

# Chapter 12

## Duty Hour Regulations of Physicians in Training and Circadian Considerations



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### Definitions

**Accreditation Council for Graduate Medical Education (ACGME)** Organization responsible for setting the standards for graduate medical education and for the accreditation of most training programs (residencies and fellowships) in the United States. In the 2017–2018 academic year, the ACGME accredited approximately 11,200 residency and fellowship programs in 180 specialties sponsored by approximately 830 institutions. The accreditation process is managed by specialty-specific Review Committees which consist of leaders from specific fields who set standards and provide peer evaluations of sponsoring institutions and their residencies and fellowships.

**Fellow** A physician in training who has completed medical school and one or more residencies and is electively undergoing further specialty training. The fellow's period of advanced training is called a fellowship which typically lasts 1–3 years. Fellows may provide clinical and educational support to interns and residents.

**Institute of Medicine** Component of the National Academies of Science which seeks to provide comprehensive information on health policy issues. This organization was recently renamed the National Academy of Medicine.

**Harvard Work Hours Health and Safety Group** Multidisciplinary group that studies occupational sleep and circadian issues and seeks strategies to improve the health and safety of workers in safety-sensitive jobs.

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**Intern** A physician in training who has completed medical school and is in his/her first year of postgraduate medical training (i.e., first-year resident). The intern's period of training is called an internship. Interns may be referred to as a "PGY-1" which stands for postgraduate year 1.

**Night Float** A patient care process in which one or more residents work only over the nighttime hours to provide relief for on-call residents by evaluating new hospital admissions and/or providing coverage for previously admitted inpatients. The night float transfers care responsibilities back to their on-call colleagues in the morning.

**Resident** A physician in training who has completed medical school and internship but has an additional 2–7 years (or more) of education in a medical or surgical discipline before independent practice. The term originates from the time when these junior doctors resided in hospitals to provide care around the clock. The resident's period of training is called a residency. This training typically occurs in hospital and clinic settings under supervision from institutional faculty (senior clinicians at the sponsoring facility) in that specialty. Residents oversee interns and assume greater autonomy as they gain experience and demonstrate competence. Residents may be referred to as a "PGY-x" with "x" referring to their current year of postgraduate medical training. Residents may also be referred to as "house staff" or "house officers" in recognition of their in-hospital (house) duties.

## Introduction

The education pathway from medical student to independent medical practitioner goes through residency and, in some cases, specialty fellowship. Residencies and fellowships are physically and emotionally demanding experiential training periods through which providers gain the skills to enter unsupervised practice through direct care of patients supplemented by clinical teaching from supervisors and structured educational events, such as conferences, lectures, journal clubs, and simulation sessions. The first year of residency is termed an internship and is traditionally the most grueling year of graduate medical education. Extended work hours, overnight call, and rotating work shifts are characteristic features of residencies and fellowships. Historically, these challenging schedules were felt necessary for comprehensive trainee learning, respect for the physician-patient relationship, and to satisfy the clinical and economic realities of providing care for patients around the clock. However, there has been greater awareness of the impact of long work hours on trainee wellbeing, education, and patient safety, leading to efforts to curb resident and fellow duty hours. This chapter will review how medical training may disrupt wake/sleep regulation, summarize literature on the impact of sleep loss and circadian disruption on trainees and patients, provide a history of duty hour restrictions for medical trainees, and examine the consequences of work hour limits on trainees and patients.

## Sleep/Wake Regulation and Medical Trainees

Sleep and wakefulness are primarily determined by the interplay of the homeostatic drive to sleep and the circadian system [1]. The homeostatic drive to sleep strengthens as time from the prior sleep bout elapses, which results in progressive sleep propensity and degradation in neurobehavioral performance. By 17 hours of continued wakefulness, the performance impairment is equivalent to that observed with alcohol intoxication in healthy subjects [2]. The circadian system, centered in the suprachiasmatic nucleus of the hypothalamus and entrained by the environmental light/dark cycle, oscillates in such a way to provide a counterbalancing drive for wakefulness during the day and reinforcing stimulus for sleep at night. Both the obtainment of adequate sleep time to satiate the homeostatic drive and the proper alignment of this drive with the circadian system are important to produce consolidated and behaviorally optimized periods of wakefulness and sleep. This interaction is routinely threatened by the prolonged and fluid work schedules typical of medical training. Before the implementation of work hour limits for residents approximately 20 years ago, it was not unusual for trainees to work 80–90-hour weeks with each week consisting of 36-hour duty shifts in hospital broken up by 12 hours or less of rest between shifts [3].

