for patients in either group.<br><br>**Complications**<br>No statistical difference for rate of ICU and |

| Author, Year | Study Design<br><br>Setting<br><br>Population (as stated by the study) | Work Schedule Comparison | Outcome Findings |
|---|---|---|---|
| | | | 30-day readmission rate for patients in either group. |
| Barger, 2023[56] | Observational study<br><br>Setting: Hospital<br><br>Population: Postgraduate year 2 and above resident physician | Long weekly work hours and shifts of extended duration (≥24 hours)<br><br>Resident physician work hours:<br>• 48 to 60 weekly work hours<br>• 60 to 70 weekly work hours<br>• 70 to 80 weekly work hours<br>• More than 80 weekly work hours | **Incidence of medical errors or adverse events**<br>Working more than 48 hours per week was associated with an increased risk of self-reported medical errors, preventable adverse events, and fatal preventable adverse events ($p < 0.001$ for call groups compared to working less than 48 hours per week). |
| Salgado, 2022[57] | Observational study<br><br>Setting: General medicine unit<br><br>Population: General medicine interns, residents, and attendings | Perceptions of care and patient outcomes on an extended (28-hour) compared with a limited (16-hour) duty hour system.<br><br>Extended duty hour call system:<br>24 hour plus 4-hour shifts every 4 days from 7 am to 11 am the following day, with 4-hour protected off-pager for in-hospital rest in private call rooms from 2:00 to 6:00 am<br><br>Limited duty hour call system:<br>"Long call" admitting shift every 3 days with a maximum single-day work hour limit of 16 hours | **Complications**<br>No statistically significant difference in patients who developed complications during admission (95% CI: -0.064 to 0.104). |
| Wen, 2017[58] | Observational study<br><br>Setting: Hospital<br><br>Population: Patients admitted to hospitals | Post-work hour reform effects on hospital-acquired conditions incidence compared to pre-2003 ACGME work hour reforms. | **Complications**<br>Patients were more likely to incur a hospital-acquired condition in the post-2003 group compared to the pre-2003 group (OR 1.10 [95% CI: 1.06 to 1.14]) |
| Desai, 2013[59] | RCT<br><br>Setting: General medicine unit<br><br>Population: Postgraduate years 1 through 3 trainees and ward nurses | 2011 ACGME duty hour regulations compared with the 2003 regulations. | **Complications**<br>No significant difference in 30-day readmission rates between groups |
| Denson, 2015[60] | Observational study<br><br>Setting: Hospital<br><br>Population: General medicine and ICU patients | The effect of 2011 ACGME duty hour regulations in comparison to pre-2011 duty hour regulations on handoff-related mortality. Within the comparison groups, data was collected on patients discharged the following 3 weeks of each 4-week rotation before resident service change and patients discharged within | **Mortality**<br>Before duty hour restrictions, team handoff group vs. no team handoff group was associated with a statistically significant higher mortality (OR 1.5 [95% CI: 1.11 to 1.86]), but after duty hour changes, the association lost statistical significance (OR 1.18 [95% CI: 0.89 to 1.56]) |

| Author, Year | Study Design<br><br>Setting<br><br>Population (as stated by the study) | Work Schedule Comparison | Outcome Findings |
|---|---|---|---|
| | | 7 days following a change in resident physician team. | |
| Rajaram, 2014[61] | Observational study<br><br>Setting: General surgery<br><br>Population: General surgery patients | Implementation of the 2011 ACGME duty hour regulations compared to pre-2011 ACGME reforms. | **Mortality**<br>No significant change in death or serious morbidity post-reform (OR 1.06 [95% CI: 0.93 to 1.20]).<br><br>**Incidence of medical errors or adverse events**<br>No association between reform and any post-operative adverse events. |
| Weaver, 2023[62] | Observational study<br><br>Setting: Hospital<br><br>Population: Resident physicians | Implementation of 16 hours 2011 ACGME work hour limit compared to data in hospitals where the restrictions were not yet implemented. | **Incidence of medical errors or adverse events**<br>Statistically significant reduction in risk of significant medical errors (RR 0.66 [ 95% CI 0.59 to 0.74])<br><br>Statistically significant reduced risk of medical errors leading to patient death (RR 0.37 [95% CI 0.28 to 0.49]) |
| Landrigan, 2020[63]<br><br>ROSTERS trial | RCT<br><br>Setting: Pediatric ICU<br><br>Population: Pediatric resident physicians | Rapidly cycling work roster that eliminated extended shifts compared to a control group working night shifts followed by approximately 24 hours off duty, and then two or three consecutive day shifts. | **Incidence of medical errors or adverse events**<br>Physicians made more serious errors during intervention schedules (RR 1.53 [95% CI: 1.37 to 1.72], p < 0.001). Serious errors unit-wide were also more frequent during intervention schedules (RR 1.56 [95% CI: 1.43 to 1.71]) |
| Rahman, 2021[64]<br><br>ROSTERS trial | RCT<br><br>Setting: Pediatric ICU<br><br>Population: Pediatric resident physicians | Rapidly cycling work rosters for postgraduate year 2 and year 3 resident physicians compared to an extended duration work roster and resident physicians exposed to both types of work rosters.<br><br>**Details**<br>Extended duration work roster: Shifts of 24+ hours every third or fourth shift. 4 day rotation with 2 ~12-hour day shifts followed by an on-call shift beginning in the morning and ending 24 to 28 hours later.<br><br>Rapidly cycling work rosters: Limit resident physicians' scheduled continuous work to 16 hours maximum. 4-day rotation with 2 ~11 to 15-hour day shifts followed by a 16-hour overnight shift that started in the evening and ended the next morning. | **Incidence of medical errors or adverse events**<br>After adjusting for workload, rapidly cycling work rosters had a lower rate of serious medical errors (rate ratio 0.48 [95% CI: 0.30 to 0.77]). |

| Author, Year | Study Design<br><br>Setting<br><br>Population (as stated by the study) | Work Schedule Comparison | Outcome Findings |
|---|---|---|---|
| | | Both work rosters: Resident physicians exposed to both times of shifts. | |
| Mirmehdi, 2016[65] | Observational study<br><br>Setting: General surgery training sites<br><br>Population: Cases operated on by residents | Implementation of flexible duty hour rules compared to surgery residents working under a traditional duty hour work schedule. | **Mortality**<br>No statistically significant difference in patient mortality after operation (1.58% institution resident cases vs. 1.30% national resident cases, p = 0.629). |
| Bilimoria, 2016[66]<br><br>FIRST Trial | RCT<br><br>Setting: General surgery residency programs<br><br>Population: Cases operated on by residents | Changing resident duty hour policies to permit greater flexibility in work hours. This was compared to existing ACGME duty hour policies. | **Mortality and complications**<br>The risk of death or serious complications did not differ significantly between patients who underwent surgery in hospitals with flexible policies and hospitals with standard policies (adjusted OR 0.96 [92% CI, 0.90 to 1.04]; p = 0.38). |
| Silber, 2019[67]<br><br>iCOMPARE Trial | RCT<br><br>Setting: General medicine<br><br>Population: Patients with Medicare claims | Implications of more flexible resident duty-hour rules with directors allowed to extend the work hour limits beyond 16 hours. This was compared to data from hospitals following the 2011 ACGME 16-hour limit on shift length. | **Mortality**<br>Change in 30-day mortality among the patients in the flexible programs (12.5% in the trial year vs. 12.6% in the pretrial year) was noninferior to that in the standard programs (12.2% in the trial year vs. 12.7% in the pretrial year). |

ACGME = Accreditation Council for Graduate Medical Education; CI = confidence interval; FIRST = Flexibility In Duty Hour Requirements for Surgical Trainees; ICU = intensive care unit; iCOMPARE=Individualized Comparative Effectiveness of Models Optimizing Patient Safety and Resident Education; IRR = incident rate ratio; OR = odds ratio; PCI = percutaneous coronary interventions; RCT = randomized controlled trial; RR = risk ratio; ROSTERS = Randomized Order Safety Trial Evaluating Resident-Physician Schedules study group; vs = versus

#### 3.2.5.1 Clinical Outcomes (Mortality, Complications, and Readmissions)

Evidence for the association between work schedule modifications and clinical outcomes is mixed. One review found that limiting all resident physicians to 80-hour work weeks and 28-hour shifts was associated with an 11 percent reduction in mortality ($p< 0.001$).[44] Similarly, another review focusing on nurses found evidence that working more than 40 hours a week had an adverse effect on patient outcomes (medication error odds ratio [OR] 1.28 [95% CI: 1.10 to 1.49]; infection OR 1.14 [95% CI: 1.02 to 1.28]), as did increased overtime (urinary tract infection OR 2.53 [95% CI: 1.66 to 3.86]; decubitus ulcer OR 1.91 [95% CI: 1.17 to 3.11]), or having insufficient time away between shifts (pneumonia mortality OR 1.24 [95% CI: 1.03 to 1.50]; abdominal aortic aneurysm mortality OR 1.39 [95% CI: 1.11 to 1.73]).[42] Supporting this, a meta-analysis revealed a significant weak association between extended duration shifts and increased patient mortality (OR 1.52 [95% CI: 0.75 to

3.07]).[38] Mixed results have been found between overtime and adverse patient outcomes,[42] as well as reduced resident duty-hours and patient outcomes (e.g., mortality, morbidity, adverse events).[45] Finally, several systematic reviews failed to find any association between shift modifications and patient outcomes. One review found no difference between sleep deprived versus non-sleep deprived surgeons, due to overnight work or extended shifts, in patient mortality or postoperative complications, and findings on intraoperative complications and length of stay were mixed.[40] In another, no significant association was identified between reduced shift length and length of stay.[43] Additionally, another systematic review found no differences in length of stay, readmission rates, mortality, or codes associated with night floats.[41]

Eight primary studies (three trials, and five observational studies) reported mortality, complications or readmissions outcomes, including three RCTs. One RCT randomized medical residents to one of three teams, one compliant with the 2003 Accreditation Council for Graduate Medical Education (AGCME) duty hour regulations, and one of two different models compliant with the 2011 requirements, one with an overnight call shift every fifth day (Q5) and one with a night float schedule.[59] There were no differences in 30-day readmission rates between shift conditions.[59] The cluster-randomized non-inferiority iCOMPARE (Individualized Comparative Effectiveness of Models Optimizing Patient Safety and Resident Education) trial, including 63 internal medicine residency programs, found no differences in patient mortality between standard and flexible scheduling. Flexible scheduling did not impose maximum shift durations or minimum time off between shifts.[67]

Additionally, the Flexibility In Duty Hour Requirements for Surgical Trainees (FIRST) trial, a large cluster randomized trial including 117 general surgery residency programs found that 'flexible' work hour systems were noninferior to the standard work hour systems compliant with ACGME policies in patient mortality or postoperative complications.[66] The flexible work hours intervention was required to maintain compliance with limitations of 80 total hours per week, 1 day off in 7, and on-call duty no more than every third night, but were not restricted on maximum shift length or minimum time off between shifts.

