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Duty Hours, Quality of Care, and Patient Safety: General Surgery Resident Perceptions

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Abstract

Background—The balance between patient treatment risks and training residents to proficiency is confounded by duty hours limits. Stricter limits have been recommended to enhance quality and safety, although supporting data are scarce.

Study Design—A previously piloted survey was delivered with the 2010 American Board of Surgery In-Training Exam (ABSITE). First postgraduate year (PGY1) and PGY2 trainees took the Junior exam (IJE); PGY3 and above took the Senior exam (ISE). Residency type, size and location were linked to examinees using program codes. Five survey items queried all residents about care quality impact of further hours limits; online test residents answered 7 more items probing medical error sources. Data were analyzed using factorial ANOVA for association with gender, PGY level, and program demographics.

Results—6161 Categorical Surgery residents (CS) took the ABSITE: 60% men, 60% ISE, 2/3 in University programs. Paper (n=5079) and online (n=1082) examinees were similar. Item response rates ranged from 91–98%. Few (<25%) perceived that stricter hours limits would improve care quality to a large or maximal extent. IJE plus West and Northeast residents significantly more often favored fewer hours. Factors perceived as contributing to medical errors usually or always by 15% of residents were incomplete handoffs, inexperience or lack of knowledge, insufficient ancillary personnel, and excessive workload.

Conclusions—Most CS do not perceive that reduced duty hours will noticeably improve quality of care. Resident perceptions of causes of medical errors suggest that system changes are more likely to enhance patient safety than further hours limits.

INTRODUCTION

A New York City grand jury's finding that resident fatigue contributed to Libby Zion's death in 1984 drew unprecedented public attention to the long, intense hours of graduate medical education (GME) (1). In 1989 the Code 405 regulations became law in New York

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state, mandating duty hours limits for all residencies, but enforcement was sketchy until 1998. In 1999, the Institute of Medicine (IOM) report *To Err is Human* (2) attributed nearly 100,000 deaths annually to medical errors, galvanizing healthcare practitioners to more rapidly adopt best practices to achieve high quality patient care outcomes and to actively foster patient safety. By 2001, intensifying public scrutiny of taxpayer funded GME and escalating patient quality and safety movements coalesced with emerging sleep science findings to produce draft federal regulations for resident duty hours (HR 3236 and S 2614). Legislated work hours limits were averted, however, by implementation of uniform minimum duty hours standards in 2003 by the Accreditation Council for Graduate Medical Education (ACGME). Continued public pressure on the GME community culminated in a Congressional request for the IOM to comprehensively review resident duty hours. In December 2008 the IOM Committee on Optimizing Graduate Medical Trainee (Resident) Hours and Work Schedules to Improve Patient Safety published their report entitled *Resident Duty Hours: Enhancing Sleep, Supervision, and Safety* (3) strongly recommending more tightly limited duty hours. In response, the ACGME charged a Taskforce to reassess the 2003 standards and their impacts through a multi-part process (4). In September, 2010 the ACGME approved revised, stricter duty hours requirements for implementation by all residencies in July, 2011 (5).

A repeated finding of both the 2008 IOM Committee and the ACGME Taskforce was the scarcity of high quality data relevant to the clinical consequences of resident fatigue and about the impact of the 2003 regulations on patient care quality and safety. To address qualitative data gaps, in January 2010 we posed two sets of questions to residents training in ACGME-accredited General Surgery programs who had experienced only the 2003 rules. First they were asked to assess the extent to which further duty hours restrictions would improve the quality of patient care. Second they were queried about potential sources of medical errors involving residents, including fatigue. Besides the mandatory minimum five years of general surgery residency in all programs, 1-2 years of research or other professional development activity are embedded within many programs. Therefore, 2010 represented the first year in which virtually all residents completed all of their graduate surgical education under the 2003 ACGME standards. Response rates were maximized by delivering the voluntary survey questions with the 2010 American Board of Surgery In-Training Examination (ABSITE).

