# The Impact of the 2011 Accreditation Council for Graduate Medical Education Duty Hour Reform on Quality and Safety in Trauma Care



Jayson S Marwaha, BA, Brian C Drolet, MD, Suma S Maddox, MD, Charles A Adams Jr, MD, FACS

BACKGROUND:	In 2011, the ACGME limited duty hours for residents. Although studies evaluating the 2011
	policy have not shown improvements in general measures of morbidity or mortality, these
	outcomes might not reflect changes in specialty-specific practice patterns and secondary
	quality measures.
STUDY DESIGN:	All trauma admissions from July 2009 through June 2013 at an academic Level I trauma
0.001.010.00	center were evaluated for 5 primery outcomes (eg. mortality and length of stay) and 10 sec.
	and any quality measures and practice netterns (eg. mortainty and relight of stay), and to see
	ondary quality measures and practice patterns (eg, operating room [OK] visits). All variables
	were compared before and after the reform (July 1, 2011). Piecewise regression was used to
	study temporal trends in quality.
RESULTS:	There were 11,740 admissions studied. The reform was not strongly associated with changes
	in any primary outcomes except length of stay (7.98 to 7.36 days; $p = 0.01$ ). However, many
	secondary quality metrics changed. The total number of OR and bedside procedures
	per admission (6.72 to 7.34; $p < 0.001$ ) and OR visits per admission (0.76 to 0.91;
	p < 0.001) were higher in the post-reform group, representing an additional 9,559
	procedures and 1.584 OR visits. Use of minor bedside procedures, such as laboratory and
	imaging studies, increased most significantly.
CONCLUSIONS	Although most major outcomes were unaffected quality of care might have changed after the
	raform Indeed a consistent change in recourse use natterns was manifested by substantial
	reform. Indeed, a consistent change in resource use patterns was mannested by substantial
	post-reform increases in measures such as bedside procedures and OK visits. No secondary
	quality measures exhibited improvements strongly associated with the reform. Several factors,
	including attending oversight, might have insulated major outcomes from change. Our
	findings show that some less-commonly studied quality metrics related to costs of care
	changed after the 2011 reform at our institution. (J Am Coll Surg 2016;222:984-991.
	© 2016 by the American College of Surgeons. Published by Elsevier Inc. All rights reserved.)

In 2011, the ACGME implemented revised standards for all residency programs in the United States that further restricted duty hours for residents. In addition to the 80-hour workweek limit set forth in the 2003 Common Program Requirements, these revised standards restrict

Disclosure Information: Nothing to disclose.

Presented at the 96th Annual Meeting of the New England Surgical Society, Newport, RI, September 2015.

PGY1 residents to shifts no longer than 16 hours, with at least 8 off-duty hours between shifts. More-senior residents with 24-hour shifts are allowed a maximum of 4 hours for transfer of care activities, followed by at least 14 off-duty hours between shifts.<sup>1,2</sup>

Although a primary goal of the 2011 Common Program Requirements was to reduce fatigue-related medical errors,<sup>3</sup> no recent studies have measured the policy's impact on these specific errors. Despite this goal, several national surveys have revealed that residency program directors and residents believe the quality and safety of care at their institution have either worsened or remained unchanged since the implementation of these new standards.<sup>4-8</sup>

In contrast to these perceptions, many retrospective studies after the 2011 policy reform have not shown

Received October 23, 2015; Revised January 5, 2016; Accepted January 5, 2016.

