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The '16-Hour Rule': A Giant Step, But in which Direction?



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In attempts to prevent the kinds of medical errors that led to the death of Libby Zion in 1984,¹ a variety of residency program reforms have been enacted. As the misdiagnosis (although the true diagnosis still remains a mystery) and mismanagement were ascribed in large part to fatigue, the most consequential focus of rule changes has been progressive restrictions in resident duty hours.¹

In 1990, the Accreditation Council for Graduate Medical Education (ACGME) set an 80-hour-per-week duty-hour limit, which includes at least one 24-hour period entirely off. By 2003, the limit was extended to all specialties, with an additional proviso of a

maximum shift length of 24 hours, with up to 6 additional hours for education and handoffs. The most recent directive,² put into effect in July 2011, restricts postgraduate year (PGY)-1s to shifts not exceeding 16 hours. In addition, it strongly encourages strategic napping.

With the threat of loss of accreditation, the consequences of noncompliance with these regulations are serious, requiring programs to have taken steps, such as barring interns from finishing their patient duties if they have gone past their allotted shift. However, few data explore whether these regulations have led to improvements in resident education and patient outcomes³; the limited findings to date are often contradictory in judging the impact of the 16-hour rule. The purpose of our study is to examine PGY-1 resident perceptions of educational and patient care experiences in the medical intensive care unit (MICU) through a survey of 2 groups completing a first year of training before and after the 16-hour rule change.

METHODS

Study Population

The study population included 2 cohorts. The first included all internal medicine PGY-1 residents in 11 ACGME-accredited programs during the 2010-2011 academic year. The second consisted of the 2011-2012 PGY-1 classes of the same programs. These cohorts are

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referred to as PreRC and PostRC, respectively. Three university programs, one US Department of Veterans Affairs (VA) program, and 7 community programs participated. Approval of the study and protocol was granted by our hospital's Institutional Review Board.

Data Collection

We sent an e-mail containing the link to a confidential, voluntary, electronic questionnaire to the program directors at the 11 teaching programs, requesting that the link be forwarded to all PGY-1 internal medicine residents. A \$10 cash incentive for completing the questionnaire was provided. Data were collected utilizing Research Electronic Data Capture (REDCap) Consortium software.

Instrument

We limited our study to MICU experiences, because in many programs 24-hour shifts applied only to intensive care units. The survey questions asked residents to evaluate their service- and education-related hours, quality of care, education, and sleepiness. To avoid a potential bias of framing the questions in a "before and after" format, we queried subjects only in their respective current PGY-1 years.

Analyses

Analyses were conducted using SPSS, version 21.0 (IBM SPSS Statistics for Windows, Version 21.0; Armonk, NY). Frequency distributions were used to describe the characteristics of the survey respondents. Chi-squared tests were used to measure associations between categorical variables; *t* tests for continuous outcome measures were utilized to compare differences between groups. Additionally, certain survey question responses were dichotomized for some statistical analyses. For the questions related to the number of days the work rule was disregarded, 1 or 2 days, 3 or 4 days, 5 or 6 days, and 7 days or more were collapsed into "Ever Violated."

RESULTS

We received 155 surveys from 263 requests (response rate 59%) and 153 of 272 requests (56%), respectively, from the PreRC and PostRC groups, a total of 308 community hospital and 227 university hospital first-year residents. (For the purposes of this study, the

VA program was tallied with the community hospital group.)

Respondent characteristics including age, sex, living arrangements, and graduation from a US/Canadian or international medical school are summarized in **Table 1**. We found no differences between the 2

cohorts except for an unexplained significantly greater age in the PreRC group.