METHODS

A resident survey given with the 2009 Internal Medicine In-training Examination (IMITE) was modified and delivered with the 2010 ABSITE. The initial IM-ITE items were derived from a literature review about the impact of the 2003 duty hours standards. Revisions were made by the IM-ITE steering committee and by a subgroup representing the American College of Physicians, the Alliance for Academic Internal Medicine and the University of Pennsylvania. The final IM-ITE items were adapted for ABSITE survey use by ABS psychometricians, Association of Program Directors in Surgery (APDS) representatives and University of Pennsylvania investigators. In 2010 the ABSITE was administered in both online and paper formats. Survey item number, however, was limited by available paper answer sheet space. The ABSITE was administered on paper at many residencies but a subset of programs accessed a computer-based version via the Internet. Programs using the online test were volunteers recruited by the ABS and APDS through a process unrelated to the survey study. Survey questions were distributed after exam completion and participation was voluntary.

To explore the relationship between duty hours and patient care quality, all examinees were asked to anticipate the degree to which five potential modifications of the 2003 duty hours

standards, then under consideration by the ACGME Taskforce, would improve quality. Answer choices were arrayed from Not at all to To a maximum extent (Table 1). Factors impacting patient safety while the 2003 regulations were in force were probed by asking residents taking the online ABSITE to estimate how often seven potential sources currently contribute to medical errors involving residents. The five response options ranged from Never to Always (Table 1). All residents also answered 12 questions concerning clinical supervision, time for educational activities and sleep habits on common rotation schedules. Findings from these 12 items have been reported separately (6).

Residency type (University versus Independent, based upon an ABS master list), size (Small 1-3, Medium 4-6, Large >6, based upon finishing chiefs per year) and location (Northeast, Southeast, Midwest, Southwest, West, based upon ABS region definitions) were linked to examinees using residency program codes. Gender and postgraduate year (PGY) level were self-reported. Two distinct tests comprise the ABSITE. First postgraduate year (PGY1) and PGY2 trainees take the Junior exam; those at PGY3 or higher are given the Senior exam. Survey responses thereby may be categorized as Junior (IJE group) or Senior (ISE group) PGY levels. Data were filtered to capture responses only from Categorical Surgery residents to eliminate any data skewing by the heterogeneous perceptions of Preliminary residents who ultimately will pursue a wide variety of specialties.

Data analyses included descriptive statistics and group mean calculations for survey item responses. Group means were derived by converting the 5 option answer arrays (Table 1) to 5 point scales (Table 2): “Not at All” and “Never” = 1, “To a maximum extent” and “Always” = 5. To determine if the online test group was representative of all residents, the survey response patterns and the ABSITE test results of the online and paper groups were examined. Answer patterns for each survey item and ABSITE mean scores at each PGY level were compared with independent t-tests and Cohen’s d. Significance was set at $\alpha = 0.01$ and $d > 0.2$. Relationships of survey responses to gender and resident level and to residency program variables were explored through factorial ANOVA. Because of the multiple and complex variables being studied, the large number of comparisons being made and the large sample size, alpha was set to <0.001 to limit statistically significant but practically unimportant results. For the same reasons, effect size also was tested (omega-squared) with significance set at 1% of variance explained.

Survey data were processed separately from ABSITE scoring. Reports provided by the ABS to the authors contained deidentified data in accordance with ABS data-sharing policy. The survey was IRB approved (University of Pennsylvania). The authors and not the Board are solely responsible for analytic accuracy and results interpretation.