The homeostatic drive to sleep may not be quenched in residents and fellows due to acute or chronic partial sleep deprivation, which in turn leads to increased sleep propensity and impaired alertness. The on-call shifts ubiquitous in training programs are often marked by acute sleep restriction. Using ambulatory electroencephalographic (EEG) monitoring, Richardson [4] documented that internal medicine residents averaged just 3.6 hours of sleep when on call. Even if afforded an opportunity to sleep on call, pager interruptions are commonly followed by sustained wakefulness [4]. Efforts to balance other life demands make it challenging for trainees to obtain adequate recovery sleep during time away from work, leading to chronic partial sleep deprivation. Nationwide surveys of residents before [3, 5] the imposition of work hour limits revealed reported average nightly sleep durations of less than 6 hours, well below the 7 hours recommended for optimal health [6]. In experimental subjects, curtailing sleep to 6 hours per night results in vigilance deficits equivalent to two nights of total sleep deprivation and an accompanying alarming inability to perceive progressive impairments [7]. From a circadian standpoint, night shifts force trainees to work at the peak of sleep propensity which may jeopardize waking performance. While the homeostatic drive to sleep is strong at the end of such a shift, ensuing daytime recovery sleep quality is jeopardized by the building circadian drive for wakefulness. Rotating work shifts (as opposed to “straight” night shifts), common in specialties such as emergency medicine and critical care medicine, may further exacerbate circadian misalignment.

Sleep deprivation and/or circadian misalignment may also increase vulnerability to sleep inertia in trainees. Sleep inertia is characterized by the desire to return to sleep upon awakening and can be accompanied by varying degrees of grogginess, disorientation, slurred speech, impaired cognition, and automatic behaviors. This

phenomenon is most prominent within the first minutes of awakening. The cognitive performance of individuals immediately upon awakening may be just 65% of their peak cognitive performance and is worse than their cognitive performance after 24 hours without sleep [8]. Sleep inertia may pose an important safety concern when trainees are awakened to provide patient care.

## **Impact of Sleep Loss and Circadian Disruptions on the Personal and Professional Lives of Trainees**

The first publication on the impact of sleep loss in residents appeared in 1971 when Friedman [9] reported that post-call interns made nearly twice as many errors when reading electrocardiograms in comparison to rested colleagues. What followed was a vast literature exploring the impact of long work hours and sleep loss on trainee wellbeing and performance and patient safety. Studies reported associations of sleep deprivation with diminished cognitive function, memory, fine motor skills, motivation, and mood, errors in patient care, and serious conflicts with other members of the healthcare team [10, 11]. Surveyed internal medicine residents admitted to falling asleep while performing clinical duties, such as writing notes in the chart (69%), reviewing medication lists (61%), interpreting labs (51%), writing orders (46%), placing central lines, drawing blood cultures, and running codes [12]! Philibert [13] compiled a list of the 30 most influential and widely cited articles from this body of literature, culled from over 1000 investigations. Works highlighted included:

- The report of Reuben [14], which was the first to associate depressive symptoms to residency, with interns exhibiting the highest prevalence. The training context was relevant, as symptoms were greatest among interns during rotations on inpatient care wards and intensive care units. Rosen [15] subsequently first reported temporally linked trends for ratings of chronic sleep deprivation, depression, and burnout in internal medicine interns.
- Jacques' [16] initial demonstration that sleep loss diminished resident performance on standardized tests. There was a significant decline in the in-training test scores among family medicine residents with decreasing sleep the night before the test.
- Hillson's [17] analysis of 22,000 internal medicine admissions that revealed patients admitted at night under the care of residents experienced an increased relative risk for inpatient mortality.
- Marcus and Laughlin's [18] survey to first report that post-call pediatric residents were significantly more likely to fall asleep while driving and to be involved in motor vehicle crashes. A disturbing 49% of surveyed residents reported falling asleep at the wheel with 90% of the events occurring post call. Steele [19] later surveyed emergency medicine residents with 8% reporting crashes and 58% reporting near miss crashes with the overwhelming majority occurring after a night shift.