We found no significant differences between the cohorts in terms of resident perceptions of the quality of care they provided (**Table 2**), with 2 exceptions: residents in the PreRC cohort were more likely to agree that the longest shift negatively influenced their care and PreRC residents expressed greater agreement with the statement that they had sufficient time to provide ideal continuity of care. With respect to resident perceptions of their educational experiences, PostRC residents reported significantly less

agreement that they had seen an adequate number of patients to prepare for the second year of residency and beyond, the number of patients seen was ideal for their training level, the education provided was ideal for advanced residency, and they had had enough time needed in the hospital to meet their educational needs. PostRC residents were more likely to agree that they had had sufficient time for reading. However, overall satisfaction with their educational experience was not statistically significantly different.

While no differences in self-reported violations of duty hours to improve quality of care were found across the 2 groups, a nonstatistically significant increase in duty-hour violations was reported by PostRC residents (**Table 3**).

Using a modified Epworth Sleepiness Scale, with a range of 0 to 12 (higher values reflecting greater sleepiness), the PreRC group mean was 3.8 (SD 2.45), while the PostRC group was 2.7 (SD 2.2), $P < .001$; indicating that the PreRC group reported greater sleepiness.

Finally, we asked if residents were completing patient care and educational activity off site to comply with training program rules (**Table 4**). Fewer hospital hours for patient-related activities, but more outside hospital hours were reported by the PostRC group, so that the combined onsite and offsite hours were not statistically different between the 2 groups. In the same line of questioning for educational activities

PERSPECTIVES VIEWPOINTS

- Residency work hour revisions have brought unexpected outcomes.
- Compared with a pre-16-hour shift medical resident cohort, a post-16-hour cohort reports little difference in provision of quality care, but significant declines in education.
- Although the post-rule-change cohort spent fewer hours in onsite patient care duties, total weekly patient care hours onsite and offsite averaged nearly the same.
- We encourage reflection on regulations in place and those in process.

Table 1 Respondent Characteristics

Characteristics	PreRC n = 155 n (%)	PostRC n = 153 n (%)	P Value Chi-squared (Dichotomized Variables)
Age, y			
<30	74 (48)	100 (66)	.002
≥30	79 (52)	52 (34)	
Sex			
Male	75 (49)	75 (49)	1.0
Cohabitation with spouse/significant other during rotation			
Yes	92 (61)	83 (55)	.296
No	60 (40)	69 (45)	
At least some responsibility for children during rotation			
Yes	35 (23)	23 (15)	.08
No	117 (77)	129 (85)	
Medical school attendance			
US or Canada	87 (57)	93 (61)	.484
Other	65 (43)	59 (39)	

RC = rule change.

(Table 5), there were no significant cohort differences in reported onsite and offsite hours.

DISCUSSION

Our study examined the effects of the newest duty-hours changes on PGY-1 resident perceptions of their educational experiences and their ability to provide quality care. Perceptions of quality of care differed somewhat, with the PreRC residents agreeing more that the longest shift negatively influenced their provision of care, but also agreeing more that they had sufficient time to provide ideal continuity of care.

We found more differences in perceptions of the educational experience. Residents with the 16-hour limitation reported less agreement with exposure to the number of patients needed for ideal training and for preparation for the second year of residency. They reported needing more time in the hospital to meet educational needs, but did indicate that they had more time to read and were less sleepy. A reported decline in onsite patient-related activities was counterbalanced by an equal amount of offsite hours dedicated to similar work. Time dedicated to educational activity on site and off site did not differ following the rules change, while a nonstatistically significant increase in voluntary duty