Five observational studies assessed the impact of work hours on patient outcomes. One study reported data from an intervention site in the FIRST trial described above, and, consistent with the overall study findings, found no differences in patient mortality for residents at their institution working under the flexible scheduling systems when compared to a representative national sample.[65] Another study found that patients in a general medicine service who were cared for by residents working more than 80 hours per week had increased length of stay and risk of ICU transfer, but not increased rates of mortality or 30-day readmission.[55]

Using data from the American College of Surgeons National Quality Improvement Program, one study used a difference in difference approach to compare changes in a composite of death or serious morbidity, and secondary outcomes of postoperative complications and resident examination performance in the two years

prior and following the 2011 ACGME duty hour restrictions.[61] Across 23 teaching hospitals and 31 nonteaching hospitals, the duty hour reform was not associated with differences in general surgery patient outcomes.

One retrospective study of adult medical patients compared a handoff group (i.e., patients discharged within 7 days after a change in resident physician team) and a control group (i.e., patients discharged the third week of a four-week resident rotation) both before and after the ACGME 2011 duty hour regulation was implemented.[60] Prior to the 2011 policy, mortality in the handoff group was significantly higher than in the control group; however, after the 2011 policy implementation, this difference lost significance.

Another study evaluated the impact of the 2017 ACGME policy relaxing extended shift restrictions on patient, intern, and resident perceptions as well as clinical outcomes (i.e., ICU transfers, length of stay, readmissions, mortality and complications).[37] There were no differences in patient satisfaction or clinical outcomes, however, interns reported being less satisfied and more fatigued and residents reported more incorrect intern orders in the extended work hours system.

One study found no difference in mortality for patients undergoing percutaneous coronary interventions performed by sleep deprived operators (defined as operators performing a case between 7 am and 11:59 pm as well as a case the preceding night, between 12 am and 6:59 am).[48]

#### 3.2.5.2 Specific Patient Safety Measures (Incidence of Medical Errors or Adverse Events)

Evidence connecting work shift modifications (e.g., limiting total hours, changes to on-call schedule, limiting consecutive nights worked) and patient safety (e.g., medical errors, near-misses) is mixed. Several systematic reviews found evidence that increased medical errors are associated with night shifts,[34, 40] and extended work shifts.[36,37] Specifically, medical errors were found to occur 12.1% more frequently during night or rotating shifts,[34] and risk of self-reported errors related to fatigue increased with more nights of work-related sleep disturbance (relative risk (RR) 1.25 [95% CI: 1.06 to 1.49]).[40] However, another systematic review found contradictory results, with one included primary study actually showing decreased diagnostic errors during night float.[41] Additionally, a meta-analysis found that extended-duration shifts were weakly associated with serious medical errors (OR 1.65 [95% CI: 1.06 to 2.58]).[38]

Limited shift durations and shorter work weeks were also found to be associated with improved patient safety in RCTs and observational studies.[44] However, other reviews found that duty hour restrictions had no association with serious medical errors[43] or on patient care.[41] Another review found mixed findings between overnight work and extended shifts with medical errors.[40] Furthermore, a review on extended-duty shifts suggested that they may cause both cognitive (e.g., attention lapses, visual tracking errors, worsened recall) and physical (e.g., decreased motor skills, increased time to react to changes) errors by clinicians.[39] Another review examining the impact

of surgical team sleep deprivation on cognitive performance found that sleep deprivation after 24 hour on-call periods is associated with an increase in errors and omissions.[35]

We identified 12 primary studies that evaluated work schedules and patient safety outcomes, including two RCTs reported in three articles. In the RCT of residents described above,[59] nurse and resident perceptions of care quality were lower in the Q5 and night float conditions, to such an extent that the study was terminated early due to safety concerns. In a pediatric ICU setting, Landrigan[63] found that a shift structure intervention (eliminating extended shifts and cycling resident physicians through day and night shifts of 16 hours or less) was associated with significantly more serious medical errors made by physicians (RR 1.53) and unit-wide medical errors made (RR 1.56) than the control condition (night shifts followed by approximately 24 hours off duty, and then two or three consecutive day shifts). This finding was contrary to expectations. However, there was wide variability in the effect across the six study sites, and a secondary analysis controlling for patient loads per resident found no difference in safety outcomes across shift conditions. Resident sleepiness and attentional failures for this study were reported in a second article[64], which showed the control extended-duration work roster was associated with a significantly higher number of attentional failures (6.8 failures per 10 minute neurobehavioral assessment compared to 2.9 in the rapid cycling roster), reaction time (18% higher in extended-duration roster), and subjective sleepiness (9% higher in extended-duration roster) than the rapidly cycling work roster.

Three studies of resident physicians evaluated shift structure on patient safety outcomes. One study[62] evaluated the impact of the 2011 ACGME policy change with a large national survey of resident physicians' perceptions of safety. They found this policy, which was rescinded in 2017, was associated with a 32% reduction in resident reported medical errors, 34% reduction in resident-reported preventable adverse events, and a 63% reduction in resident reported medical errors resulting in patient death. All differences were statistically significant.

Using the Agency for Healthcare Research Quality (AHRQ) National Inpatient Sample, one observational study[58] evaluated the impact of the 2003 ACGME duty hour restriction policy limiting residents to no more than 80-hour work weeks on hospital-acquired conditions. They found that patients in the two years following the year of the policy change were 10% more likely to experience a hospital-acquired condition than in the two years prior to the policy implementation. This effect was predominantly in teaching hospitals.

A large prospective cross-sectional survey of 4,826 post-graduate year 2 or greater resident physicians found that, when compared to working 40 hours a week or less, working greater than 48 hours per week was significantly associated with increased risk for self-reported medical errors, and preventable adverse events and fatal preventable adverse events (ORs 1.61, 1.54, and 0.66). In addition, working between 60 and 70 hours a week more than doubled the risk of preventable adverse events (OR 2.93), and fatal preventable adverse events (OR 2.75), compared to working 48 hours or less. Working one or more extended shifts a month while averaging no more than

80 hours per week was associated with increased risk of these outcomes as well when compared to working 48 hours or less in a week (OR for medical errors of 4.01, preventable adverse events 3.84, and fatal preventable adverse events 3.67).[56]

Three observational studies evaluated work hours for nurses and patient safety outcomes. One large cross-sectional survey of 3,710 pediatric nurses across 342 acute care hospitals[53] found that nurses working shifts greater than 13 hours reported significantly worse job outcomes (i.e., burnout, job satisfaction), and lower safety and quality of care for patients (i.e., nurse reported central line blood stream infections, urinary tract infections, patient complaints) than nurses who reported working shifts of 8 hours or less.

A retrospective study of 5,372 nurses triggering 420,706 near-miss medication alerts over the course of two years found that nurses working greater than 60 hours per week were more likely to trigger a near miss alert (4% weekly near-miss alert rate) compared to nurses working less than 60 hours (3% weekly near miss alert).[54]

Another study evaluated the impact of mandatory nursing overtime protection regulations and hours worked on adverse patient events, surveying nurses from a state which had protections in place (West Virginia) and one that did not (North Carolina).[52] Findings were mixed for the effect of mandatory overtime protection regulations, but when compared to nurses working 40 hours per week or less, nurses working more than 40 hours per week had increased risk of reporting involvement in adverse events (OR 14.36).[52]

Four studies evaluated clinician sleep and safety outcomes. One prospective observational study of 30 emergency department nurses found that lower quality of sleep measured through actigraphy immediately before a 12-hour shift was associated with more minor self-reported errors during the shift.[47] The amount of sleep was not associated with errors.

One observational study evaluated differences between surgeons who were sleep deprived (defined as more than 2 hours of nighttime clinical duties the night prior to a procedure) and those who were not; no differences in errors between groups were found, though errors were uncommon in both groups.[50]

Another observational study surveyed practicing neurointerventionalists and found that less than four hours of sleep was significantly related to more self-reported medical errors (OR 2.60).[49]

A survey of 1,215 first year residents found that sleep durations less than six hours and work hours exceeding 70 hours per week were both associated with increased likelihood of self-reported medical errors.[51] There was a significantly higher RR of self-reported medical errors for interns reporting short sleep duration (< 6 hours) at 3 months (1.3, $p = 0.03$) but a nonsignificant difference at 6 months. There was a significantly higher RR of self-reported medical errors for interns working 70 hours per week or more at both 3 and 6 months (RR 1.5, $p < 0.01$ and RR 1.4, $p = 0.01$, respectively).

#### 3.2.5.3 Risk Management Practices

Less than half of the included systematic reviews investigated risk management practices. Results on the impact of risk management practices on patient safety and outcomes are mixed. One review focusing on the ergonomic design of workstations found that increasing ambient lighting was associated with decreased detection and identification errors for radiologists.[37] Another found no direct effect between breaks and patient safety, but found that increased breaks are associated with less missed care (e.g., hand washing, turning a patient). This could be meaningful as they also found that missed care had a significant negative effect on patient safety (i.e., falls with injury and medication error).[42] However, another review found that protected time for brief sleep breaks (i.e., approximately 2 to 4 hours in duration) had no impact on patient care in a Veterans Affairs center or hospital settings.[41]

We identified no primary studies evaluating the impact of a fatigue risk management practice on outcomes of interest.

### 3.2.6 Question 6. What Are Common Barriers and Facilitators to Implementing the PSPs?

Three primary studies, but no systematic reviews, included information about barriers or facilitators. The RCT of work schedules for residents reported faculty barriers to implementing work schedules such as less time for teaching, increased burden to perform clinical duties, and the pressure to "get the resident out on time."[59] A qualitative interview study of nurses found a wide range of barriers that aggravated fatigue including barriers at work (i.e., workload, shift structures [i.e., multiple shifts in a row, night shifts, 12-hour shifts, rotating shifts, and staying late], slowing down across a shift, and eating during a shift), and at home (i.e., not getting enough sleep, and competing demands).[68]

Two studies mentioned training programs for effective handoffs[60,61] and hiring midlevel support staff[61] as facilitators to safe continuity of care with implementation of shorter shift lengths.

### 3.2.7 Question 7. What Resources (e.g., cost, staff, time) Are Required for Implementation?

No primary studies or systematic reviews included information about resources required to support implementation. A recent scoping review of the economic benefits and costs associated with nonstandard work hours (i.e., shiftwork and long shift durations) across industries found that cost analysis of these issues is generally absent from the literature and an important research need.[69]

### 3.2.8 Question 8. What Toolkits Are Available To Support Implementation of the PSPs?

No systematic reviews included information about toolkits to support implementation of PSPs targeting risks of clinician fatigue and sleepiness due to work hours. Several online resources for learning more about work and fatigue and potential interventions were identified.