- Parks' [20] finding of a 1.5-fold increased risk of experiencing a blood-borne pathogen exposure (needle stick, laceration, or splash) for residents and medical students working during night versus daytime hours.
- Bellini's [21] report of decreased trainee caring and enthusiasm after the transition from medical school to residency. Five months into training, residents showed increased scores of depression/dejection, anger/hostility, fatigue/inertia, distress, and decreased empathy.
- Barger's [22] results from a national survey of approximately 2700 interns who completed online monthly reports detailing their work schedules, work activities, and sleep. The odds of a motor vehicle crash increased twofold and of a near miss accident fivefold during the trip home after an extended work shift compared to nonextended shifts. Each extended work shift increased the risk of crash on the home commute by 16%. Although not cited by Philibert [13], these investigators used the same survey process to also reveal an increased risk for sustaining a percutaneous injury the day after working overnight compared to the same time period on the previous day [23]. Self-reported fatigue-related medical errors climbed from 4% during months with no extended shifts to 10% during months with one to four extended shifts to 16% during months with five or more extended shifts [24]. Self-reported falling asleep during educational and patient care activities also increased in proportion to the number of extended shifts worked.

Although compelling, this literature suffers from limitations [25], as studies often involve only one institution or a single specialty, which limits generalizability. The studies also fail to account for circadian factors, baseline chronic partial sleep deprivation in control residents, practice differences, and trainee motivation. Moreover, some results were contradictory, which may have been a result of small sample sizes, leaving studies open to confounding from interindividual differences in resilience to sleep loss [26]. It is challenging to distinguish the impact of sleep loss per se from that of long hours and other job-related stressors characteristic of residency training. Finally, study designs have been heterogeneous, and outcomes measures may not be sensitive to more subtle levels of impairment or may lack relevance to actual work performed by residents. Despite these drawbacks, a meta-analysis of the literature concluded that sleep loss has significant effects on resident clinical performance, cognitive function, memory, and vigilance [27].

Other challenges with this literature include a paucity of analyses performed in true-to-life circumstances and a careful accounting of whether resident impairment actually led to patient harm. Landrigan [28] and colleagues of the Harvard Work Hours Health and Safety Group endeavored to address these shortcomings by performing a carefully designed prospective trial comparing a modified work schedule without shifts longer than 16 hours to a traditional every third night 24-hour call schedule among interns working in the intensive care unit. Greater than 2200 patient-days were monitored in a comprehensive multidisciplinary manner. Interns in the traditional schedule worked 19.5 hours more per week, slept 6 less hours per week, and committed 36% more serious errors (defined by the investigators as "a medical error that causes harm or has the potential to cause harm" [28]), including

21% more serious medication errors and six times more serious diagnostic errors in comparison to their peers on the modified schedule. This group also experienced twice the rate of ambulatory-EEG captured attentional failures during on-call nights [28, 29]. Despite these differences, the adverse event rates for patients cared for by each group were similar, highlighting that the support on-call residents receive from supervisory staff and other members of the multidisciplinary care team (e.g., nurses, pharmacists, therapists) makes it very challenging to determine the extent to which resident sleep deprivation and circadian misalignment result in adverse patient outcomes.

## History of Resident Work Hour Reforms (Table 12.1)

The death of 18-year-old Libby Zion on March 5, 1984 in a New York hospital while under the care of residents is widely considered a seminal catalyst with respect to residency training reforms in the United States. Resident fatigue was determined to be a contributing factor to Ms. Zion's death. Her father, Sidney Zion, a journalist and former federal prosecutor, pushed for an investigation and mounted a crusade publicizing the inadequacies of the residency training system. In a *New York Times* op-ed, he wrote, "You don't need kindergarten to know that a resident working a 36-hour shift is in no condition to make any kind of judgment call—forget about life and death" [30]. A grand jury decided not to indict Ms. Zion's doctors, but the case prompted the creation of the Bell Commission, which issued a report recommending greater resident supervision and limits on residency work hours. In 1989, the State of New York became the first jurisdiction to mandate that residents work no more than 80 hours per week. In 1989, the Internal Medicine Residency Review Committee endorsed the same.