Table 2 Resident Perceptions of Quality of Care and Education in the MICU*

	PreRC n = 155 Mean [SD]	PostRC n = 153 Mean [SD]	P Value t Test
Longest shift of the week <i>negatively</i> influenced provision of high-quality patient care.	3.32 [1.19]	2.86 [1.25]	.001
Sufficient time to provide ideal quality of care.	4.02 [0.96]	3.95 [0.97]	.511
Sufficient time to provide ideal continuity of care.	3.87 [1.04]	3.59 [1.14]	.027
Overall satisfaction with patient care experience.	4.31 [0.91]	4.22 [0.79]	.404
Satisfaction with the amount of residency supervision.	4.22 [1.01]	4.38 [0.79]	.137
Number of patients sufficient to prepare for the second year of residency and beyond.	4.16 [0.83]	3.79 [1.05]	.001
The number of—and exposure to—patients at an appropriate level for ideal training.	4.24 [0.89]	3.98 [0.92]	.012
Education was ideal preparation for the second year of residency and beyond.	3.98 [1.023]	3.74 [0.94]	.031
Adequate time for reading.	2.59 [1.16]	2.87 [1.2]	.044
More time needed in the hospital to meet educational needs.	2.56 [1.6]	2.88 [1.2]	.021
Overall satisfaction with educational experience.	4.08 [0.96]	3.93 [0.94]	.184

MICU = medical intensive care unit; RC = rule change.

*Tables include all those who responded to each item; however, not all respondents completed every item. Likert scale is 5 points: 1 = Strongly Disagree, 2 = Somewhat Disagree, 3 = Neutral, 4 = Somewhat Agree, 5 = Strongly Agree.

Table 3 Resident Reports of Incidence of Voluntary Work-Hour Violations to Deliver Quality Care and Improve Education*

	PreRC n = 155 n (%)	PostRC n = 153 n (%)	Chi-squared
During an average MICU month, I disregarded work hour rules in order to deliver quality patient care:			
Never violated	60 (39)	59 (39)	.979
Ever violated	94 (61)	93 (61)	
During an average MICU rotation month, I disregarded the work hour rules to improve my educational experience:			
Never violated	93 (61)	78 (51)	.0829
Ever violated	59 (39)	74 (49)	

MICU = medical intensive care unit; RC = rule change.

*Tables include all responders; however, not all respondents completed every item.

hour violations to improve education was seen in the PostRC group. The difference in overall satisfaction with education, however, was not statistically significant.

Regarding the effects of decreasing duty hours, the literature remains in flux. An investigation from 2004 demonstrated that the elimination of extended work shifts significantly reduced the number of hours worked, improved sleep duration, and, most importantly, decreased the rate of attentional failures.⁴ What that work was not designed to do was to study whether such interventions improve resident health and education as well as patient safety.⁴ Alertness is not necessarily a simple inverse of sleepiness, because fund of knowledge, experience, and limiting stress may obviate the advantages of increased sleep.⁵

In a randomized trial utilizing a single-center intensive care unit setting of medical interns, Landrigan et al⁶ did show that interns in a schedule limited to 16-hour shifts versus a traditional every-third-night rotation made significantly fewer serious medical errors, but no difference was found in preventable adverse events. Potential small biases in fully blinding the observers were pointed out by the authors. However, after publication of this study, 3 residents from the

intervention group wrote that residents and attending physicians, worried that interns in the intervention group may have known little about their patients, took a much more active role in patient care, resulting in hypervigilance that could have potentially biased the study.⁷ Furthermore, a fourth intern was reportedly added to the service of the intervention group.⁸

In a subsequent prospective cohort study of 3 pediatric residencies, Landrigan and colleagues⁹ found that after the 2003 rule changes, rates of resident burnout decreased, but total work hours, sleep, depression, medication errors, and education showed no improvement.

In a single institution survey of internal medicine residents in 2001, Goitein et al¹⁰ administered a survey in 2003 after the 80-duty-hour regulations went into effect, and compared well-being, patient care, and education in these 2 groups of a total of 161 residents (118 respondents). They found an increase in career satisfaction and a decrease in burnout, but negative effects on patient care and education.¹⁰

Although we did not demonstrate a decrement in perception of patient care, our data do support the concept of a negative impact of the 16-hour rule change on resident education.