- The *National Institute of Occupational Safety and Health (NIOSH)* maintains a web resource on work and fatigue outlining their research and learning resources.[70]
- The *Canadian Fatigue Risk Management Taskforce* maintains a comprehensive toolkit of strategies for healthcare workers.[71]

# 4. Discussion

## 4.1 Interpretation of Findings

This rapid response identified 12 systematic reviews and 20 primary studies (reported in 21 articles) evaluating a patient safety practice (PSP) targeting patient harms associated with clinician fatigue and sleepiness due to long work hours. Consistent with the previous Making Healthcare Safer (MHS) II brief review on this topic, research on PSPs related to reducing the risks associated with clinician fatigue and sleepiness due to work hours continues to focus primarily on shift scheduling in physician trainee populations. All identified randomized controlled trials (RCTs) involved evaluating the impact of shift schedules compliant with different versions of the Accreditation Council for Graduate Medical Education (ACGME) duty hour regulations, and 7 of the observational studies also evaluated the impact of these policy changes. Studies involving practicing nurses or physicians were all observational.

Also consistent with MHS II, the evidence surrounding PSPs for mitigating the risks of fatigue and sleepiness due to duty hours remains mixed. The three RCTs on resident duty hour limitations included in this review generated conflicting findings. While the RCT for internal medicine residents found no difference in 30-day patient readmissions, self-reported patient safety was sufficiently lower in the two duty hour restricted conditions that they were terminated early (i.e., the study was halted due to safety concerns).[59]

Two large cluster-randomized trials, one in internal medicine and one in general surgery residency programs, found a flexible scheduling system (which did not impose maximum shift durations or time off between shifts) to be non-inferior to scheduling systems compliant with the ACGME 2011 regulations.[72] However, a trial in general surgery programs has been criticized on both ethical and methodological grounds.[73] Specifically, one interpretation of the meaning of the non-inferiority findings is that the ACGME should loosen regulations and give programs more discretion in flexibility, while others take the noninferiority to be evidence that the suspected risks of reduced continuity of care from reduced shift lengths is not meaningful.[73]

Findings from the RCT in pediatric residents[63,64] first found that duty hour restricted scheduling systems had worse safety outcomes. However, follow-on analyses clearly demonstrated that the effects of fatigue on patient safety were not solely due to the amount of hours worked but to the intensity of workload experienced during those work hours.

Given the heterogeneity of findings, the ACGME duty hour policies remain contentious. Two prominent criticisms of the duty hour restrictions have been that they reduce educational opportunities for trainee physicians, and that they reduce continuity of care by increasing the number of patient handoffs as shorter shifts require more handoffs between clinicians.[10] One included study showed decreased educational opportunities in duty hour restricted systems.[59] However, research has directly examined differences for physicians who trained under duty hour restricted systems

and those who did not. No differences in patient complications[74] or mortality[75] were found for surgeons, though patients with surgeons who trained under duty hour restrictions did have longer length of stay, anesthesia time and increased cost.[75] No differences in mortality, readmissions, length of stay or cost was found for internists who trained under duty hour restrictions and those who did not.[75-77,45] One included primary study evaluated handoffs during resident team rotations prior to and after implementation of work hour restrictions and found that resident team transitions elevated risk of patient mortality, but this risk was significantly lower after the restrictions were in place.[60]

The literature remains sparse on fatigue risk management practices beyond modifying work schedules. No primary studies were identified, and only three interventions (i.e., lighting, breaks, and naps) were mentioned in systematic reviews, each with a focus in only one study. Lighting and breaks showed beneficial effects, but brief protected time for sleep was not related to patient care outcomes. Given the complexity of shift scheduling, the mixed findings to date, and the paucity of research linking risk mitigation PSPs to safety outcomes, more research is needed in this area.

## 4.2 Limitations

We discuss limitations of the rapid response methods employed here as well as the literature on PSPs targeting clinician fatigue and sleepiness. First, rapid responses use streamlined processes to complete the effort in a short timeline. We only included primary studies and systematic reviews published between January 2013 and September 2023 that reported data on the impact of an intervention or strategy related to work hours on patient outcomes. Additionally, this rapid response report only focuses on acute care settings and studies based in the United States, which limits the generalizability to other settings and countries.

Findings from this rapid response revealed that there are several limitations to the literature on this topic, including a lack of evaluation of the impact of risk management practices on patient outcomes, inconsistent terminology, heterogeneity in both interventions and outcomes across studies, as well as the reliance on observational research making it difficult to draw strong conclusions from the literature. Information regarding the facilitators and barriers for the interventions and strategies identified is limited. Additionally, no primary study or review provided resources or toolkits for implementing these interventions.

This rapid response did not cover healthcare worker outcomes such as burnout or wellness or organizational outcomes like employee retention. This is important given overall concerns about the wellness of the healthcare workforce. Recent research from the World Health Organization and the International Labor Organization identified an increased risk of ischemic heart disease and stroke associated with working more than 55 hours a week.[78,79]

## 4.3 Implications and Conclusions

The inconsistent findings from this body of research make it difficult to determine the most appropriate evidence-based policies for mitigating the risk of patient harm from clinician fatigue and sleepiness due to long work hours. Research remains inconsistent on the ability of PSPs to mitigate the risks of patient harm from clinician fatigue and sleepiness due to long work hours. Most studies focused on the resident physician population and work hour interventions. Higher quality studies are needed, particularly for practicing clinicians. Increased healthcare consolidation and shifts in employment models (i.e., more hospital employed physicians) may enable larger prospective studies of scheduling and fatigue risk mitigation strategies. Additionally, research is needed to develop fatigue risk management interventions beyond work hour restrictions or changes in shift structure. A recent Delphi study prioritized research needs for reducing risks of fatigue due to long work hours in the healthcare setting and identified developing better designs for work schedules and improving culture and leadership approaches to shift work and long work hours as the highest priority.[80]

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# Disclaimers

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The information in this report is intended to help healthcare decision makers—patients and clinicians, health system leaders, and policymakers, among others—make well-informed decisions and thereby improve the quality of healthcare services. This report is not intended to be a substitute for the application of clinical judgment. Anyone who makes decisions concerning the provision of clinical care should consider this report in the same way as any medical reference and in conjunction with all other pertinent information, i.e., in the context of available resources and circumstances presented by individual patients.



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# Afterword

Recognized for excellence in conducting comprehensive systematic reviews, the Agency for Healthcare Research and Quality (AHRQ) Evidence-based Practice Center (EPC) Program is developing a range of rapid evidence products to assist end-users in making specific decisions in a limited timeframe. AHRQ recognizes that people are struggling with urgent questions on how to make healthcare safer. AHRQ is using this rapid format for the fourth edition of its Making Healthcare Safer series of reports, produced by the EPC Program and the General Patient Safety Program. To shorten timelines, reviewers make strategic choices about which processes to abridge. However, the adaptations made for expediency may limit the certainty and generalizability of the findings from the review, particularly in areas with a large literature base. Transparent reporting of the methods used and the resulting limitations of the evidence synthesis are extremely important.

AHRQ expects that these rapid evidence products will be helpful to health plans, providers, purchasers, government programs, and the healthcare system as a whole. Transparency and stakeholder input are essential to AHRQ. If you have comments related to this report, they may be sent by mail to the Task Order Officer named below at: Agency for Healthcare Research and Quality, 5600 Fishers Lane, Rockville, MD 20857, or by email to MHS@ahrq.hhs.gov.


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# Appendixes

## Appendix A. Methods

## Search Strategies for Published Literature

**Table A-1. PubMed search strategy**

| # | Concept | Search Terms |
|---|---|---|
| 1 | Population | "Medical Staff, Hospital"[mh] OR "Physicians"[mh] OR "hospital medical staff" [tiab] OR physician[tiab] OR physicians[tiab] OR clinician[tiab] OR clinicians[tiab] OR "health care providers"[tiab] OR "healthcare providers"[tiab]OR "health professional"[tiab] OR "health professionals"[tiab] OR "health provider"[tiab] OR "health providers"[tiab] OR "healthcare professional"[tiab] OR "health care professional"[tiab] OR hospitalist[tiab] OR hospitalists[tiab] OR "house staff"[tiab] OR "house staffs"[tiab] OR doctor [tiab] OR doctors [tiab] OR "healthcare workers"[tiab] OR "healthcare staff" [tiab] OR nurse [tiab] OR nurses [tiab] OR surgeons[tiab] |
| 2 | Fatigue and sleep | "duty hour"[tiab] OR "duty hours"[tiab] OR "Work Schedule Tolerance"[mh] OR "Shift Work Schedule" [mh] OR "work hours"[tiab] OR "working hours"[tiab] OR "shift work"[tiab] OR "work shift" [tiab] OR "work shifts" [tiab] OR "shift patterns"[tiab] OR "shift duration"[tiab] OR "service hour"[tiab] OR "service hours"[tiab] OR "shift rotation" [tiab] OR "shift rotations"[tiab] OR "Fatigue management" [tiab] OR "Fatigue risk" [tiab] OR "fatigue monitoring"[tiab] OR "fatigue reporting"[tiab] OR "Sleep hygiene" [tiab] OR napping [tiab] OR "workplace lighting"[tiab] OR "fatigue interventions" [tiab] OR "fatigue intervention" [tiab] OR "Sleep depriv*"[tiab] OR "Sleep Deprivation" [mh] OR "sleep patterns" [tiab] OR sleep [mh] OR "sleep management"[tiab] OR "fatigue self-management" [tiab] OR "Managing Fatigue" [tiab] OR stimulant [tiab] OR stimulants [tiab] OR caffeine [tiab] OR caffeine [mh] OR "pharmacologic interventions" [tiab] |
| 3 | Patient safety and harm | "patient safety"[mh] OR "patient safety" [tiab] OR "Patient Harm"[mh] OR "Patient Harm*"[tiab] OR "patient risk*"[tiab] OR "quality of care" [tiab] OR "adverse event*"[tiab] OR "undesired event*"[tiab] OR "medical errors"[mh] OR "medical error*"[tiab] OR "Diagnostic Errors" [mh] OR "diagnostic error*"[tiab] OR "diagnostic mistake*"[tiab] OR "health care error*"[tiab] OR "healthcare error*"[tiab] OR "medical fault*"[tiab] OR "medical mistake*"[tiab] OR "erroneous diagnos*"[tiab] OR "failure to diagnose"[tiab] OR "false diagnos*"[tiab] OR "faulty diagnos*"[tiab] OR misdiagnos*[tiab] OR "mistaken diagnos*"[tiab] OR "wrong diagnos*"[tiab] OR "well being"[tiab] OR wellbeing[tiab] OR wellness[tiab] OR satisfaction [tiab] OR complication [tiab] OR complications [tiab] OR mortality [tiab] OR coping [tiab] OR distress[tiab] OR distressed[tiab] OR distresses[tiab] OR distressing[tiab] OR injury [tiab] OR injuries [tiab] OR "work life balance"[tiab] OR "Work Health and Safety" [tiab] OR accident [tiab] OR accident [mh] OR exhaustion[tiab] OR "safety management" [tiab] OR "safety management" [mh] OR "burned out"[tiab] OR "burn out"[tiab] OR "burn outs"[tiab] OR burnout[tiab] OR burnouts[tiab] OR "burnt out"[tiab] OR "adverse effects" [tiab] OR exhausted[tiab] OR exhaustion[tiab] OR exhausting[tiab] OR exhausts[tiab] |
| 4 | | 1 AND 2 AND 3 |
| 5 | Pubmed filter | Publication date 2013 – September 18th, 2023] |

| # | Concept | Search Terms |
|---|---|---|
| 6 | Exclude | (“Animals”[Mesh] NOT “Humans”[Mesh]) OR address[pt] OR “autobiography”[pt] OR “bibliography”[pt] OR “biography”[pt] OR congress[pt] OR “dictionary”[pt] OR “directory”[pt] OR “festschrift”[pt] OR “historical article”[pt] OR lecture[pt] OR “legal case”[pt] OR “legislation”[pt] OR “periodical index”[pt] OR Comment[pt] OR Letter[pt] OR Editorial[pt] OR “news”[pt] OR “newspaper article”[pt] OR “patient education handout”[pt] OR “periodical index”[pt] OR “study guide”[pt] OR “Study protocol” [ti] OR “trial protocol” [ti] OR “review protocol” [ti] OR editorial[pt] OR letter[pt] OR “case reports”[pt]OR rats[tw] OR cow[tw] OR cows[tw] OR chicken[tw] OR chickens[tw] OR horse[tw] OR horses[tw] OR mice[tw] OR mouse[tw] OR bovine[tw] OR sheep[tw] OR ovine [tw] OR murine[tw] OR “environmental scan”[ti] |