In 1998, the European Working Time Directive became law for all workers in the European Union. This statute called for a maximum work week of 48 hours, a minimum rest period of 11 consecutive hours per 24-hour duty, and a minimum rest period of 24 hours per 7-day duty. The rollout for medical trainees across the continent has been uneven with full implementation in the United Kingdom delayed until 2009 [31].

Under pressure from various advocacy groups and the threat of federal intervention, the Accreditation Council for Graduate Medical Education (ACGME), the organization responsible for overseeing residency and fellowship training programs in the United States, instituted compulsory nationwide work limits for residents and fellows in July 2003. The requirements imposed a maximum 80-hour work week averaged over 4 weeks (with an allowance of up to 88 hours in programs with a compelling educational rationale), capped duty shift length to a maximum of 24 hours with an additional 6 hours allowed to maintain continuity of care and participate in didactic activities ("24 + 6"), limited in-hospital call frequency to no more than every third night, stipulated a minimum time between shifts of 10 hours, and mandated 1 day in seven free from all training responsibilities (the latter 3

**Table 12.1** Timeline of selected events in the regulation of work hours for medical trainees

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| 1971 | Friedman [9] report of increased electrocardiogram interpretation errors in post-call interns as compared to rested colleagues  |
| 1984 | Death of New York college student, Libby Zion, which was ultimately attributed to suboptimal residency supervision and resident fatigue from extended work hours  |
| 1989 | New York imposes 80-hour week limit for medical trainees within the state in response to investigations following Ms. Zion's death  |
| 1989 | Internal Medicine Residency Review Committee endorses 80-hour work week for its accredited training programs  |
| 1998 | European Working Time Directive enacted which established a maximum work week of 48 hours for European Union workers  |
| 2003 | Implementation of first ACGME duty hour limits which mandated an 80-hour work week limit, maximum shift length of 24 + 6 hours, maximum on-call frequency of every third night, and 1 day off in 7  |
| 2006 | Harvard Work Hours Health and Safety Group [28] report demonstrating less sleep and more errors in intensive care unit interns working on traditional call schedule with 24-hour shifts compared with interns on a schedule with a maximum shift length of 16 hours   |
| 2008 | Release of Institute of Medicine's report, <i>Resident Duty Hours: Enhancing Sleep, Supervision, and Safety</i> [33], which advocated for more stringent resident duty hour limits  |
| 2011 | Implementation of second ACGME duty hour limits [34] which capped the maximum intern work shift at 16 hours and 24 + 4 hours for all other residents. The 80-hour work week limit, maximum on-call frequency of every third night, and 1 day off in 7 continued   |
| 2016 | FIRST [35] results published demonstrating equivalent patient outcomes from surgical programs managed under the 2011 ACGME work limits versus those with flexibility with respect to maximum shift length and time off between shifts. Residents expressed a strong preference for training under more flexible conditions [37] |
| 2017 | Implementation of third ACGME duty hour limits [38] which reversed the 16-hour maximal shift length cap for interns and subjected all residents to the 24 + 4 hour shift limit. The 80-hour work week limit, maximum shift length of 24 + 6 hours, maximum on-call frequency of every third night, and 1 day off in 7 continued |
| 2018 | iCOMPARE [36] results published demonstrating more resident dissatisfaction yet greater residency program director satisfaction in internal medicine residencies that allowed flexibilities with respect to maximum shift length and time off between shifts versus programs managed under the 2011 ACGME work limits           |
| 2019 | Internal medicine programs with flexible duty hours participating in iCOMPARE report noninferior patient outcomes compared to standard duty hour programs [38]  |

averaged over 4 weeks). Internal moonlighting performed by residents (covering extra shifts within their teaching institution) counted toward the 80-hour weekly limit. The requirements also obligated training programs to adhere to principles of prioritizing resident learning over service duties, to provide appropriate supervision of resident patient care activities, and to educate faculty and residents on recognizing and mitigating sleep deprivation.