From the Department of Surgery, Warren Alpert Medical School, Brown University (Marwaha, Drolet, Maddox, Adams) and Department of Surgery, Rhode Island Hospital (Drolet, Maddox, Adams), Providence, RI. Correspondence address: Jayson S Marwaha, BA, Department of Surgery, Warren Alpert Medical School, Brown University, 222 Richmond St, Box G-9079, Providence, RI 02903. email: jayson\_marwaha@brown.edu

#### Abbreviations and Acronyms

- ISS = Injury Severity Score
- $LOS\ = length\ of\ stay$
- OR = operating room TPN = total parenteral nutrition

any change in mortality, length of stay, readmission rates, and other general outcomes metrics.<sup>9-12</sup> Similarly, most studies after the original (2003) Common Program Requirements reported no improvements in mortality and major indicators of morbidity.<sup>3,13-16</sup>

Although mortality and serious morbidity have ostensibly not been affected by duty hour standards, more specific effects of the 2011 regulations on quality and safety have not been studied extensively. The ACGME and others have noted that the study of nonspecific patient outcomes, such as all-cause mortality, has made it difficult to identify the source of any changes in quality, as these measures are also influenced by several other factors unrelated to duty hours.<sup>3,9,11,12,17</sup> Studying the effects of the reform with more granular and specialty-specific variables is important because quality of care can change without impacting major outcomes. Overall morbidity and mortality are influenced by many factors, and can remain insulated from the reform's effects due to safeguards such as attending oversight. However, clinically significant practice patterns (eg, surgical resource use) and secondary measures of quality (eg, thoracostomy site infections) might have changed.

Surgical residents and, therefore, surgical patients, might be more affected by duty hour restrictions, given the rigorous training and generally longer working hours.<sup>18</sup> Because trauma is a large component of surgical training, any effects of the policy would be particularly relevant in this field. In this study, our objective was to assess whether the 2011 duty hour reform was associated with changes in trauma care at 2 levels of specificity: first, in commonly studied measures of overall morbidity and mortality; and second, in more specific quality and safety measures. We selected these 2 levels based on our hypothesis that major outcomes might not reflect all changes in quality and safety.

# METHODS

#### Data collection

After IRB approval, we collected data from the Trauma Registry of Rhode Island Hospital, a database containing information on all patients admitted to the trauma service at our institution. We included only those patients admitted within 2 years before and after the implementation of the ACGME guidelines on July 1, 2011 (July 1, 2009 through June 30, 2013). Data were collected from the entirety of each patient's admission, including demographic data, all injuries and diagnoses, all procedures and interventions, outcomes, and follow-up.

Patients were divided into 2 groups: admissions before implementation of the 2011 Common Program Requirements (pre-reform: July 1, 2009 to June 30, 2011) and after implementation (post-reform: July 1, 2011 to June 30, 2013).

## Variables studied

We chose to study 10 secondary measures of quality and practice patterns a priori from the Trauma Registry of Rhode Island Hospital that are considered good markers of clinical judgment and performance. We included the following variables: total number of procedures per admission, number of operating room (OR) visits per admission, number of missed injuries per admission, number of consults per admission, rate of repeat central lines, rate of empyema after chest tube placement, and the following rates of complications after laparotomy: total parenteral nutrition (TPN), peritoneal abscess, organ/space infection, and unplanned reopening.

Our institutional trauma registry collects procedural data in procedure codes specified by ICD-9-CM. This coding scheme includes all bedside and OR interventions. Subgroup analysis on the number of ICD-9-CM procedures per patient was performed with Injury Severity Score (ISS) as an independent variable to address any potential confounding effects. Subgroup analysis on this variable was also performed by procedure type. All procedures were categorized in 1 of 4 groups using the 2015 ICD-9-CM Procedure Classes Tool, created by the AHRQ. The 4 groups were minor diagnostic (bedside, eg, imaging study), minor therapeutic (bedside, eg, chest tube placement), major diagnostic (OR, eg, staging laparotomy), and major therapeutic (OR, eg, exploratory laparotomy).

We measured 4 complications after laparotomy by including patients receiving exploratory laparotomy (ICD-9-CM code 54.11) and identifying those with subsequent TPN (99.15), percutaneous abdominal drain (54.91), or organ/space infection (collected by registry). Unplanned reopening of laparotomy was identified as those patients with more than one exploratory laparotomy, but without abdominal negative pressure wound therapy (collected by registry) coded between the 2 procedures. Although TPN administration is not itself a complication, we considered it a surrogate indicator of complications and morbidity. At our institution, enteral feeding is begun with nearly all patients after laparotomy unless there is a complication, such as anastomotic breakdown, fistula, or other unusual circumstance that requires TPN.