**Table A-2. Cochrane search strategy**

| # | Concept | Search Terms |
|---|---|---|
| 1 | Population | "Medical Staff, Hospital"[mh] OR "Physicians"[mh] OR ("hospital medical staff" OR physician OR physicians OR clinician OR clinicians OR "health care providers" OR "healthcare providers" OR "health professional" OR "health professionals" OR "health provider" OR "health providers" OR "healthcare professional" OR "health care professional" OR hospitalist OR hospitalists OR "house staff" OR "house staffs" OR doctor OR doctors OR "healthcare workers" OR "healthcare staff" OR nurse OR nurses OR surgeons):ti OR ("hospital medical staff" OR physician OR physicians OR clinician OR clinicians OR "health care providers" OR "healthcare providers" OR "health professional" OR "health professionals" OR "health provider" OR "health providers" OR "healthcare professional" OR "health care professional" OR hospitalist OR hospitalists OR "house staff" OR "house staffs" OR doctor OR doctors OR "healthcare workers" OR "healthcare staff" OR nurse OR nurses OR surgeons):ab |
| 2 | Fatigue and sleep | "Work Schedule Tolerance"[mh] OR "Shift Work Schedule"[mh] OR "Sleep Deprivation"[mh] OR sleep[mh] OR caffeine[mh] OR ("duty hour" OR "duty hours" OR "work hours" OR "working hours" OR "shift work" OR "work shift" OR "work shifts" OR "shift patterns" OR "shift duration" OR "service hour" OR "service hours" OR "shift rotation" OR "shift rotations" OR "Fatigue management" OR "Fatigue risk" OR "fatigue monitoring" OR "fatigue reporting" OR "Sleep hygiene" OR napping OR "workplace lighting" OR "fatigue interventions" OR "fatigue intervention" OR "sleep patterns" OR "sleep management" OR "fatigue self-management" OR "Managing Fatigue" OR stimulant OR stimulants OR caffeine OR "pharmacologic interventions" OR "sleep deprive" OR "sleep deprived"):ti OR ("duty hour" OR "duty hours" OR "work hours" OR "working hours" OR "shift work" OR "work shift" OR "work shifts" OR "shift patterns" OR "shift duration" OR "service hour" OR "service hours" OR "shift rotation" OR "shift rotations" OR "Fatigue management" OR "Fatigue risk" OR "fatigue monitoring" OR "fatigue reporting" OR "Sleep hygiene" OR napping OR "workplace lighting" OR "fatigue interventions" OR "fatigue intervention" OR "sleep patterns" OR "sleep management" OR "fatigue self-management" OR "Managing Fatigue" OR stimulant OR stimulants OR caffeine OR "pharmacologic interventions" OR "sleep deprive" OR "sleep deprived"):ab OR |

| # | Concept | Search Terms |
|---|---|---|
| 3 | Patient safety and harm | "patient safety"[mh] OR "Patient Harm"[mh] OR "medical errors"[mh] OR "Diagnostic Errors"[mh] OR accident[mh] OR "safety management"[mh] OR ("patient safety" OR "patient harm" OR "patient harms" OR "patient risk" OR "patient risks" OR "quality of care" OR "adverse event" OR "adverse events" OR "undesired event" OR "undesired events" OR "medical error" OR "medical errors" OR "diagnostic error" OR "diagnostic errors" OR "diagnostic mistake" OR "diagnostic mistakes" OR "health care error" OR "health care errors" OR "healthcare error" OR "healthcare errors" OR "medical fault" OR "medical faults" OR "medical mistake" OR "medical mistakes" OR "erroneous diagnose" OR "erroneous diagnoses" OR "failure to diagnose" OR "false diagnose" OR "false diagnoses" OR "faulty diagnose" OR "faulty diagnoses" OR misdiagnose OR misdiagnoses OR "mistaken diagnose" OR "mistaken diagnoses" OR "wrong diagnose" OR "wrong diagnoses" OR "well being" OR wellbeing OR wellness OR satisfaction OR complication OR complications OR mortality OR coping OR distress OR distressed OR distresses OR distressing OR injury OR injuries OR "work life balance" OR "work health and safety" OR accident OR exhaustion OR "safety management" OR "burned out" OR "burn out" OR "burn outs" OR burnout OR burnouts OR "burnt out" OR "adverse effects" OR exhausted OR exhaustion OR exhausting OR exhausts):ti OR ("patient safety" OR "patient harm" OR "patient harms" OR "patient risk" OR "patient risks" OR "quality of care" OR "adverse event" OR "adverse events" OR "undesired event" OR "undesired events" OR "medical error" OR "medical errors" OR "diagnostic error" OR "diagnostic errors" OR "diagnostic mistake" OR "diagnostic mistakes" OR "health care error" OR "health care errors" OR "healthcare error" OR "healthcare errors" OR "medical fault" OR "medical faults" OR "medical mistake" OR "medical mistakes" OR "erroneous diagnose" OR "erroneous diagnoses" OR "failure to diagnose" OR "false diagnose" OR "false diagnoses" OR "faulty diagnose" OR "faulty diagnoses" OR misdiagnose OR misdiagnoses OR "mistaken diagnose" OR "mistaken diagnoses" OR "wrong diagnose" OR "wrong diagnoses" OR "well being" OR wellbeing OR wellness OR satisfaction OR complication OR complications OR mortality OR coping OR distress OR distressed OR distresses OR distressing OR injury OR injuries OR "work life balance" OR "work health and safety" OR accident OR exhaustion OR "safety management" OR "burned out" OR "burn out" OR "burn outs" OR burnout OR burnouts OR "burnt out" OR "adverse effects" OR exhausted OR exhaustion OR exhausting OR exhausts):ab |
| 4. | | 1 AND 2 AND 3 |
| 5 | Cochrane filter | Publication date 2013 – September 18, 2023 |
| 6 | Exclude | ("Animals"[Mesh] NOT "Humans"[Mesh]) OR (address OR autobiography OR bibliography OR biography OR congress OR dictionary OR directory OR festschrift OR "historical article" OR lecture OR "legal case" OR legislation OR periodical index OR comment OR letter OR editorial OR news OR "newspaper article" OR "patient education handout" OR "periodical index" OR "study guide" OR editorial OR letter OR "case report"):pt OR ("study protocol" OR "environmental scan" OR "trial protocol" OR "review protocol"):ti OR (rats OR cow OR cows OR chicken OR chickens OR horse OR horses OR mice OR mouse OR bovine OR sheep OR ovine OR murine):kw OR |

# Appendix B. List of Excluded Studies Upon Full-Text Review

1. Abera H, Hunt M, Levin JH. Sleep Deprivation, Burnout, and Acute Care Surgery. Curr Trauma Rep. 2023;9(2):40-6. doi: 10.1007/s40719-023-00253-9. PMID: 36721843. - **Narrative or scoping review**
2. Actrn. Sleep health management for healthcare workers. http://www.who.int/trialsearch/Trial2.aspx?TrialID=ACTRN12616000369426. 2016 PMID: CN-02440080. - **No original data**
3. Alexander R, Waite S, Bruno MA, et al. Mandating Limits on Workload, Duty, and Speed in Radiology. Radiology. 2022 Aug;304(2):274-82. doi: 10.1148/radiol.212631. PMID: 35699581. - **Narrative or scoping review**
4. Alfonsi V, Scarpelli S, Gorgoni M, et al. Healthcare Workers after Two Years of COVID-19: The Consequences of the Pandemic on Psychological Health and Sleep among Nurses and Physicians. Int J Environ Res Public Health. 2023 Jan 12;20(2)doi: 10.3390/ijerph20021410. PMID: 36674167. - **Does not address fatigue and sleepiness of clinicians related to hours of service**
5. Alfonsi V, Scarpelli S, Gorgoni M, et al. Sleep-Related Problems in Night Shift Nurses: Towards an Individualized Interventional Practice. Front Hum Neurosci. 2021;15:644570. doi: 10.3389/fnhum.2021.644570. PMID: 33796014. - **Narrative or scoping review**
6. Al-Hammouri MM, Rababah JA. Work family conflict, family work conflicts and work-related quality of life: The effect of rotating versus fixed shifts. J Clin Nurs. 2023 Aug;32(15-16):4887-93. doi: 10.1111/jocn.16581. PMID: 36369607. - **Non-US study**
7. Al-Kofahi M, Mohyuddin GR, Taylor ME, et al. Reducing Resident Physician Workload to Improve Well Being. Cureus. 2019 Jun 29;11(6):e5039. doi: 10.7759/cureus.5039. PMID: 31501731. - **No outcome of interest**
8. Amirian I, Andersen LT, Rosenberg J, et al. Working night shifts affects surgeons' biological rhythm. Am J Surg. 2015 Aug;210(2):389-95. doi: 10.1016/j.amjsurg.2014.09.035. PMID: 25678472. - **Non-US study**
9. An R, Li C, Ai S, et al. Effect of shift work on fatigue, reaction time and accuracy of nurses in the Department of Neurology: A cross-sectional observational study. J Nurs Manag. 2022 Sep;30(6):2074-83. doi: 10.1111/jonm.13665. PMID: 35510385. - **Non-US study**
10. Anagnostopoulos F, Demerouti E, Sykioti P, et al. Factors associated with mental health status of medical residents: a model-guided study. J Clin Psychol Med Settings. 2015 Mar;22(1):90-109. doi: 10.1007/s10880-014-9415-2. PMID: 25554496. - **No concurrent or historical comparison groups**
11. Anderson C, Ftouni S, Ronda JM, et al. Self-reported Drowsiness and Safety Outcomes While Driving After an Extended Duration Work Shift in Trainee Physicians. Sleep. 2018 Feb 1;41(2)doi: 10.1093/sleep/zsx195. PMID: 29281091. - **No outcome of interest**
12. Angerer P, Schmook R, Elfantel I, et al. Night Work and the Risk of Depression. Dtsch Arztebl Int. 2017 Jul 16;114(24):404-11. doi: 10.3238/arztebl.2017.0404. PMID: 28669378. - **No outcome of interest**
13. Arbour MW, Gordon IK, Saftner M, et al. The experience of sleep deprivation for midwives practicing in the united states. Midwifery. 2020 Oct;89:102782. doi: 10.1016/j.midw.2020.102782. PMID: 32554134. - **Qualitative study with no quantitative data**
14. Arzalier-Daret S, Buléon C, Bocca ML, et al. Effect of sleep deprivation after a night shift duty on simulated crisis management by residents in anaesthesia. A randomised crossover study. Anaesth Crit Care Pain Med. 2018 Apr;37(2):161-6. doi: 10.1016/j.accpm.2017.05.010. PMID: 28882740. - **Non-US study**
15. Asaoka S, Aritake S, Komada Y, et al. Factors associated with shift work disorder

in nurses working with rapid-rotation schedules in Japan: the nurses' sleep health project. Chronobiol Int. 2013 May;30(4):628-36. doi: 10.3109/07420528.2012.762010. PMID: 23445510. - **Non-US study**