The duty hour limits were immediately controversial and have remained so to the present day. Critics voiced concern that increased rest for residents and the accompanying personal wellbeing benefits would be offset by increased transitions of

patient care, decreased professionalism (clock-based versus patient-based ethic), reduced access to procedures and educational activities, and greater differences between training and real-life practice encountered after training completion [32]. There was also the realization that work hour limits didn't necessarily translate into dramatically longer recovery sleep. A nationwide survey of trainee self-reported sleep revealed a modest increase in mean nightly sleep duration of 22 minutes (from 5.91 hours to 6.27 hours) [5]. Proponents argued that the work limits were not stringent enough, as aggregate data suggested residents working within the 30-hour maximal allowable shift may function at a level comparable to the 15th percentile of rested colleagues [27]. Beyond the debate was the practical challenge of replacing care coverage previously provided by residents. On the eve of the 2003 work hour limits' implementation, first-year obstetrics/gynecology and general surgery trainees provided an average of 91 and 102 hours of patient care per week, respectively [3]. Hospitals responded by hiring more advanced practice providers and hospitalists, by implementing night-only call teams ("night floats") to relieve on-call residents, and by shifting duties to supervising faculty physicians.

The Landrigan modified intern schedule study [28] and recommendations from the Institute of Medicine's (IOM) 2008 report, *Resident Duty Hours: Enhancing Sleep, Supervision, and Safety* [33], significantly influenced the ACGME's next version of its duty hour regulations. The IOM advocated for further work hour limits, improved patient handoffs, and closer resident supervision. Specific recommendations included no change in the 80-hour work week limit, but a reduction in the maximum allowable shift length for all residents to either 16 or 30 hours (the latter if there were 5 hours protected time for sleep between the circadian favorable periods of 10 PM–8 AM); a minimum of 10 and 12 hours off after a day and night shift, respectively; 14 hours off after an extended duty period with no return to the hospital before 6 AM the next day; a mandatory 5 days off per month with at least 1 day off per week (not averaged); a maximum of four in-hospital night shifts per month with 48 hours off after three or four consecutive night shifts to minimize circadian disruption; and inclusion of internal and external moonlighting hours toward the 80-hour weekly limit. The economic reality of hiring the personnel to implement these changes was estimated at \$1.7 billion.

The second version of the ACGME revised common program requirements, enacted in 2011, further limited the maximum duty period for interns to 16 hours [34]. The maximum shift length for intermediate and senior residents remained at 24 hours, but the extra time allowed for transitional and educational activities was cut to 4 hours ("24 + 4"). The rules granted residents the flexibility to remain beyond their maximal allowable duty period to continue to provide care to a single patient under special clinical, academic, or humanistic circumstances. Strategic napping between 10 PM and 8 AM was strongly suggested for intermediate or senior residents working beyond 16 hours without mandating protected time for this rest. The mandatory minimum time off between 24-hour shifts was increased to 14 hours. Night duty was limited to six consecutive nights, interns were now prohibited from moonlighting, and internal *and* external moonlighting now counted against the 80-hour work week limit. The foundational requirements of the 80-hour work week



limit, maximum on-call frequency of every third night, and 1 day off in 7 were preserved. The revised rules encouraged residents to prioritize sleep over other discretionary activities when away from work (so as to arrive on duty appropriately rested), required training programs to adjust schedules to alleviate burdensome service demands while minimizing patient handoffs, and mandated the provision of adequate sleep facilities and/or transportation options for residents too sleepy to return home, with an overall cultural emphasis of safety, quality improvement, trainee wellbeing, and team-based patient care.