RESULTS

The ABSITE was administered to 7588 examinees in 2010. Excluding Preliminary residents left a study group of 6161 Categorical General Surgery trainees: 2545 IJE (41%) and 3616 ISE (59%). Gender or program codes were missing for <2% of residents; their survey responses were excluded from related subgroup analyses. Women comprised 40% of Categorical residents. University-sponsored programs contained two-thirds of trainees, Independent programs about 30%, and military programs 3%. About one-half of residents were enrolled in medium-size programs while the rest were fairly evenly split between small and large programs. Northeast and Midwest residencies accounted for about one-half of all residents, Southeast and West about one-third, and Southwest about 10%. Demographics of the IJE and ISE groups are indistinguishable (Table 3). The paper exam was given to 5079 residents (2088 IJE, 2991 ISE) and the online test was taken by 1082 trainees (457 IJE, 625 ISE). Survey response patterns and mean ABSITE scores did not differ significantly

between the paper and online test groups, supporting that the online survey findings may be considered a valid representation for all Categorical General Surgery residents.

Residents were asked to rate the degree to which each of five new proposed duty hours limitations would improve the quality of patient care. The response rate was 91% for each quality item. The greatest potential quality gain was anticipated for longer rest periods after overnight or extended (24 + 6 hrs) calls, yet fewer than 20% of residents foresaw a large or maximum gain from this change. Less than 15% expected a large or maximum improvement from restricting continuous duty to 16 hours or from required napping during extended calls. Junior residents were significantly more likely than senior residents to rate the quality improvement potential higher for all three of these interventions. Program location also was associated significantly with results for these three items, with Northeast and West region trainees more likely to perceive benefit. Northeast and West residents also significantly favored reducing the weekly cap below 80 hours. No quality items were significantly related to gender, program type or program size (Table 1, Table 2).

Resident views of patient safety were addressed by survey items exploring how frequently seven factors were implicated in medical errors involving residents. The response rate for each safety item was 98%. Sources most often identified as contributing to errors usually or always were insufficient ancillary support (15% IJE, 12% ISE), inexperience or lack of knowledge (16% IJE, 18% ISE), excessive workload (14% IJE, 17% ISE) and incomplete handoffs (19% IJE 16% ISE). Insufficient ancillary support was implicated significantly less often by Small program trainees. Trends were found for Midwest and West region residents more often to identify inexperience or lack of knowledge ($p = 0.008$, variance 1.0%) and for Large program trainees to cite excessive workload ($p = 0.002$, variance 1.0%). Inadequate electronic medical records, although thought by fewer trainees overall to contribute to medical errors usually or always, was picked significantly more often by Northeast and Midwest residents and significantly less often by Independent program residents. Incomplete handoffs did not vary with program type, size or location. Notably, resident fatigue was cited as a common cause of medical error by only 11% of IJE and 8% of ISE, while inadequate supervision was identified by only 5% each of IJE and ISE. Gender and PGY level was not significantly associated with safety perceptions (Tables 1, 2).

DISCUSSION

Despite over 7 years of nationwide implementation, resident duty hours limits remain controversial, especially within surgical specialties (7, 8, 9). Controversy persists in part because reliable data about the consequences of regulated hours are scarce, as noted by both the IOM and the ACGME. Credible controlled clinical trials of work hours configurations whose relevance spans all specialties are undermined by the complexity and diversity of GME, while meaningful educational outcome studies will require detailed performance measurements of many physicians over extended periods. Notable is a prospective, single institution, single specialty, crossover design trial comparing medical error rates for PGY-1 Internal Medicine residents assigned to either traditional overnight (24+6) or 16 hour duty periods in the Medical ICU or Coronary Care Unit (10). Serious errors occurred significantly more often during the traditional overnight schedule. This widely cited finding contributed to the 2008 IOM recommendation and the 2011 ACGME rule limiting the maximum duty period of PGY-1 residents to 16 hours. Interestingly, this study also found no significant differences in rates of overall preventable adverse events, serious procedural errors, or serious errors that were not intercepted by other healthcare professionals, suggesting that the system of care preserved patient safety despite PGY-1 errors.