16. Asfour L, Asfour V, McCormack D, et al. In surgeons performing cardiothoracic surgery is sleep deprivation significant in its impact on morbidity or mortality? Interact Cardiovasc Thorac Surg. 2014 Sep;19(3):479-87. doi: 10.1093/icvts/ivu118. PMID: 24879643. - **Narrative or scoping review**
17. Assaye AM, Wiechula R, Schultz TJ, et al. Impact of nurse staffing on patient and nurse workforce outcomes in acute care settings in low- and middle-income countries: a systematic review. JBI Evid Synth. 2021 Apr;19(4):751-93. doi: 10.11124/jbisrir-d-19-00426. PMID: 32881732. - **Non-US studies**
18. Asta ML, Lo Presti S, Pasetti P, et al. [Relation between sleep deprivation and nursing errors during the night shift]. Prof Inferm. 2022 Jul 1;75(2):101-5. doi: 10.7429/pi.2022.752101. PMID: 36964920. **- Not written in English**
19. Ayas NT, Jeklin AT, Tholin H, et al. Consecutive nursing shifts and the risk of hypoglycemia in critically ill patients who are receiving intravenous insulin: a multicenter study. J Clin Sleep Med. 2020 Jun 15;16(6):949-53. doi: 10.5664/jcsm.8382. PMID: 32065114. - **Non-US study**
20. Aydin Guclu O, Karadag M, Akkoyunlu ME, et al. Association between burnout, anxiety and insomnia in healthcare workers: a cross-sectional study. Psychol Health Med. 2022 Jun;27(5):1117-30. doi: 10.1080/13548506.2021.1874434. PMID: 33486992. **- Non-US study**
21. Babu R, Thomas S, Hazzard MA, et al. Worse outcomes for patients undergoing brain tumor and cerebrovascular procedures following the ACGME resident duty-hour restrictions. J Neurosurg. 2014 Aug;121(2):262-76. doi: 10.3171/2014.5.jns1314. PMID: 24926647. **- Narrative or scoping review**
22. Bakhru RN, Basner M, Ecker A, et al. The effects of nocturnal in-hospital intensivist coverage on sleep, work and behavioral alertness in faculty and fellows. American journal of respiratory and critical care medicine. 2013;187 PMID: CN-01091785. - **Conference/meeting abstract/poster**
23. Bakhru RN, Basner M, Kerlin MP, et al. Sleep and Work in ICU Physicians During a Randomized Trial of Nighttime Intensivist Staffing. Crit Care Med. 2019 Jul;47(7):894-902. doi: 10.1097/ccm.0000000000003773. PMID: 30985450. **- No outcome of interest**
24. Ball J, Day T, Murrells T, et al. Cross-sectional examination of the association between shift length and hospital nurses job satisfaction and nurse reported quality measures. BMC Nurs. 2017;16:26. doi: 10.1186/s12912-017-0221-7. PMID: 28559745. **- Non-US study**
25. Barger LK, Sullivan JP, Blackwell T, et al. Effects on resident work hours, sleep duration, and work experience in a randomized order safety trial evaluating resident-physician schedules (ROSTERS). Sleep. 2019 Aug 1;42(8)doi: 10.1093/sleep/zsz110. PMID: 31106381. - **No outcome of interest**
26. Bari A, Khan RA, Rathore AW. Medical errors; causes, consequences, emotional response and resulting behavioral change. Pak J Med Sci. 2016 May-Jun;32(3):523-8. doi: 10.12669/pjms.323.9701. PMID: 27375682. **- No concurrent or historical comparison groups**
27. Bashir K, Elsotohy HH, Elmoheen A. Do Night Shifts Increase the Risk of Benign Paroxysmal Positional Vertigo Among Doctors and Nurses? J Multidiscip Healthc. 2020;13:963-6. doi: 10.2147/jmdh.s256055. PMID: 32982272. **- Non-US study**
28. Basner M, Dinges DF, Shea JA, et al. Sleep and Alertness in Medical Interns and Residents: An Observational Study on the Role of Extended Shifts. Sleep. 2017 Apr 1;40(4)doi: 10.1093/sleep/zsx027. PMID: 28329124. **- No outcome of interest**
29. Beebe D, Chang JJ, Kress K, et al. Diet quality and sleep quality among day and night shift nurses. J Nurs Manag. 2017

Oct;25(7):549-57. doi: 10.1111/jonm.12492. PMID: 28695685. - **Does not address fatigue and sleepiness of clinicians related to hours of service**

30. Bell T, Sprajcer M, Flenady T, et al. Fatigue in nurses and medication administration errors: A scoping review. J Clin Nurs. 2023 Sep;32(17-18):5445-60. doi: 10.1111/jocn.16620. PMID: 36707921. - **Narrative or scoping review**
31. Berastegui P, Jaspar M, Ghuysen A, et al. Fatigue-related risk perception among emergency physicians working extended shifts. Appl Ergon. 2020 Jan;82:102914. doi: 10.1016/j.apergo.2019.102914. PMID: 31422293. - **Non-US study**
32. Bihari S, Venkatapathy A, Prakash S, et al. ICU shift related effects on sleep, fatigue and alertness levels. Occup Med (Lond). 2020 Apr 20;70(2):107-12. doi: 10.1093/occmed/kqaa013. PMID: 31974569. - **Non-US study**
33. Blackwell T, Kriesel DR, Vittinghoff E, et al. Design and recruitment of the randomized order safety trial evaluating resident-physician schedules (ROSTERS) study. Contemp Clin Trials. 2019 May;80:22-33. doi: 10.1016/j.cct.2019.03.005. PMID: 30885799. - **No outcome of interest**
34. Blasche G, Pasalic S, Bauböck VM, et al. Effects of Rest-Break Intention on Rest-Break Frequency and Work-Related Fatigue. Hum Factors. 2017 Mar;59(2):289-98. doi: 10.1177/0018720816671605. PMID: 27760865. - **Other: Mixed population**
35. Blouin AS, Smith-Miller CA, Harden J, et al. Caregiver Fatigue: Implications for Patient and Staff Safety, Part 1. J Nurs Adm. 2016 Jun;46(6):329-35. doi: 10.1097/nna.0000000000000353. PMID: 27214335. - **Does not include clinicians in an acute care setting**
36. Bogossian F, Winters-Chang P, Tuckett A. "The pure hard slog that nursing is..": a qualitative analysis of nursing work. J Nurs Scholarsh. 2014 Sep;46(5):377-88. doi: 10.1111/jnu.12090. PMID: 25163354. - **Qualitative study with no quantitative data**
37. Booker LA, Sletten TL, Barnes M, et al. The effectiveness of an individualized sleep and shift work education and coaching program to manage shift work disorder in nurses: a randomized controlled trial. J Clin Sleep Med. 2022 Apr 1;18(4):1035-45. doi: 10.5664/jcsm.9782. PMID: 34870586. - **Non-US study**
38. Bordley J, Agustin AG, Ahmed MA, et al. Restoration of resident sleep and wellness with block scheduling. Med Educ. 2017 Dec;51(12):1241-9. doi: 10.1111/medu.13392. PMID: 28971499. - **No outcome of interest**
39. Brainch N, Schule P, Laurel F, et al. Psychiatric Emergency Services - Can Duty-Hour Changes Help Residents and Patients? Psychiatr Q. 2018 Dec;89(4):771-8. doi: 10.1007/s11126-018-9579-2. PMID: 29654393. - **No outcome of interest**
40. Breaux J, McLendon R, Stedman RB, et al. Developing a Standardized and Sustainable Resident Sign-Out Process: An AIAMC National Initiative IV Project. Ochsner J. 2014 Winter;14(4):563-8. PMID: 25598721. - **Does not include clinicians in an acute care setting**
41. Brown C, Abdelrahman T, Lewis W, et al. To bed or not to bed: the sleep question? Postgrad Med J. 2020 Sep;96(1139):520-4. doi: 10.1136/postgradmedj-2018-135795. PMID: 31874910. - **Non-US study**
42. Brum MCB, Dantas Filho FF, Schnorr CC, et al. Night shift work, short sleep and obesity. Diabetol Metab Syndr. 2020;12:13. doi: 10.1186/s13098-020-0524-9. PMID: 32064002. - **Non-US study**
43. Buchvold HV, Pallesen S, Waage S, et al. Shift Work and Lifestyle Factors: A 6-Year Follow-Up Study Among Nurses. Front Public Health. 2019;7:281. doi: 10.3389/fpubh.2019.00281. PMID: 31750282. - **No outcome of interest**
44. Burchiel KJ, Zetterman RK, Ludmerer KM, et al. The 2017 ACGME Common Work Hour Standards: Promoting Physician Learning and Professional Development in a Safe, Humane Environment. J Grad Med Educ. 2017 Dec;9(6):692-6. doi:

10.4300/jgme-d-17-00317.1. PMID: 29270256. - **Narrative or scoping review**

45. Busireddy KR, Miller JA, Ellison K, et al. Efficacy of Interventions to Reduce Resident Physician Burnout: A Systematic Review. J Grad Med Educ. 2017 Jun;9(3):294-301. doi: 10.4300/jgme-d-16-00372.1. PMID: 28638506. - **No outcome of interest**

46. Cappadona R, De Giorgi A, Boari B, et al. Nurses, sleep disturbances, desynchronization of circadian rhythms, and performance: a dangerous liaison? A narrative mini-review. Eur Rev Med Pharmacol Sci. 2021 Nov;25(22):6924-33. doi: 10.26355/eurrev_202111_27241. PMID: 34859854. - **Narrative or scoping review**