Empyema after chest tube placement was measured by including patients diagnosed with pneumothorax or hemothorax (860.0 to 860.5) who had a tube thoracostomy (34.04) followed by thoracoscopic drainage (34.06), thoracotomy (34.02), or empyema (collected by registry). Repeat central line placement was measured by including patients receiving a central line (38.97) and identifying those with a second central line. All patients were reevaluated 24 hours after presentation; missed injuries were defined as injuries not found on initial presentation but identified during this re-evaluation.

In addition to these 10 secondary quality metrics, we also studied the following 5 major outcomes: mortality, hospital length of stay (LOS), ICU LOS, number of complications per patient, and number of days on mechanical ventilation. Many recent studies of the 2011 duty hour policy have studied exclusively primary outcomes and have reported negligible changes in these metrics after the reform.<sup>9-12</sup> We included these variables for comprehensiveness, despite secondary quality measures being the main consideration in this study.

#### Statistical analysis

Student's *t*-test was performed on all continuous variables and Pearson's chi-square test on all categorical variables to compare overall rates for each end point between the preand post-reform groups. An  $\alpha$  of 0.05 was used. All analysis was performed in SPSS, version 22.0 (IBM Corp).

When comparing outcomes between 2 groups, the results of *t*-tests and chi-square tests alone can be affected by external influences (eg, other policy changes during the study period) and population differences. Therefore, we also conducted piecewise regression analysis on all variables to validate the findings of our chi-square and *t*-tests. Also known as "segmented regression analysis," this quasiexperimental approach has been described as an effective method for studying changes after policy interventions by comparing 2 separate regression functions, one before an intervention and one after.<sup>19,20</sup> The purpose of this test in our study was to determine whether any observed differences in overall rates between the pre-reform and post-reform groups were truly associated with the reform; differences not associated with the reform might simply represent ongoing background trends during the study period unrelated to the reform.

For each variable studied, 2 separate generalized linear piecewise regression models were created: one each for the pre-reform and post-reform cohorts. Binomial logistic regression models were used for dichotomous variables, such as mortality, and Poisson log-linear and negative binomial with log-link models were used for continuous variables, such as LOS and number of procedures per admission; the probability distribution that best fit each variable was used to construct its regression model. Models adjusted for patient demographics and comorbidities. The 2 regression coefficients were then compared to identify any change in temporal trends when the policy was implemented. This test produces 3 metrics: the prereform rate of change, post-reform rate of change, and difference in rates on July 1, 2011. A statistically significant difference in rates indicates that the reform is associated with a changing trend in that variable. It is possible for a variable to exhibit different pre-reform and postreform means by t-test, but no change in trends by piecewise regression. In this case, the observed difference in means is not considered to be associated with the reform; instead it might be a reflection of prevailing background trends unrelated to the reform.

# RESULTS

There were 11,740 admissions included in the analysis. Table 1 displays the baseline characteristics of all patients

Table 1.	Baseline	Characteris	stics of A	II Patients	Admitted
Before and	d After the	Duty Hour	Reform	Date	