Table 4 Self-Reported Hours Spent Engaged in MICU Patient Care, Onsite and Offsite*

	PreRC Mean [SD]	PostRC Mean [SD]	P Value 2-Tailed t Test
Hospital hours per week for MICU patient-related activities (patient care, work rounds, paperwork, etc.)	n = 135 74.29 [7.38]	n = 141 70.36 [8.75]	P < .001
Outside hospital hours per week for MICU patient related activities (paperwork, dictations, phone calls, etc.)	n = 134 4.65 [9.64]	n = 140 8.91 [25.86]	P = .070
Combined hospital and outside hospital hours for MICU patient-related activities	n = 135 78.90 [10.95]	n = 141 79.21 [26.26]	P = .900

MICU = medical intensive care unit; RC = rule change.

*Hours engaged in patient care were filtered to include only those responding with >40 hours and <90 hours per week. Results were similar when filtering out only zero- and 160-hour extremes, as were results with no filtering at all.

Table 5 Hours Spent Engaged in MICU Educational Activities, Onsite and Offsite*

	PreRC Mean [SD]	PostRC Mean [SD]	P Value 2-Tailed <i>t</i> Test
Hospital hours per week for MICU education-related activities (teaching rounds, conferences, reading, etc.)	n = 134 11.72 [7.38]	n = 140 12.24 [8.75]	<i>P</i> = .71
Outside hospital hours per week for MICU education-related activities (study, preparation of reports, etc.)	n = 134 4.81 [5.01]	n = 140 5.27 [8.88]	<i>P</i> = .60
Combined hospital and outside hospital hours for MICU education-related activities	n = 134 16.53 [13.51]	n = 140 17.51 [19.28]	<i>P</i> = .63

MICU = medical intensive care unit; RC = rule change.

*Hours engaged in educational activities were filtered to include only those responding with >40 hours and <90 hours of working hours per week. Results were similar when filtering out only zero- and 160-hour extremes, as were results with no filtering at all.

While fatigue in its own right can be identified and quantitated, it is a much greater challenge to ascertain its effects on patient care and resident education, because the 16-hour rule also has impact on handoffs, supervision, education, accumulation of experience, and ownership of patients. All of these issues affect patient outcomes; it is unclear how the new systems have affected these variables. As a result, these rules have not been free of controversy. In a recent survey of program directors, 83% agreed with an 80-hour weekly maximum of duty hours, but only 14% prospectively supported the 16-hour rule.¹¹

In a pilot study of creating a 16-hour shift in one of 2 gastroenterology services at the Mayo Clinic, patient care was unchanged in the intervention and control groups. However, in the intervention group, residents reported feeling less prepared to manage cross-covered patients and trended toward decreased perception of quality of education and balance between personal and professional life. They also reported fewer time-off hours between shifts.¹²

In 2010, a large, nationwide survey asked residents how they felt about the upcoming rule change.¹³ These residents came from multiple specialties and all years of training, so it is a large, broader look than our study; moreover, the survey population was not necessarily directly affected by the change. Nevertheless, these 2561 respondents indicated that while they expected the changes to have a positive effect on their quality of life, they also anticipated negatives regarding quality of care, education, experience, fund of knowledge, and resident preparation for more senior roles. Opinions were closer regarding patient safety, with 34% feeling that it would be positively affected and 39% that it would be negatively affected. The results for overall education showed a 48% negative versus 26% positive.¹³

A follow-up survey after the rules change demonstrated similar feelings to those that had been anticipated. In the move to a 16-hour maximum shift, 42.8% of residents reported no change in the quality of education, while 40.9% reported that it had worsened and

16.3% said it had improved. More than 50% said that preparation for more senior roles was worse. Decreased exposure to patients, conferences, and continuity of care were all reported, as was a 72% increase of handoffs.¹⁴ Although improvement in the quality of life predicted for interns was borne out, about one-half of the senior residents reported worsening. Overall, only 22.9% of the residents were in favor of the new regulations, compared with 48.4% who were opposed.¹⁴

Finally, 2 recent studies report that reducing intern duty hours has disrupted training, increased error rate, and has had minimal impact on sleep. The first study surveyed 51 residency programs in 14 institutions. After the rules change, duty hours fell from 67 to 64.3, while sleep hours, depression, and well-being scores did not change. Self-reported medical error rate, however, increased significantly, from 19.9% to 23.3%. Not measured was the author's speculation, based on anecdotal data, that interns were leaving at the end of the shift to comply with the rules, but were completing administrative work off site.¹⁵ Our own data support the existence of that phenomenon.