Inferences about the impact of the 2003 duty hours standards on patient quality of care and safety have been pursued by analyzing large administrative databases including Medicare and Veterans Administration (VA) files and the National Inpatient Sample (NIS) pre and post work hours implementation. Volpp (11) reported that risk-adjusted VA mortality rates for selected common medical diagnoses declined more at high intensity teaching hospitals more than at low or no intensity facilities after 2003 standards implementation but surgical disease death rates were unaffected. A similar analysis of Medicare patients showed no mortality rate changes by teaching hospital intensity for medical or surgical conditions (12). Analysis of the Medicare discharge database for readmissions likewise showed no change in readmission rates for either medical or surgical diagnoses (13). Silber (14) similarly sought duty hours effects on prolonged inpatient lengths of stay by Medicare and VA patients and reported no significant changes for either medical or surgical patients. Rosen (15) queried the VA and Medicare databases pre and post 2003 standards using the Agency for Healthcare Research and Quality Patient Safety Indicators and reported no systematic effect of resident work hours on potentially preventable patient safety events. In a pre and post study of 2003 standards using the NIS, Shetty (16) identified decreased mortality risk for some medical diagnoses but no change for surgical conditions. These quantitative studies in aggregate suggest that neither positive nor negative impact on overall patient quality or safety can be inferred consistently from large healthcare outcome databases.

Quantitative pre and post analyses limited to surgical patient care likewise do not support a clear and major impact of the 2003 duty hours standards upon quality and safety. Hutter (17) and Kaarafani (18) in single center studies using NSQIP failed to find significant impacts in overall trauma related mortality or morbidity rates. Morrison (19) using the National Trauma Data Bank documented small declines in overall mortality at university hospitals versus small increases at nonteaching facilities. Using local data repositories, two single center studies reported no change in deaths or complications after urgent appendectomies and cholecystectomies (20, 21). Of note, in both studies all complications occurred within the initial 18 hours of the resident on call period, calling into question safety enhancement by limiting duty periods to 16 hours or less.

Numerous prior qualitative investigations of the impact of the 2003 duty hours have yielded heterogeneous results, unsurprising since studies have varied widely in their scope, size, focus and duration (22). Factors potentially confounding data analysis have included specialty, gender, resident seniority, program type, study intervals spanning changing regulations, and ongoing duty hours adaptations by teaching hospitals and residencies (23, 24, 25). Nevertheless, because residents are viewed as “filling all the cracks in our broken system” (26), seeking their healthcare delivery system assessments through qualitative investigations adds value to the debate about the impact of duty hours limits on patient quality and safety. While further work restrictions were implemented after our survey was conducted, our study substantially expands the qualitative data pool reflecting only the 2003 standards, against which results from 2011 and future regulatory eras will be compared. We asked residents whose training was conducted entirely under the 2003 limits to judge whether stricter rules would improve the quality of patient care, an outcome anticipated by those advocating tighter limits. Surgery residents rated the likelihood of substantially improved quality from any of five different reduced work hours options at 6-19% (Table 1). When our five quality item results are considered collectively, they strongly suggest that major gains in quality of surgical care are unlikely to be driven primarily by resident hours limits. Our results are consistent with surveys conducted soon after 2003 standards implementation, in which 10-28 % of General Surgery residents related the work hours limits to improved quality of care (27, 28, 29). Dozois (30) reported that 33% of junior residents judged care improved post 2003 standards implementation versus 21% of senior residents, consonant with the somewhat higher quality expectations of IJE versus ISE in our

study. Coverdill (23) noted a gender effect, with 24% of male residents and 52% of women finding improved quality after 2003 standards implementation. Gender did not significantly influence quality improvement perceptions in our study, perhaps due to our larger sample size. Residency location has not been addressed in previous work, and we lack a clear explanation for our finding that Northeast and West residents were more optimistic about quality gains than those in the Southeast, Midwest, and Southwest. Our study goes beyond prior work by addressing specific work hours provisions rather than simply the global concept of regulated hours. Of particular note is the rejection by over 85% of residents that patient care would notably improve with the 16 hour continuous duty limit that was subsequently enacted for PGY-1 residents in July 2011 or with mandated naps during overnight call that were advocated by the IOM in 2008 but not implemented by the ACGME in 2011. In an interesting analogy to our study, when Whang (31) in 2002 asked residents from 19 programs to predict the impact on quality of the upcoming 2003 standards, 45% expected a positive or very positive effect. Our considerably lower results in anticipation of the 2011 regulations suggest that resident optimism about duty hours limits has declined over time.