	Pre-reform group	Post-reform group	
Baseline characteristic	(n = 5,449)	(n = 6,291)	p Value
Age, y, mean (SD)	53.45 (22.92)	56.19 (23.15)	< 0.001
Male	3333 (61.17)	3667 (58.29)	0.002
Race			
American Indian	3 (0.06)	3 (0.05)	0.860
Asian	43 (0.79)	50 (0.79)	0.973
Black	426 (7.82)	398 (6.33)	0.002
Native Hawaiian	8 (0.15)	10 (0.16)	0.867
White	4,555 (83.61)	5,321 (84.58)	0.152
Other	414 (7.58)	509 (8.09)	0.319
Injury Severity Score,			
mean (SD)	9.44 (8.33)	9.51 (8.04)	0.632
Injury type			
Blunt	4,621 (84.80)	5,313 (84.45)	0.600
Penetrating	562 (10.31)	607 (9.65)	0.230
Burn	163 (2.99)	159 (2.53)	0.125
Other	103 (1.90)	212 (3.37)	< 0.001
Comorbidities			
Hypertension	2,077 (38.12)	2,447 (38.90)	0.377
Smoking	1,318 (24.19)	1,654 (26.29)	0.008
Diabetes mellitus	679 (12.46)	772 (12.27)	0.776
Bleeding disorder	505 (9.27)	707 (11.24)	< 0.001
Functional dependency	481 (8.83)	681 (10.82)	< 0.001
Respiratory disease	533 (9.78)	596 (9.47)	0.593

Data are n (%) unless otherwise noted.

admitted before and after the reform date. There were some differences between the pre-reform and postreform populations. Mean age (53.45 years to 56.19 years; p < 0.001), sex (male: 61.17% to 58.29%; p =0.002), and black race (7.82% to 6.33%; p = 0.002) changed, and ISS and distribution of blunt trauma, penetrating trauma, and burn patients did not change. The 6 most prevalent comorbidities in each population are also presented in Table 1; these account for 67% of all comorbidities across the entire patient sample. Although the prevalence of hypertension requiring medication, diabetes mellitus, and respiratory disease did not change, the post-reform population exhibited 2% increases in patients with bleeding disorders (9.27% to 11.24%; p < 0.001), functional dependency (8.83% to 10.82%; p < 0.001), and current smoking status (24.19% to 26.29%; p = 0.008). Other comorbidities were excluded from analysis due to registry definition changes during the study period.

#### Chi-square and t-test analyses

Although most major indicators of morbidity and mortality did not change (Table 2), mean LOS was lower in the post-reform group (7.98 days to 7.36 days; p = 0.01). Many secondary metrics changed, as shown in Table 3. Mean number of procedures per admission was higher in the post-reform group, both overall (6.72 to 7.34; p < 0.001) and in all ISS subgroups. This difference was most significant in the least severely injured patients (ISS  $\leq$  15) (5.70 to 6.07; p < 0.001). Mean number of bedside procedures per admission was higher in the post-reform group, including minor diagnostic procedures, such as laboratory and imaging studies (3.61 to 3.87; p < 0.001), and minor therapeutic procedures, such as chest tube and central line placement (2.16 to 2.41; p < 0.001). Mean number of OR visits per admission also increased overall (0.76 to 0.91; p < 0.001) and in all ISS subgroups, most significantly in the least severely injured patients (ISS  $\leq 15$ ; 0.68 to 0.82; p < 0.001). This amounted to an additional 9,559 total

**Table 2.** Major Indicators of Morbidity and Mortality Before

 and After the Duty Hour Reform Date

Outcome	Pre-reform group	Post-reform group	p Value
Mortality, n (%)	309 (5.67)	361 (5.74)	0.875
Hospital length of stay, d	7.98 (14.45)	7.36 (11.46)	0.010
Days on mechanical ventilator	6.66 (10.36)	7.32 (10.07)	0.243
Days in ICU	6.47 (9.49)	6.24 (9.06)	0.474
No. of complications per admission	0.29 (0.79)	0.30 (0.76)	0.552

Data are mean (SD) unless otherwise noted.