Controversy continued after the implementation of the 2011 duty hour requirements, especially surrounding the 16-hour shift limit for interns. There was concern, especially from surgical disciplines, that this limit was diminishing continuity of care and imperiling trainee opportunities to witness the trajectory of acute clinical conditions. The ACGME heeded the call of the IOM [33] to foster multicenter research on the impacts of duty hour limits by providing seed funding and waivers for several duty hour requirements for programs involved in two national trials that examined the impact of work hour limits: the Flexibility in Duty Hour Requirements for Surgical Trainees (FIRST) trial [35] and the Individualized Comparative Effectiveness of Models Optimizing Patient Safety and Resident Education (iCOMPARE) trial [36, 38]. FIRST was a noninferiority trial that randomized 117 general surgery programs during the 2014–2015 academic year to the 2011 ACGME duty hour policies (standard policy group) or to more flexible policies that waived limits on maximum shift lengths and time off between shifts (flexible policy group) while still abiding by the 80-hour work week limit, maximum on-call frequency of every third night, and an average of 1 day off in every 7 days. There was no difference between groups in the primary composite outcome measure of 30-day rate of postoperative death or serious complications or of secondary postoperative outcomes determined through the American College of Surgeons' National Surgical Quality Improvement Program. Residents in the flexible policy group did not report greater dissatisfaction with their education quality and were less likely than standard group residents to perceive negative impacts of their duty hours on patient safety, care continuity, clinical skills acquisition, operative skills acquisition, autonomy, operation volumes and case completion, conference attendance, and professionalism, but they were more likely to notice negative effects on case preparation, research work, family time, extracurricular activity participation, and rest. Only 14% of FIRST residents surveyed expressed a preference for training under standard ACGME policies [37].

The iCOMPARE trial similarly randomized 63 internal medicine programs to the 2011 ACGME duty hour policies or to more flexible policies that waived limits on maximum shift lengths and time off between shifts. Trainees in the two groups had similar average percentages of directly observed shift time spent in direct patient care, in-training examination scores, perception of appropriate balance of service demands and education in their clinical rotations, and burnout scores. The flexible group residents were more likely to report dissatisfaction with the overall quality of their education and impact of work on their personal lives but less likely to report negative impacts of duty hours on continuity of care [36].

Faculty perceived the balance of resident workload to capacity equivalent in both groups, while program directors in flexible duty hour programs were less likely to report dissatisfaction with many aspects of the training environment, including intern responsibility for patient care, intern morale, frequency of handoffs, continuity of care, and time for teaching [36]. Programs with flexible duty hours had noninferior differences in pre-trial year to trial year 30-day mortality, 7-day readmission rates, and patient safety indicators, compared to programs adhering to standard ACGME duty hours [38].

The ACGME's third version of its program requirements for duty hours was implemented during the 2017–2018 academic year (Table 12.2) [39]. Based on review of published research, including FIRST, and broad input from multiple stakeholders, the ACGME reversed its decision on the intern 16-hour cap and restored the maximum work shift duration for interns to that of all other trainees (the aforementioned “24 + 4”). The 80-hour work week, maximum on-call frequency of every third night, and 1 day off in 7 limits endure. The requirements add to the 2011 rules by expanding the focus on trainee and faculty wellbeing, by mandating that faculty and residents engage in patient safety and quality improvement activities, and by requiring programs to design systems to optimize transitions in patient care and to maintain an environment that promotes the joy of professional and intellectual development.

**Table 12.2** Requirements pertaining to duty hours from Section VI of the 2017 ACGME Common Program Requirements [39]

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| <i>Maximum hours of clinical and education work per week</i>   |
| Clinical and educational work must be limited to no more than 80 hours per week, averaged over a 4-week period, inclusive of all in-house clinical and educational activities, work done from home, and all moonlighting   |
| <i>Mandatory time free of clinical work and education</i>  |
| The program must design an effective program structure that is configured to provide residents with educational opportunities, as well as reasonable opportunities for rest and personal wellbeing   |
| Residents should have 8 hours off between scheduled clinical work and educational periods. There may be circumstances when residents choose to stay to care further for patients or to return to the hospital with fewer than 8 hours free of clinical experience and education. This must occur within the context of the 80-hour and the 1 day off in 7 requirements |
| Residents must have at least 14 hours free of clinical and educational work after 24 hours of in-house call  |
| Residents must be scheduled for a minimum of 1 day off in 7 free of clinical work and required education (when averaged over 4 weeks). At-home call cannot be assigned on these free days.   |
| <i>Maximal clinical work and education period length</i>   |
| Clinical and educational work periods for residents must not exceed 24 hours of continuous scheduled clinical assignments  |
| Up to 4 hours of additional time may be used for activities related to patient safety, such as providing effective transitions of care, and/or resident education. Additional patient care responsibilities must not be assigned to resident during this time  |