47. Carr MM, Friedel JE, Foreman AM, et al. Perceptions of Safety Climate and Fatigue Related to ACGME Residency Duty Hour Restrictions in Otolaryngology Residents. Otolaryngol Head Neck Surg. 2022 Jan;166(1):86-92. doi: 10.1177/01945998211010108. PMID: 33940962. - **No concurrent or historical comparison groups**

48. Caruso CC. Negative impacts of shiftwork and long work hours. Rehabil Nurs. 2014 Jan-Feb;39(1):16-25. doi: 10.1002/rnj.107. PMID: 23780784. - **Narrative or scoping review**

49. Centofanti S, Banks S, Colella A, et al. Coping with shift work-related circadian disruption: A mixed-methods case study on napping and caffeine use in Australian nurses and midwives. Chronobiol Int. 2018 Jun;35(6):853-64. doi: 10.1080/07420528.2018.1466798. PMID: 29764218. - **Non-US study**

50. Chaiard J, Deeluea J, Suksatit B, et al. Short sleep duration among Thai nurses: Influences on fatigue, daytime sleepiness, and occupational errors. J Occup Health. 2018 Sep 26;60(5):348-55. doi: 10.1539/joh.2017-0258-OA. PMID: 29743391. - **Non-US study**

51. Chang WP, Peng YX. Differences between fixed day shift nurses and rotating and irregular shift nurses in work-related musculoskeletal disorders: A literature review and meta-analysis. J Occup Health. 2021 Jan;63(1):e12208. doi: 10.1002/1348-9585.12208. PMID: 33682989. - **No outcome of interest**

52. Chong MYF, Lin SHX, Lim WY, et al. Burnout in anaesthesiology residents: A systematic review of its prevalence and stressors. Eur J Anaesthesiol. 2022 Apr 1;39(4):368-77. doi: 10.1097/eja.0000000000001585. PMID: 34397509. - **No outcome of interest**

53. Choshen-Hillel S, Ishqer A, Mahameed F, et al. Acute and chronic sleep deprivation in residents: Cognition and stress biomarkers. Med Educ. 2021 Feb;55(2):174-84. doi: 10.1111/medu.14296. PMID: 32697336. - **Non-US study**

54. Cochran KR. An Examination of Work Characteristics, Fatigue, and Recovery Among Acute Care Nurses. J Nurs Adm. 2021 Feb 1;51(2):89-94. doi: 10.1097/nna.0000000000000975. PMID: 33449598. - **No outcome of interest**

55. Coffyn S, Siengsukon CF. Poor Sleep Hygiene is Associated with Decreased Discrimination and Inattention on Continuous Performance Task in Doctor of Physical Therapy Students: A Cross-sectional Study. J Phys Ther Educ. 2020 Jun;34(2):160-5. doi: 10.1097/jte.0000000000000135. PMID: 34211256. - **No concurrent or historical comparison groups**

56. Cohee BM, Hartzell JD, Shimeall WT. Achieving balance on the inpatient internal medicine wards: a performance improvement project to restructure resident work hours at a tertiary care center. Acad Med. 2014 May;89(5):740-4. doi: 10.1097/acm.0000000000000213. PMID: 24667506. - **No outcome of interest**

57. Coleman JJ, Robinson CK, von Hippel W, et al. What Happens on Call Doesn't Stay on Call. The Effects of In-house Call on Acute Care Surgeons' Sleep and Burnout: Results of the Surgeon Performance (SuPer) Trial. Ann Surg. 2023 Oct 1;278(4):497-505. doi: 10.1097/sla.0000000000005971. PMID: 37389574. - **No outcome of interest**

58. Coleman JJ, Robinson CK, Zarzaur BL, et al. To Sleep, Perchance to Dream: Acute and Chronic Sleep Deprivation in Acute Care Surgeons. J Am Coll Surg. 2019 Aug;229(2):166-74. doi: 10.1016/j.jamcollsurg.2019.03.019. PMID: 30959105. - **No outcome of interest**

59. Corpolato RC, Mantovani MF, Willig MH, et al. Standardization of the duty shift in a General Adult Intensive Care Unit. Rev Bras Enferm. 2019 Feb;72(suppl 1):88-95. doi: 10.1590/0034-7167-2017-0745. PMID: 30942349. - **No outcome of interest**

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353. White EM, Freedman-Weiss MR, Heller DR, et al. What's it Worth?: The Costs and Benefits of an Initiative to Decrease Post-Call Fatigued Driving Among Surgery Residents. J Surg Res. 2021 May;261:248-52. doi: 10.1016/j.jss.2020.12.039. PMID: 33460970. - **No outcome of interest**
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358. Wong LR, Flynn-Evans E, Ruskin KJ. Fatigue Risk Management: The Impact of Anesthesiology Residents' Work Schedules on Job Performance and a Review of Potential Countermeasures. Anesth Analg. 2018 Apr;126(4):1340-8. doi: 10.1213/ane.0000000000002548. PMID: 29049076. **- Narrative or scoping review**

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363. Yu SJ, Cao YJ, Ma DD. [A survey on night sleep quality and daytime tiredness among shift nurses in a tertiary teaching hospital]. Zhonghua Lao Dong Wei Sheng Zhi Ye Bing Za Zhi. 2018 Nov 20;36(11):855-8. doi: 10.3760/cma.j.issn.1001-9391.2018.11.016. PMID: 30646654. **- Not written in English**

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# Appendix C. Data Tables

**Evidence Table C-1. Characteristics of included primary studies addressing fatigue and sleepiness of clinicians related to hours of service**

| Author, year | Objectives | Study design<br>Setting<br>Study years | Population<br><br>Number of participants, n<br>Participants per arm, n | Funding |
|---|---|---|---|---|
| Abdalla, 2022[49] | Assess correlation between frequency and burden of neurointerventional surgery calls and sleep deprivation with fatigue-related medical errors | Observational study with comparison group<br><br>Setting: Neurosurgery<br>March 2018 to May 2018 | Neurointerventional surgeons<br><br>Number of participants: 164<br>Less than four hours of total sleep on call: 20<br>4-6 hours of total sleep on call: 106<br>6-8 hours of total sleep on call: 38 | NR |
| Bae, 2013[52] | To examine the relationship between the presence of mandatory nurse overtime regulations and nurse injuries and adverse patient events and to assess the effect of nurse overtime on the relationship between the regulations and outcomes after controlling for other nurse work characteristics. | Observational study with comparison<br><br>Setting: Hospital (not specified)<br>2010 to 2011 | Registered nurses<br><br>Number of participants: 173<br>Nurse overtime without regulations: NR<br>Nurse overtime with regulations: NR<br>No overtime: NR<br>Nurse overtime (mandatory, voluntary, or on-call): 104<br>Nurses working ≤40 hours per week: 146<br>Nurses working ≥40 hours per week: 27 | The School of Nursing Garman Funding at University at Buffalo and the Sigma Theta Tau Gamma Kappa Chapter |
| Barger, 2023[56] | Determine whether long weekly work hours and shifts of extended duration (≥24 hours) are associated with adverse patient and physician safety outcomes in more senior resident physicians | Observational study with comparison<br><br>Setting: Hospital (not specified)<br>2002 to 2007, 2014 to 2017 | Postgraduate year 2 and above resident physicians<br><br>Number of participants: 4,826<br>N per arm not reported | NR |

| Author, year | Objectives | Study design<br>Setting<br>Study years | Population<br><br>Number of participants, n<br>Participants per arm, n | Funding |
|---|---|---|---|---|
| Bilimoria, 2016[66] | Test whether surgical-patient outcomes under flexible, less-restrictive duty-hour policies would be no worse than outcomes under standard ACGME policies | RCT<br><br>Setting: General surgery residency programs<br>July 2014 to June 2015 | Cases operated on by residents<br><br>Number of participants: 138,691<br>Standard policy: 65,849<br>Flexible policy: 72,842 | American Board of Surgery, the American College of Surgeons, and the Accreditation Council for Graduate Medical Education |
| Denson, 2015[60] | Investigate handoff-related mortality and the effect of duty-hour regulations. | Observational study with comparison<br><br>Setting: Hospital (not specified)<br>July 2010 to June 2012 | General medicine and ICU patients<br><br>Number of participants: 23,736<br>Control: 17,888<br>Handoff period: 5,848 | Reported no funding source |
| Desai, 2013[59] | Determine the effects of the 2011 ACGME duty hour regulations compared with the 2003 regulations concerning sleep duration, trainee education, continuity of patient care, and perceived quality of care among internal medicine trainees. | RCT<br><br>Setting: General medicine<br>January 2011 to April 2011 | Postgraduate years 1 through 3 trainees and ward nurses<br><br>Number of participants: 43 (cross-over)<br>Control: 44<br>Q5: 40<br>NF: 140 | NR |
| Iverson, 2018[48] | Compare clinical outcomes of percutaneous coronary interventions performed by sleep and non-sleep deprived operators | Observational study with comparison group<br><br>Setting: Cardiac surgery<br>June 2009 to December 2016 | Patients undergoing PCI<br><br>Number of participants: 12,680<br>Sleep Deprived Group: 367<br>No Sleep Deprivation Group: 12,313 | Minneapolis Heart Institute Foundation |

| Author, year | Objectives | Study design<br>Setting<br>Study years | Population<br><br>Number of participants, n<br>Participants per arm, n | Funding |
|---|---|---|---|---|
| Kalmbach, 2022[51] | Characterize risk of depression and medical errors based on sleep disturbance, sleep duration, and work hours | Observational study with comparison<br><br>Setting: Hospitals<br>Study years: NR | First year medical residents<br><br>Number of participants: N=1215<br>Total sleep time < 6 hours: 255<br>Total sleep time > 6 hours: 960<br>Work hours ≥ 70 hours: NR<br>Work hours < 70 hours: NR | National Institute of Mental Health |
| Landrigan, 2020[63] | Trial of the effects on patient safety of implementing a rapidly cycling work roster that eliminated extended shifts | RCT<br>(ROSTERS study group)<br>Setting: PICU<br>July 2013 to March 2017 | Pediatric resident physicians<br><br>Number of participants: 360<br>Control: 172<br>Intervention: 188 | National Heart, Lung, and Blood Institute |
| Mirmehdi, 2016[65] | Analyze whether quality of care and patient outcomes are improved after implementation of flexible duty-hour rules | Observational study with comparison<br>Setting: General surgery training sites<br>July 2014 to January 2015 | Cases operated on by residents<br><br>Number of participants: 49,443<br>National Resident Cases: 49,064<br>Institution Resident Cases: 379 | NR |
| Ouyang, 2016[55] | Investigated whether patient care on an inpatient general medicine service at a large academic medical center is impacted when residents work more than 80 hours per week. | Observational study with comparison<br>Setting: General medicine<br>June 2013 to June 2014 | General medicine patients<br><br>Number of participants: 4,767<br>Control: 2,815<br>Intervention: 1,952 | VA Office of Academic Affiliations, Health Services Research and Development Service Research funds, the National Institute of Environmental Health Sciences |