**Table 3.** Practice Patterns and Secondary Measures ofQuality Before and After the Duty Hour Reform Date

.,	Pre-reform	Post-reform	
Variable	group	group	p Value
No. of procedures			
per admission	6.72 (6.37)	7.34 (6.76)	< 0.001
ISS 0 to 15	5.70 (4.90)	6.07 (4.69)	< 0.001
ISS 16 to 25	9.78 (6.36)	11.53 (6.76)	0.035
ISS 26 to 75	15.80 (11.68)	17.75 (12.54)	0.081
Minor diagnostic	3.61 (3.42)	3.87 (3.56)	< 0.001
Minor therapeutic	2.16 (2.05)	2.41 (2.22)	< 0.001
Major diagnostic	0.00 (0.00)	0.00 (0.00)	0.086
Major therapeutic	1.11 (1.05)	1.12 (1.03)	0.758
No. of operating room			
visits per admission	0.76 (1.10)	0.91 (1.37)	< 0.001
ISS 0 to 15	0.68 (0.97)	0.82 (1.25)	< 0.001
ISS 16 to 25	0.94 (1.09)	1.19 (1.37)	0.007
ISS 26 to 75	1.43 (1.96)	1.53 (2.15)	0.588
No. of consults per			
admission	1.02 (0.81)	1.42 (1.04)	< 0.001
After laparotomy, %			
Total parenteral			
nutrition	5.08	6.72	0.445
Peritoneal abscess	5.93	5.53	0.850
Organ/space infection	4.23	5.93	0.397
Unplanned reopening	8.08	6.66	0.601
Empyema after chest tube			
placement, %	9.49	11.36	0.419
No. missed injuries			
per admission	0.68 (0.23)	0.40 (0.27)	0.036
Repeat central lines, %	26.08	27.93	0.671

Data are mean (SD) unless otherwise noted.

ISS, Injury Severity Score.

procedures and 1,584 total OR visits in the post-reform group.

Mean number of consults per admission was also higher in the post-reform group (1.02 to 1.42; p < 0.001), and mean number of missed injuries per admission was lower (0.68 to 0.40; p = 0.036). Rates of complications after laparotomy, empyema after chest tube placement, and repeat central lines exhibited no difference between groups.

#### **Piecewise regression analysis**

Table 4 summarizes the results of piecewise regression analysis. For each variable, a separate regression function was constructed for the pre-reform and post-reform groups. The following covariates were used to construct each regression model: age, sex, black race, "other" injury type, current smoker status, bleeding disorder, and functional dependency. The exponentiation of the regression coefficient (ie, change per month in Table 4) reflects the

	Pre-reform group		Post-reform group		July 1, 2011	
Variable*	Change per month <sup>†</sup> (95% CI)	p Value	Change per month (95% CI)	p Value	Change in trend (95% CI)	p Value
Mortality	1.00 (0.99-1.01)	0.926	1.02 (1.00-1.04)	0.011	1.01 (0.99-1.03)	0.385
Hospital length of stay, d	1.00 (1.00-1.00)	0.509	0.99 (0.99-0.99)	< 0.001	0.99 (0.99-1.00)	0.024
Days on mechanical ventilator	1.00 (1.00-1.01)	0.070	1.00 (0.99-1.00)	0.051	1.00 (0.99-1.00)	0.306
Days in ICU	1.00 (1.00-1.00)	0.031	0.99 (0.99-1.00)	< 0.001	1.00 (0.99-1.00)	0.524
No. of complications	0.98 (0.98-0.99)	< 0.001	1.00 (0.99-1.00)	0.504	1.02 (1.01-1.03)	< 0.001
No. of procedures per admission	1.01 (1.01-1.02)	< 0.001	0.99 (0.99-1.00)	< 0.001	0.98 (0.98-0.98)	< 0.001
No. of operating room visits per admission	0.99 (0.98-0.99)	< 0.001	1.00 (0.99-1.00)	0.027	1.02 (1.02-1.03)	< 0.001
No. of consults per admission	1.02 (1.01-1.02)	< 0.001	1.01 (1.00-1.01)	< 0.001	0.99 (0.99-1.00)	0.002
After laparotomy						
Total parenteral nutrition	0.99 (0.93-1.05)	0.722	1.04 (0.96-1.12)	0.377	1.02 (0.91-1.14)	0.736
Peritoneal abscess	0.97 (0.91-1.03)	0.266	1.05 (0.96-1.14)	0.264	1.08 (0.96-1.21)	0.192
Organ/space infection	1.03 (0.96-1.09)	0.433	1.03 (0.95-1.12)	0.458	0.95 (0.85-1.08)	0.449
Unplanned reopening	1.09 (1.02-1.16)	0.009	0.99 (0.90-1.09)	0.882	0.87 (0.77-0.98)	0.027
Empyema after chest tube placement	0.97 (0.93-1.01)	0.136	1.02 (0.97-1.06)	0.450	1.05 (0.98-1.13)	0.178
No. of missed injuries per admission	1.00 (0.97-1.04)	0.866	1.02 (0.96-1.08)	0.515	1.03 (0.96-1.11)	0.437
Repeat central line rate	1.01 (1.00-1.02)	0.008	0.99 (0.98-1.00)	0.268	0.98 (0.97-1.00)	0.010