The second report was a 3-month crossover study comprising 4 medical resident teams at Johns Hopkins University School of Medicine, which worked in shifts simulating the pre- and post-16-hour rule. Sleep increased, but the number of patients admitted to each intern per month decreased strikingly, as did the increase in the number of handoffs and the number of different interns caring for a patient. There was also a loss of education time of 25%; interns, nurses, and attending physicians expressed dissatisfaction with the 16-hour rule change schedule.¹⁶

Patient handoffs seem to be a particular menace, because an estimated 80% of significant medical errors involve miscommunication between caregivers at these times, according to the Joint Commission Center for Transforming Healthcare.¹⁷ Communication breakdowns were the leading cause of sentinel events reported to the Joint Commission from 1995 to 2006. A report from Australia showed that of 25,000-30,000 preventable severe adverse events, 11% were due to

communication lapses, compared with only 6% secondary to inadequate practitioner skills.¹⁷

Limitations

Our data are based on a relatively small number of residents. A few survey responses were clearly erroneous—eg, one reported a workweek of 0 hours and another tallied 160 hours—but inclusion and exclusion of outliers did not produce statistically different conclusions. Self-reporting can introduce bias, although the absence of reference to the rules change perhaps negated some of that risk. Finally, as in all surveys with a sizable number of nonresponders, data may not be necessarily generalizable.

CONCLUSIONS

A misdiagnosis in 1984, albeit tragic but mistakenly attributed to exhaustion, has led to still evolving and pronounced changes in the training of residents. Despite all that has been written, a relative paucity of data still exist regarding resident perception of their education and patient care before and after the most recent rules changes for 2011. The mistakes in the management of the Libby Zion case—and many cases prior and since—may have involved a component of fatigue; most likely the lack of experience, supervision, and an absence of a safety net computerized drug interaction system all played substantial roles.

It remains unclear if the changes in the education of residents and the quality of teaching by attending physicians have improved since universal rules changes began in 2003. Faculty is participating in more direct patient care and has less time to teach. Residents, despite reduced duty hours, often have less time to do the same amount of work with a consequent detriment to education and an increased risk for burnout.¹⁸

Without yet having elucidated to this day the actual cause of Libby Zion's death, we have witnessed how pressure from the public and Congress has had wide impact.¹⁹ Changes in work hours have generally come from neither analysis of evidence-based data nor input from those on the front lines. Although one recent study showed an increase in educational benefit and even patient exposure after the 16-hour rule change,²⁰ most work, including ours, suggests that the results of the new rules have largely negated the purpose of the changes.

We offer this cautionary signal and express concern that the 16-hour rule has the potential to erode resident education, morale, and consequently, the safety and future care of their patients. We urge further study and policy flexibility if more data emerge that confirm our conclusions. The implications of any detriment to resident education are profound; theories about improving educational and patient safety outcomes by

adding “strategic napping” and “alertness management” to program curricula are simplistic approaches to very complex processes, most of which can be best advised by the program directors and residents who are currently burdened by the very real constraints of untested rules. The administrative representation of ACGME itself has conceded that, “We’ve created a rigid monster without flexibility.”³

We believe that very few educators seek to return to the punishing days of old, but sufficient data now allow us to speak against a leap to the other end of the spectrum. Our residents are providing input that we cannot afford to ignore. And the individuals who inculcate evidence-based medicine—that is, who are directly responsible for propagating our next generation of physicians—need to regain custody of their training programs.

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