| Author, year | Objectives | Study design<br>Setting<br>Study years | Population<br><br>Number of participants, n<br>Participants per arm, n | Funding |
|---|---|---|---|---|
| Quan, 2023[50] | Assess the impact of sleep deficiency on surgical outcomes | Observational study with comparison<br>Setting: Surgery<br>NR | Surgeons<br><br>Number of participants: 362 total surgeries performed<br>Post call: 150<br>non-post call: 210 | NR |
| Rahman, 2021[64] | Examined impact of rapid cycling work rosters on postgraduate year 2 and year 3 resident physicians | RCT<br>(ROSTERS study group)<br>Setting: PICU<br>NR | Pediatric resident physicians<br><br>Number of participants: 294<br>EDWR: 125<br>RCWR: 145<br>EDWR+RCWR: 24 | National Heart, Lung, and Blood Institute |
| Rajaram, 2014[61] | Determine if the 2011 ACGME duty hour reform was associated with a change in general surgery patient outcomes or in resident examination performance. | Observational study with comparison<br>Setting: General surgery<br>2009 to 2013 | General surgery patients<br><br>Number of participants: 204,641<br>Control: 104,236<br>Intervention: 100,315 | Reported no direct funding for this study |
| Salgado, 2022[57] | Evaluate perceptions of care and patient outcomes on an extended compared with a limited duty hour system | Observational study with comparison<br>Setting: General medicine<br>September 2017 to May 2018 | General medicine interns, residents, and attendings<br><br>Number of participants: 449<br>Extended Duty: 228<br>Limited Duty: 221 | NR |

| Author, year | Objectives | Study design<br>Setting<br>Study years | Population<br><br>Number of participants, n<br>Participants per arm, n | Funding |
|---|---|---|---|---|
| Silber, 2019[67] | Addressing questions concerning the safety of patients who are cared for by those trainees, the education that trainees receive, and their sleep patterns and well-being. | RCT<br>Setting: General medicine<br>2014 to 2016 | Patients with Medicare claims<br><br>Number of participants: 264,585<br><br>Standard duty hour<br>Pre-trial year: 60,757<br>Trial year: 61,194<br><br>Flexible duty hour<br>Pre-trial year: 70,972<br>Trial year: 71,662 | National Heart, Lung, and Blood Institute and Accreditation Council for Graduate Medical Education |
| Stimpfel, 2013[53] | Describe the shift lengths of pediatric nurses and to measure the association of shift length with nurse job outcomes, nurse-reported patient outcomes, and nurse-assessed safety and quality of care in hospitals. | Cross-sectional study with comparison group<br>Setting: Hospital (not specified)<br>NR | Registered nurses<br><br>Number of participants: 3,710<br>8 hours shift: 946<br>12 hours shift: 2,643<br>>13 hours shift: 121 | National Institute of Nursing Research, the Children's Hospital of Philadelphia |
| Weaver, 2016[47] | Investigated the hypothesis that fatigue and impaired mentation, due to sleep disturbance and shortened overall sleeping hours, would lead to increased nursing errors. | Cross-sectional study with comparison group<br>Setting: ED<br>NR | Registered nurses<br><br>Number of participants: 30<br>Day shift: 16<br>Night shift: 14 | NR |
| Weaver, 2023[62] | Analyze trends in resident reported medical errors before and after implementation of 16 hours 2011 ACGME work hour limit | Observational study with comparison group<br>Setting: Hospitals<br>2002-2007, 2014-2017 | Resident physicians<br><br>Number of participants: 14796<br>2002-2007: 5485<br>2014-2017: 9311 | National Institute for Occupational Safety and Health<br>National Heart, Lung, and Blood Institute |

| Author, year | Objectives | Study design<br>Setting<br>Study years | Population<br><br>Number of participants, n<br>Participants per arm, n | Funding |
|---|---|---|---|---|
| Wen, 2017[58] | Evaluate post-work hour reform effects on hospital-acquired conditions incidence | Observational study with a comparison group<br>Setting: Hospitals<br>2000-2006 | Patients admitted to hospitals<br><br>Number of participants: 228,000,000<br>Pre-2003: 111,000,000<br>Post-2003: 117,000,000 | American Association of Neurological Surgeon's Medical Student Summer Research Fellowship |
| Westley, 2020[54] | To investigate the impact of nurses' work hours on near-miss medication error alerts as captured through the bar-code medication administration system. | Observational study with comparison<br>Setting: Hospital (not specified)<br>2016 to 2018 | Bedside and clinic registered nurses<br><br>Number of participants: 5,372<br>Less than 60 hours work within 7 days: 3,076<br>60 or more hours work within 7 days: 2,296 | NR |

ACGME = Accreditation Council for Graduate Medical Education; ED = emergency department; ICU = intensive care unit; N = sample size; NF = night float schedule; NR = not reported; PCI = percutaneous coronary interventions; PICU = pediatric intensive care unit; Q5 = fifth night overnight call; RCT = randomized controlled trial; VA = Department of Veteran Affairs

**Evidence Table C-2. Findings of included primary studies addressing fatigue and sleepiness of clinicians related to hours of service**

| Author, year | Comparison | Outcome findings |
|---|---|---|
| Denson, 2015[60] | **Resident pre-duty hour change (2010-2011)**<br>**Control:** Patient discharged the following 3 weeks of each 4-week rotation before resident service change.<br>**Handoff group:** Patient discharged within 7 days following a change in resident physician team.<br><br>Resident **post ACGME duty hour change (2011-2012)**<br>**Control:** Patient discharged the 3 weeks of each 4-week rotation before resident service change.<br>**Handoff group:** Patient discharged within 7 days following a change in resident physician team. | **Mortality**<br>Pre-duty hour handoff group vs control group showed a statistically significant association with adjusted mortality (OR 1.5 (95% CI: 1.11 to 1.86)), however in the post-duty hour change, the association lost statistical significance (OR 1.18 (95% CI: 0.89 to 1.56)). Before duty hour restrictions, team handoff group vs. no team handoff group was associated with a statistically significant higher mortality (OR 1.5 [95% CI: 1.11 to 1.86]), however after duty hour changes, the association lost statistical significance (OR 1.18 [95% CI: 0.89 to 1.56]) |
| Desai, 2013[59] | **Control:** Overnight on-call shift every fourth night, beginning at 12 pm and concluding no later than 6 pm the next day, with a maximal continuous duty of 30 hours.<br><br>**Q5:** Overnight call every fifth night beginning at 9 pm and concluding no later than 1 pm the next day, for a maximal continuous duty of 16 hours.<br><br>**NF:** Day and night shifts with an intern working for approximately 6 consecutive nights, each with maximal continuous duty of 14 hours and with day shifts. | **Complications**<br>No significant difference in operations outcomes between groups (30 day readmissions). No significant difference in 30-day readmission rates between groups |
| Rajaram, 2014[61] | **Control:** before ACGME reform (2009-2011)<br><br>**Intervention:** after ACGME reform (2011-2013) | **Mortality**<br>No significant change in death or serious morbidity post-reform (OR, 1.06 [95% CI: 0.93] to 1.20]).<br><br>**Incidence of medical errors or adverse events**<br>No association between reform and any postoperative adverse events. |
| Weaver, 2023[62] | **2002-2007:** Resident physicians who contributed data from 2002-2007 when the 16-hour ACGME restriction was not yet implemented<br><br>**2014-2017:** Resident physicians who contributed data from 2014-2017 (after the implementation of the 16-hour shift restriction) | **Incidence of medical errors or adverse events**<br>Statistically significant reduction in risk of significant medical errors (RR 0.66 [95% CI 0.59 to 0.74])<br>Statistically significant reduced risk of medical errors leading to patient death (RR 0.37 [95% CI 0.28 to 0.49]) |
| Wen, 2017[58] | **Pre-2003:** Hospital admissions which occurred prior to 2003 ACGME reform | **Complications**<br>Patients were more likely to incur a hospital-acquired |

| Author, year | Comparison | Outcome findings |
|---|---|---|
| | **Post-2003:** Hospital admissions which occurred after 2003 ACGME reform | condition in the post-2003 group compared to the pre-2003 group (OR 1.10 [95% CI: 1.06 to 1.14]) |
| Bilimoria, 2016[66] | **Standard policy:** Adhere to existing ACGME duty-hour policies.<br><br>**Flexible policy:** Limiting work to 80 hours per week, 1 day off in 7 days, and on-call duty no more frequently than every third night. Residents were granted a waiver to waive four duty-hour requirements concerning maximum shift length and minimum time off between shifts. | **Mortality and complications**<br>The risk of death or serious complications did not differ significantly between patients who underwent surgery in hospital affiliated with the flexible policy and those in the standard policy hospitals (adjusted OR [0.96; 92% CI, 0.90 to 1.04]; p= 0.38). |
| Mirmehdi, 2016[65] | **National resident cases:** Operations performed by surgery residents with a traditional duty-hour work schedule<br><br>**Institution Resident Cases:** Operations performed by surgery residents in a hospital which implemented a flexible work hour schedule | **Mortality**<br>No statistically significant difference in patient mortality after operation (1.58% institution resident cases vs 1.30% national resident cases p=0.629). |
| Silber, 2019[67] | **Standard duty-hour rules:** Following the 2011 ACGME duty-hour regulations with its 16-hour limit on intern shift length.<br><br>**Flexible duty hours:** Directors allowed to extend work-hour limits beyond the 16-hour limit. | **Mortality**<br>Change in 30-day mortality among the patients in the flexible programs (12.5% in the trial year vs. 12.6% in the pretrial year) was noninferior to that in the standard programs (12.2% in the trial year vs. 12.7% in the pretrial year). |
| Bae, 2013[52] | **Control groups:**<br>Nurse overtime without regulations<br>No overtime<br>Nurses working ≤40 hours per week<br><br>**Intervention groups:**<br>Nurse overtime with regulations<br>Nurse overtime (mandatory, voluntary, or on-call)<br>Nurses working ≥40 hours per week | **Complications**<br>No significant difference in number of any adverse events between comparisons. Only for nurses working ≥40 hours per week was there significantly higher adverse events in comparison to nurses working ≤40 hours per week (OR 14.36 [95% CI: 1.20 to 171.9]).<br><br>Rates of patient falls were significantly higher among nurses with overtime regulations, and among voluntary overtime nurses. Rates of patient pressure ulcers were significantly higher among nurses with overtime regulations, voluntary overtime nurses, and nurses working ≥40 hours per week.<br><br>Rates of patient nosocomial infection rates were significantly higher among nurses with overtime regulations, on-call nurses, and nurses working ≥40 hours |