Table 4. Generalized Linear Piecewise Regression Models for All Variables

\*The following covariates were used to construct each regression: age, sex, black race, "other" injury type, bleeding disorder, current smoker status, and functional dependency.

<sup>†</sup>Change per month is displayed as an odds ratio for dichotomous variables, such as mortality, and as a multiplier for continuous variables, such as length of stay.

monthly trend for that variable. For binary variables, this is interpreted as an odds ratio. For example, in the post-reform period, the odds of mortality in any given month was 1.02 that of the previous month (95% CI, 1.00-1.04). For continuous variables, this is interpreted as a multiplier. For example, in the post-reform period, LOS in any given month was 0.99 times that of the previous month (95% CI, 0.99-0.99).

Piecewise analysis compares the pre- and post-reform exponentiated coefficients against one another. If the 2 are significantly different, then the duty hour reform is associated with this changing trend. In the case of mortality, the possibility that there is no difference between the 2 coefficients cannot be ruled out (p = 0.385), therefore, mortality does not exhibit any changing trends associated with the reform.

Piecewise regression analysis confirmed that changes in variables related to resource use, such as procedures and OR visits, were associated with the reform. Number of procedures per admission exhibited a changing trend associated with the reform date (0.98; 95% CI, 0.98–0.98; p < 0.001), as did OR visits per admission (1.02; 95% CI, 1.02–1.03; p < 0.001) and number of consults per admission (0.99; 95% CI, 0.99–1.00; p = 0.002). Length of stay exhibited a decreasing trend associated with the reform (0.99; 95% CI, 0.99–1.00; p = 0.024), consistent with the finding of a lower post-reform mean.

Despite the mean number of missed injuries per admission being lower in the post-reform group, as revealed by *t*-test, missed injuries exhibited an unchanged trend on the reform date (1.03; 95% CI, 0.96–1.11; p = 0.437), indicating that the observed improvements in missed injuries was not associated with the reform.

Trends in the rate of repeat central lines, unplanned laparotomy site reopenings, and the number of complications per admission, all changed from being statistically significant in the pre-reform era to exhibiting no evidence of change over time in the post-reform era (Table 4). However, there was no difference in overall rates between cohorts for any of these variables (Table 3).

A goodness-of-fit summary for each regression function is provided in Table 5. The parameter displayed provides information about how well the model approximates the dispersion of the data. A value >1 implies that the model is overdispersed relative to the data, and a value <1implies that an underdispersed model was fit to the data.