Our results also establish the post 2003 duty hours standards baseline of resident judgments about patient safety as reflected by medical errors. Residents whose training was conducted entirely under the 2003 limits were asked to estimate how often errors involving residents could be attributed to seven potential causes including resident fatigue. Most previous studies have asked only if patient safety has been impacted generically by the 2003 duty hours rules. In multicenter studies Coverdill (23) and Irani (29) reported perceived increases in error rates by 21-32% of respondents, compared to Vaughn's (32) single program study in which over 90% of residents disagreed that errors had increased. We did not ask residents to assess overall error rates but instead asked about specific contributing factors. Incomplete handoffs, inexperience or lack of knowledge, excessive workload and insufficient ancillary personnel were identified most often as major contributors though no one of these was said to explain 20% or more of errors. Residents from 9 programs most often agreed that lack of familiarity not fatigue is a major source of medical errors (23), consistent with our result that resident fatigue was judged to underlie medical errors by only 11% of IJE and 8% of ISE. Irani (29) reported that perceptions of increased medical errors by work hours restrictions were not related to resident gender, PGY level, or program type. We also found that gender and resident seniority did not significantly influence our results. Residents from small programs significantly less often implicated insufficient ancillary support in our study and large program trainees more often invoked excessive workload; prior studies did not report program size effects. We hypothesize that larger programs are more often located at large, publicly funded, safety net hospitals with limited budgets for ancillary personnel, but we have no supporting data.

The strengths of our study include a rigorous survey construction process, large sample size and very high response rates for every survey item. Lack of confirmatory objective metrics and failure to predefine "medical error" represent weaknesses that we cannot redress. Potential weaknesses include the smaller sample size for the patient safety items, survey administration to residents after the ABSITE was completed, and residents feeling pressured to respond because the ABSITE originates from the Board by whom they hope to become certified. Our smaller online group who answered the safety items comprised over 1000 residents and was representative of the entire group in terms of their survey answer patterns, so we believe our safety data represent a credible baseline for all Categorical Surgery residents. Residents may have been too fatigued to thoughtfully complete the survey after three or more hours of multiple choice testing, but the very high voluntary response rates argue against this effect. We cannot disprove that participation was pressured or that responses were biased due to ABS sponsorship of our survey. However, residents are

surveyed annually on various topics via the ABSITE with uniformly high response rates and accurate self reporting on verifiable answers.

In summary, we surveyed Categorical Surgery residents about work hours limits in relation to quality of care and about factors contributing to medical errors. The vast majority of trainees do not view resident fatigue as a frequent source of medical error nor do they believe more limited duty hours will enhance the quality of surgical patient care. From the resident perspective, system solutions to issues of ancillary support and incomplete handoffs seem more likely to impact medical errors than tighter work hours regulations.

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Abbreviations and Acronyms

NSQIP	National Surgical Quality Improvement Program
ANOVA	Analysis of Variance
IRB	Institutional Review Board