| Author, year | Comparison | Outcome findings |
|---|---|---|
| | | per week. There were no statistically significant differences among comparison groups for failure to rescue.<br><br>**Incidence of medical errors or adverse events**<br>No significant difference in medication errors between comparisons of overtime vs no overtime, and nurses with overtime regulation vs without regulations. There was a significant increase in medication errors for nurses working ≥ 40 hours per week compared to nurses working ≤ 40 hours per week (OR 3.71 [95% CI: 1.16-11.84]) |
| Weaver, 2016[47] | **Day shift:** Shifts included: 7:00 am to 7:00 pm, 9:00 am to 9:00 pm, 11:00 am to 11:00 pm<br><br>**Night shift:** Shifts included: 1:00 pm to 1:00 am, 3:00 pm to 3:00 am, and 7:00 pm to 7:00 am | **Incidence of medical errors or adverse events**<br>Sleep quantity was not associated with minor, moderate or severe perceived errors. |
| Landrigan, 2020[63] | **Control:** Night shift followed by approximately 24 hours off duty, and then two or three consecutive day shifts.<br><br>**Intervention:** Schedules that eliminated extended shifts and cycled resident physicians through day and night shifts of 16 hours or less. | **Incidence of medical errors or adverse events**<br>Physicians made more serios errors during intervention schedules (RR 1.53 ;[95% CI: 1.37 to 1.72], p<0.001). Serious errors unit wide were also higher during intervention schedules (RR 1.56 [95% CI: 1.43 to 1.71]). |
| Rahman, 2021[64] | **Extended duration work roster (EDWR):** Shifts of 24 or more hours every third or fourth shift. 4 day rotation with 2 ~12-hour day shifts followed by an on-call shift beginning in the morning and ending 24 to 28 hours later.<br><br>**Rapid cycling work roster (RCWR**): Limit resident physicians' scheduled continuous work to 16 hours maximum. 4 day rotation with 2 ~11 to 15-hour day shifts followed by a 16-hour overnight shift that started in the evening and ended the next morning.<br><br>**EDWR+RCWR:** Resident physicians' worked both times of shifts. | **Incidence of medical errors or adverse events**<br>After adjustment, RCWR had a protective effect and lower rate of serious medical errors (rate ratio 0.48 (95% CI: 0.30 to 0.77)). |
| Abdalla, 2022[49] | **6-8 hours of total sleep on call:** Neurointerventional surgeons who reported 6-8 hours of total sleep while on call<br><br>**4-6 hours of total sleep on call:** Neurointerventional surgeons who reported 4-6 hours of total sleep while on call | **Incidence of medical errors or adverse events**<br>Risk of medical errors showed strong association in respondents reporting <4 hours of uninterrupted sleep (45.7% versus 25.5%, p=0.008).<br><br>Statistically significant association of sleeping <6 hours |

| Author, year | Comparison | Outcome findings |
|---|---|---|
| | **Less than four hours of total sleep on call:** neurointerventional surgeons who reported less than 4 hours of total sleep while on call | and fatigue related medical errors (38.9% vs 18.4%, p=.02). |
| Iverson, 2018[48] | **Sleep deprivation:** Patients who underwent PCI performed by a sleep deprived operator<br><br>**No sleep deprivation:** Patients who underwent PCI performed by a non-sleep deprived operator<br><br>Non-sleep deprived defined as operators performing a case between 7 am and 11:59 pm as well as a case the preceding night, between 12 am and 6:59 am. | **Complications**<br>Major procedural complication: no statistically significant difference (p=0.42)<br><br>Bleeding event: no statistically significant difference (p=0.29)<br><br>**Mortality**<br>In-hospital mortality: no statistically significant difference (p=1.0) |
| Quan, 2023[50] | **Non-post call:** Surgery performed by surgeon who was non post-call status<br><br>**Post-call:** Surgery case performed by a surgeon who was post-call status | **Incidence of medical errors or adverse events**<br>No statistically significant difference in incidence of medical errors: IRR 3.16 comparing non-post call and post call error rate p=0.165 |
| Kalmbach, 2022[51] | **Sleep time > 6hours:** First year residents with sleep time greater than 6 hours<br>**Work hours < 70 hours:** Less than 70 work hours per week<br><br>**Sleep time < 6hours:** First year residents with sleep time less than 6 hours<br>**Work hours ≥ 70 hours:** Equal or more than 70 work hours per week | **Incidence of medical errors or adverse events**<br>Residents with less than 6 hours of sleep more likely to make medical errors (RR = 1.3, p=0.03) at 3 months.<br><br>Error rates higher for residents who work more than 70 hours per week (RR = 1.5, p<0.01) at 3 months. |
| Barger, 2023[56] | **Control:** less than 48 weekly work hours<br><br>**>48 and ≤60:** 48 to 60 weekly work hours<br>**>60 and ≤70:** 60 to 70 weekly work hours<br>**>70 and ≤80:** 70 to 80 weekly work hours<br>**>80:** More than 80 weekly work hours | **Incidence of medical errors or adverse events**<br>Working more than 48 hours per week was associated with an increased risk of self-reported medical errors, preventable adverse events, and fatal preventable adverse events (p<0.001 for call groups compared working less than 48 hours per week). |
| Ouyang, 2016[55] | **Control:** Residents who worked less than 80 hours that week.<br><br>**Intervention:** Residents who worked more than 80 hours that week. | **Mortality**<br>No statistical difference for rate of in-hospital mortality for patients in either group.<br><br>**Complications**<br>No statistical difference for rate of ICU and 30-day readmission rate for patients in either group. |

| Author, year | Comparison | Outcome findings |
|---|---|---|
| Salgado, 2022[57] | **Extended duty hour call system:** 24-hour plus 4-hour shifts every 4 days from 7 am to 11 am the following day, with 4-hour protected off-pager for in-hospital rest in private call rooms from 2:00 to 6:00 am (extended duty hours)<br><br>**Limited duty hour call system:** "Long call" admitting shift every 3 days with a maximum single-day work hour limit of 16 hours. | **Complications**<br>No statistically significant difference in patients who developed complications during admission (95% CI of -0.064 to 0.104) |
| Stimpfel, 2013[53] | 8-hour shift length<br><br>12-hour shift length<br><br>Shift length longer than 13 hours | **Incidence of medical errors or adverse events**<br>The likelihood of a nurse reporting poor quality or a poor safety grade on their unit was greater for nurses working > 13 hours compared to nurses working 8 hours (adjusted ORs 2.76 and 3.14, respectively). |
| Westley, 2020[54] | 60 hours or more work within 7 days<br><br>Less than 60 hours work within 7 days | **Incidence of medical errors or adverse events**<br>Nurses working 60 hours or more in a week had an average near-miss rate of 4% compared to 3% (p <.001) for nurses who did not. Nurses working extended hours had a significantly increased risk of triggering a near-miss alert compared to those not working extended hours. |

ACGME = Accreditation Council for Graduate Medical Education; CI = confidence interval; EDWR = extended duration work rosters; ICU = intensive care unit; IRR = incident rate ratio; OR = odds ratio; PCI = percutaneous coronary intervention; RCWR = rapid cycling work rosters; RR = relative risk

**Evidence Table C-3. Barriers and facilitators identified in primary studies addressing fatigue and sleepiness of clinicians related to hours of service**

| Author, Year | Facilitators | Barriers |
|---|---|---|
| Denson, 2015[60] | In preparation for duty-hour modifications, the ACGME revised its Common Program Requirements to "ensure that residents are competent in communicating with team members in the hand-over process." This revision prompted training programs to formalize education on effective handoff communication. | NR |
| Desai, 2013[59] | NR | Disruption in education can reduce the effectiveness of training programs' current provision of formal and informal curricula. |
| Desai, 2013[59] | NR | Faculty often face increased clinical duties to compensate for the work previously done by residents, reducing time to teach. Coupled with pressures to "get the resident out on time," will further reduce teaching opportunities even during daytime hours. |
| Rajaram, 2014[61] | Continuity of care may be negatively affected by duty hour policies, this may be mitigated by hospitals anticipating the effects of these regulations and responding accordingly (e.g., hiring midlevel support staff, formalized training in patient handoffs, etc). | NR |

ACGME = Accreditation Council for Graduate Medical Education; NR = not reported

**Evidence Table C-4. Risk of bias assessment for randomized controlled trials from included primary studies addressing fatigue and sleepiness of clinicians related to hours of service**

| Author, year | Random sequence generation | Allocation concealment | Blinding of participants and personnel | Blinding of outcome assessment | Incomplete outcome data | Selective reporting | Other bias | Overall risk of bias |
|---|---|---|---|---|---|---|---|---|
| Bilimoria, 2016[66] | Unclear | Unclear | Low | Low | Low | Low | Low | Unclear |
| Desai, 2013[59] | Low | Low | Low | Low | Low | Low | Low | Low |
| Landrigan, 2020[63] | Unclear | Unclear | Low | Low | Low | Unclear | Low | Unclear |
| Rahman, 2021[64] | Unclear | Unclear | Low | Low | Low | Unclear | High | High |
| Silbar, 2019[67] | Unclear | Low | Low | Low | Low | Low | Low | Unclear |

**Evidence Table C-5. Risk of bias assessment for non-randomized studies from included primary studies addressing fatigue and sleepiness of clinicians related to hours of service**

| Author, year | Confounding | Patient Selection | Classifying Interventions | Deviations from intended interventions | Missing data | Measurement of outcomes | Selection of reported results | Overall Assessment |
|---|---|---|---|---|---|---|---|---|
| Abdalla, 2022[49] | Moderate | Low | Low | Low | Low | Low | Low | Moderate |
| Bae, 2013[52] | Critical | Low | Serious | Low | Low | Critical | Low | Critical |
| Barger, 2023[56] | Moderate | Low | Low | Low | Low | Low | Low | Moderate |
| Denson, 2015[60] | Low | Low | Low | Low | Low | Low | Low | Low |
| Iverson, 2018[48] | Serious | Low | Low | Low | Low | Low | Low | Serious |
| Kalmbach, 2017[51] | Moderate | Low | Moderate | Low | Serious | Low | Low | Serious |
| Mirmehdi, 2016[65] | Serious | Low | Low | Low | Low | Low | Low | Serious |
| Ouyang, 2016[55] | Low | Low | Low | Low | Low | Low | Low | Low |
| Quan, 2023[50] | Low | Low | Low | Low | Low | Low | Low | Low |
| Rajaram, 2014[61] | Low | Low | Low | Low | Low | Low | Low | Low |
| Salgado, 2022[57] | Serious | Low | Low | Low | Low | Low | Low | Serious |
| Stimpfel, 2013[53] | Low | Low | Low | Low | Low | Low | Low | Low |
| Weaver, 2016[47] | Moderate | Low | Low | Low | Low | Low | Low | Moderate |
| Weaver, 2023[62] | Low | Low | Low | Low | Low | Low | Low | Low |
| Wen, 2017[58] | Low | Low | Low | Low | Low | Low | Low | Low |
| Westley, 2020[54] | Critical | Low | Low | Low | Low | Moderate | Low | Critical |