#### DISCUSSION

In 2011, the ACGME implemented new resident duty hour restrictions. There has been concern that these work hour limitations have not had the intended effect of improving patient safety.<sup>4-8</sup> Recent studies analyzing mortality and serious morbidity have found no significant

Variable	Pre-reform group*	Post-reform group
Mortality	1.014	1.001
Hospital length of stay, d	2.225	1.809
Mechanical ventilator days	1.834	1.634
ICU days	1.769	1.744
No. of complications per admission	1.615	1.589
No. of procedures per admission	0.708	0.684
No. of operating room visits per admission	1.004	1.136
No. of consults per admission	0.894	0.896
After laparotomy		
Total parenteral nutrition	1.003	1.006
Peritoneal abscess	0.969	0.913
Organ/space infection	1.018	0.953
Unplanned reopening	0.943	0.939
Empyema after chest tube	1.004	1.011
No. missed injuries per admission	0.982	0.985
Repeat central line rate	0.435	0.507

 Table
 5.
 Distribution
 Parameters
 for
 All
 Piecewise

 Regression
 Models
 Image: All State of the sta

\*The distribution parameter presented is Pearson's chi-square statistic/degrees of freedom.

positive changes.<sup>9-12</sup> However, these outcomes measures are influenced by many factors beyond just duty hours, and might not reflect changes in more specialty-specific practice patterns and quality metrics. In this study, we assessed changes in both primary outcomes and secondary measures of quality and safety in trauma care after the 2011 duty hour reform.

We found that none of the major indicators of morbidity and mortality included in this study exhibited changes strongly associated with the reform, with the exception of LOS, which had both a lower mean and decreasing trend after the reform. These variables were likely insulated from change due to many safeguards at our institution—such as an in-house trauma attending at all times—that prevent the exacerbation of minor errors and oversight of immediate or serious clinical concerns.

Many secondary variables exhibited substantial changes associated with the reform. Variables related to resource use changed most consistently. Both the total number of procedures per admission and the number of OR visits per admission increased overall. In particular, minor procedures, such as laboratory and imaging studies, increased most significantly, as did all procedures in the least severely injured patients. No secondary variables exhibited consistent improvements in both overall rates and trends after the reform.

Our findings are consistent with the new regulations, which most heavily affect work hour limits for PGY1 residents. We found that the most significant practice pattern changes were seen consistently in the least severely injured patients, who are most often admitted to the floor and cared for in a setting with less immediate oversight of junior residents. Therefore, it is possible that less-injured patients had more junior resident involvement in their care plan, thereby influencing procedural use more than patients with a higher ISS.

Identifying specific components of the 2011 policy that might have contributed to these practice pattern changes is difficult. One potential source is an increasing frequency of resident handoffs, which have been associated with errors and decreased quality of care.<sup>21,22</sup> Less resident experience is another possible explanation, as educational opportunities might have decreased after the policy change in the form of fewer didactic conferences attended, admission or operative experiences, and total hours of training.<sup>22,23</sup> Non-fatigue-related factors can contribute to medical errors, as reported in a study of 240 cases involving medical error, in which fatigue was a contributing factor for only 5% of errors, and handoffs and lack of technical competence or knowledge were contributing factors in 19% and 58% of errors, respectively.<sup>24</sup>

When analyzing the effects of policy reform, it is important to consider the effects of any external influences during the study period, including changes to personnel or to the care environment, that might distort the results of comparing pre-reform and post-reform groups. During our study period, there were no changes to divisional management, no other departmental regulations changes, no infrastructural changes in trauma patient care or transport, and no changes in the state trauma center landscape. In addition, there were no notable changes in the number of beds, attending physicians, mid-level providers, or residents on the trauma service at any given time during the study period. We were unable to identify any external influences that might have affected our findings.