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Table 1

Survey Item Percentage Responses by Postgraduate Year Level

Indicate the degree to which you think each of the following would <u>improve the quality of patient care</u>	Not at all	To a small extent	To a moderate extent	To a large extent	To a maximum extent
IJE *					
Reduce the cap from 80 hrs	63	21	10	4	2
Limit shift to 16 hours	43	26	17	10	4
Require naps during 30 hr shifts	49	22	16	9	5
Increase hours off after nights and extended shifts	31	27	24	13	6
Enforce 80 hour rule each week	46	24	15	9	6
ISE †					
Reduce cap from 80 hrs	71	14	9	4	2
Limit shift to 16 hours	54	22	15	7	3
Require naps during 30 hr shifts	58	20	12	6	3
Increase hours off after nights and extended shifts	42	24	19	10	4
Enforce 80 hour rule each week	54	20	14	7	5
When medical errors involving residents occur in your work setting, how frequently are they due to each of the following?	Never	Rarely	Occasionally	Usually	Always
IJE *					
Inadequate supervision	21	53	21	5	0
Incomplete handoffs	8	37	37	16	3
Resident fatigue	16	48	26	9	2
Insufficient ancillary support	18	40	28	11	4
Inexperience or lack of knowledge	5	41	38	15	1
Excessive workload	16	42	28	11	3
Inadequate electronic medical records	33	39	17	8	3
ISE †					
Inadequate supervision	24	51	21	4	1

Indicate the degree to which you think each of the following would improve the quality of patient care	Not at all	To a small extent	To a moderate extent	To a large extent	To a maximum extent
Incomplete handoffs	10	37	37	15	1
Resident fatigue	20	53	20	6	2
Insufficient ancillary support	19	39	27	12	2
Inexperience or lack of knowledge	7	40	36	16	2
Excessive workload	16	45	22	14	3
Inadequate electronic medical records	37	39	16	5	3

Totals may exceed 100% due to rounding.

* IJE, junior exam group, PGY-1 and PGY-2 residents.

[†] ISE, senior exam group, PGY-3, PGY-4, and PGY-5 residents.

[C.E. Allow Table 1 to be set with a subhead row in the middle; exception to JACS style]

Table 2

Group Means and Statistics for Survey Items Reaching Significance

	Limit shift to 16 h	Require naps during 30-h shifts	Increase hours off after nights and extended shifts	Inexperience or lack of knowledge*	Inadequate EMR	Reduce cap from 80 h	Insufficient ancillary support	Excessive workload*
Postgraduate level								
IIE	2.05	1.99	2.36					
ISE	1.83	1.77	2.10					
p Value	<0.001	<0.001	<0.001					
% Variance	1.1	1.0	1.3					
Program type								
University					2.10			
Independent					1.89			
Military					2.16			
p Value					<0.001			
% Variance					1.2			
Program size								
Small							2.27	2.46
Medium							2.57	2.44
Large							2.42	2.70
p Value							<0.001	0.002
% Variance							2.0	1.0
Program location								
Northeast	2.02	2.06	2.33	2.57	2.13	1.65		
Southeast	1.83	1.73	2.10	2.62	1.90	1.47		
Midwest	1.85	1.75	2.10	2.84	2.08	1.47		
Southwest	1.76	1.69	2.02	2.57	1.98	1.42		
West	2.07	1.90	2.36	2.71	1.92	1.66		
p Value	<0.001	<0.001	<0.001	0.008	<0.001	<0.001		
% Variance	1.0	1.5	1.2	1.0	1.9	1.0		

*Trend, meeting one of two significance criteria (see text).
EMR, electronic medical record.

Table 3

Distribution of Sex and Program Demographics by Resident Level

Variable	All	IJE*	ISE*
Total, n	6,161	2,545	3,616
Sex, %			
Women	40	41	40
Men	60	59	60
Program type, %			
University	68	68	67
Independent	29	28	30
Military	3	4	2
Program size, %			
Small	23	23	23
Medium	49	50	49
Large	28	28	28
Program location, %			
Northeast	34	33	35
Southeast	17	18	17
Midwest	22	22	22
Southwest	11	11	11
West	14	14	14

Totals may exceed 100% due to rounding.

* IJE, junior exam group, PGY-1 and PGY-2 residents.

† ISE, senior exam group, PGY-3, PGY-4, and PGY-5 residents.