**Table 12.2** (continued)

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| <i>Clinical and educational work hour exceptions</i>  |
| In rare circumstances, after handing off all other responsibilities, a resident, on their own initiative, may elect to remain or return to the clinical site in the following circumstances: to continue to provide care to a single severely ill or unstable patient, to provide humanistic attention to the needs of the patient or family, or to attend unique educational events. These additional hours of care or education will be counted toward the 80-hour weekly limit |
| A Review Committee may grant rotation-specific exceptions for up to 10% or a maximum of 88 clinical and educational work hours to individual programs based on a sound educational rationale  |
| <i>Moonlighting</i>   |
| Moonlighting most not interfere with the ability of the resident to achieve the goals and objectives of the educational program and must not interfere with the resident's fitness for work nor compromise patients' safety   |
| Time spent by residents in internal and external moonlighting must be counted toward the 80-hour maximum weekly limit   |
| Postgraduate year 1 residents are not permitted to moonlight  |
| <i>In-house night float</i>   |
| Night float must occur within the context of the 80-hour and 1 day off in 7 requirements  |
| <i>Maximum in-house on-call frequency</i>   |
| Residents must be scheduled for in-house call no more frequently than every third night (when averaged over a 4-week period)  |
| <i>At-home call</i>   |
| Time spent on patient care activities by residents on at-home call must count toward the 80-hour maximum weekly limit. The frequency of at-home call is not subject to the every-third-night limitation, but must satisfy the requirement of 1 day off in 7 free of clinical work and education, when averaged over 4 weeks   |
| At-home call must not be so frequent or taxing so as to preclude rest or reasonable personal time for each resident   |
| Reasons are permitted to return to the hospital while on at-home call to provide direct care for new or established patients. These hours of inpatient patient care must be included in the 80-hour maximum weekly limit  |

## Effect of Resident Duty Hour Limitations on Resident Wellbeing, Resident Education, and Patient Safety

Despite an ever-expanding number of studies, a definitive sense of the impact of the ACGME's efforts to limit resident work hours on trainees and the patients they care for has not fully emerged. The varied findings are evident in the following high-impact studies selected by Philibert [13]:

- Poulouse [40] reported that the frequency of adverse patient safety indicators for surgical residents increased after implementation of the New York state work hour limits.
- Gopal [41] found that the original 2003 work hour limits were associated with decreased internal medicine resident exhaustion, depersonalization, and depression rates at a large academic medical institution, although resident educational conference attendance dropped and overall residency satisfaction fell.

- Examining on-call residents assigned to a schedule that provided protection from clinical duties from midnight to 7 AM versus a standard 24-hour call schedule, Arora [42] observed that many residents on the protected schedule chose not to use the coverage because of their desire to avoid discontinuity of care.
- Volpp [43] revealed that the 2003 ACGME work limits were not associated with statistically significant improvements or declines in mortality of Medicare medical or surgical patients when comparing the 3 years prior to the 2003 work hour limits with the two subsequent years.
- Jagannathan [44] reported that work hour limits were associated with reduced performance on the American Board of Neurological Surgery written exam and that while resident registration to national meetings increased, the number of resident abstracts dropped 7% when comparing 2002 with 2007.
- McCoy [45] observed that internal medicine residents on a rotation with a 16-hour shift limit felt less prepared to manage cross coverage of patients, although patient care metrics were unchanged.
- Desai [46] randomized internal medicine interns to schedules compliant with the 2003 or 2011 work hour limits and showed that the 2011-compliant schedules increased intern sleep but decreased intern participation in didactic sessions and increased patient handoffs. The study was terminated early because of concerns of reduced quality of care delivered by the night float.
- In a cohort of 2300 interns who self-reported information on work and wellbeing quarterly over the course of a year, Sen [47] learned that the 2011 work hour limits reduced weekly work hours but did not increase sleep. Depressive symptoms and wellbeing did not change and self-reported medical errors increased.

These conflicting findings explain why systematic reviews of this literature have come to different conclusions. In Bolster and Rourke's [48] analysis of the systematic reviews of the 2003 work hour limits' literature, five reviews examined the impact of duty hour limits on resident wellbeing with four reviews [33, 49–51] concluding the impact was favorable and one [52] determining the literature was inconclusive; five reviews examined the impact on resident education with two [51, 53] concluding there was no impact, two [49, 50] concluding the impact was inconclusive, and one [52] concluding the impact was unfavorable; and eight reviews examined the impact of duty hour limits on patient safety with two [33, 52] concluding there was a positive impact, two [53, 54] finding no impact, and four [50, 51, 55, 56] concluding the impact was inconclusive. Bolster and Rourke then reviewed literature regarding the 2011 duty hours and similarly found mixed results for resident- and patient-focused outcomes. Night float in particular, with its attendant circadian disruption from consecutive nights worked, was found in the majority of studies to have a negative impact on residents, including decreased sleep, more stress and fatigue, decreased conference attendance, and less exposure to attending physicians [48].

The complexity of studying duty hour reforms exposes the many methodologic limitations of this vast literature [57]. As mentioned above, studies often suffer from small sample sizes and may only describe a single institution's experience.

A glaring and persistent shortcoming has been the very limited attention paid to circadian factors. Investigations employing large national administrative databases for patient outcomes may lack the fidelity to account for the impact of local training processes. Follow-up of residents or patients involved in studies may be too short. Some studies have mixed and others segregated medical and surgical residents and patients. Conclusions from studies only involving interns may not generalize to residents nearing graduation. Many studies employ surveys which may not be validated and/or have low response rates. These surveys gather stakeholder perceptions of the impact of duty hour reforms but lack objective data for corroboration of their impressions. A large array of endpoints of varying rigor and appropriateness has been used to capture facets of resident wellbeing, resident education, and patient safety. Finally, investigators struggle to account for the many other factors that can influence the resident learning experience, such as care process changes that have accompanied duty hour limits or advances in medical knowledge.

Amidst all mixed findings, the ACGME drew conclusions from its literature review [51] that informed creation of their 2017 duty hour regulations. The duty hour limits have increased resident sleep, albeit modestly, and objective measures of alertness. The majority of studies have indicated a reduction in resident burnout with work hour limits, yet how this impacts the physician-patient relationship is understudied. The majority of studies have not shown a negative impact of duty hour limits on procedural volumes or in-training exam scores. Trainee work has been compressed into fewer hours which may result in a negative impact on the resident-patient relationship, patient outcomes, and resident participation in educational activities. The impact of duty hour limits may differ between medical and surgical trainees (as per FIRST and iCOMPARE). The impact on patient safety has been mixed and also medical specialty context dependent. Single-institution studies involving internal medicine residency programs have generally found a positive effect, while studies using large national datasets have found negative impacts on surgical patients.

## Conclusion

The need to improve the work and learning environments of resident and fellow physicians which were so disruptive to sleep and circadian mechanisms was indisputable, yet how best to modify these conditions while simultaneously achieving the goals of training professional practitioners ready for fulfilling careers and the provision of excellent patient care remains in dispute. The primary approach has been to address sleep deprivation through work hour restrictions. The expansive literature examining how the duty hour limitations have influenced trainee wellbeing/education and patient safety has yielded decidedly mixed findings, although there is a suggestion that medical and surgical disciplines are differentially impacted, raising the possibility of more specialty tailored future work hour regulations.

Far less attention has been paid to studying and mitigating the circadian misalignments integral to the house staff training experience. The unpredictable trajectory of medical conditions and the complexity of modern-day inpatients require hospitals to maintain the capacity to deliver care around the clock which inevitably means trainees will work and sleep at times that are inopportune from the circadian standpoint and that places residents at increased risk for adverse events, such as percutaneous injuries. The commonly employed strategy of limiting resident exposure to overnight duty by providing them night float coverage has been understudied, and the limited data suggest inconsistent impacts. Grossly underexplored are strategies to facilitate resident circadian acclimatization in the setting of extended and/or rotating work shifts.

ACGME acknowledges that its duty hour policies are a “living document that will continue to evolve in response to changing medical and educational practices, cultural mores, and research findings” [58]. The continuing effort to optimize resident working conditions will result in an ongoing tension between sleep homeostatic and circadian considerations. To date, work hour restrictions have been prioritized, but they are just one component of the very complex training environment, and further attention to circadian and other contextual elements, such as faculty supervision and handoffs of information at transition points in patient care, is anticipated.

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