This study has several limitations. The pre-reform and post-reform populations exhibited some differences in baseline characteristics, most notably an increase in mean age of 2.74 years and an increase in the prevalence of 3 comorbidities—bleeding disorders, functional dependence, and current smoker status—of 2% each. We considered the magnitude of these population differences to be marginal. In addition, after adjusting for these factors in our regression models, we still observed many meaningful changes in secondary quality measures. An older post-reform population with more comorbidities raises the possibility that the observed increase in resource use might actually have constituted appropriate care. The post-reform improvement in LOS also supports the interpretation that increased resource use was necessary. Our analysis was limited by using data from only a single institution, preventing us from comparing changes between teaching and nonteaching hospitals to better isolate the effect of the reform on residents, as has been done by several recent studies using a difference-in-differences approach.<sup>9-12</sup> Another limitation was the use of retrospective data. Although we selected variables from the registry that we considered to be good surrogate markers of clinical judgment and performance, we were limited by what our institutional registry collected. Whether better metrics exist for examining the effects of work hour limitations on practice patterns and quality is uncertain; additional study should be done to identify specific metrics affected by the reform.

### CONCLUSIONS

In summary, although most major indicators of morbidity and mortality remained insulated from change after the implementation of the 2011 duty hour reform at our institution, many secondary measures of quality in trauma care still changed. In particular, practice patterns related to resource use, such as the use of bedside procedures and the number of OR visits, increased most consistently. No secondary variables exhibited improvements strongly associated with the reform. Changes in these measures were not accurately reflected in the behavior of major outcomes and, in fact, suggest that lesscommonly studied areas of quality in the context of the 2011 duty hour reform, such as cost of care, should be studied. These institutional trends should be validated on a national level.

### **Author Contributions**

- Study conception and design: Marwaha, Drolet, Maddox, Adams
- Acquisition of data: Marwaha, Drolet, Maddox, Adams
- Analysis and interpretation of data: Marwaha, Drolet, Maddox, Adams
- Drafting of manuscript: Marwaha, Drolet, Maddox, Adams
- Critical revision: Marwaha, Drolet, Maddox, Adams

Acknowledgments: The authors would like to acknowledge Jason T Machan, PhD, Director of Biostatistics at Rhode Island Hospital, for guidance on statistical methods, and Ann George, RN, Trauma Program Manager at Rhode Island Hospital, for guidance on data collection and quality.

#### REFERENCES

1. ACGME. ACGME Common Program Requirements. Chicago, IL: ACGME; 2014.

- Nasca TJ, Day SH, Amis ES Jr. The new recommendations on duty hours from the ACGME Task Force. N Engl J Med 2010;363:e3.
- **3.** ACGME Task Force on Quality Care and Professionalism. The ACGME 2011 Duty Hour Standard: Enhancing Quality of Care, Supervision and Resident Professional Development. Chicago, IL: ACGME; 2011.
- Drolet BC, Christopher DA, Fischer SA. Residents' response to duty-hour regulations—a follow-up national survey. N Engl J Med 2012;366:e35.
- Drolet BC, Khokhar MT, Fischer SA. The 2011 duty-hour requirements—a survey of residency program directors. N Engl J Med 2013;368:694–697.
- 6. Drolet BC, Sangisetty S, Tracy TF, Cioffi WG. Surgical residents' perceptions of 2011 Accreditation Council for Graduate Medical Education duty hour regulations. JAMA Surg 2013; 148:427–433.
- 7. Drolet BC, Spalluto LB, Fischer SA. Residents' perspectives on ACGME regulation of supervision and duty hours—a national survey. N Engl J Med 2010;363:e34.
- Antiel RM, Thompson SM, Hafferty FW, et al. Duty hour recommendations and implications for meeting the ACGME core competencies: views of residency directors. Mayo Clin Proc 2011;86:185–191.
- **9.** Rajaram R, Chung JW, Cohen ME, et al. Association of the 2011 ACGME resident duty hour reform with postoperative patient outcomes in surgical specialties. J Am Coll Surg 2015;221:748–757.
- Rajaram R, Chung JW, Jones AT, et al. Association of the 2011 ACGME resident duty hour reform with general surgery patient outcomes and with resident examination performance. JAMA 2014;312:2374–2384.
- Scally CP, Ryan AM, Thumma JR, et al. Early impact of the 2011 ACGME duty hour regulations on surgical outcomes. Surgery 2015;158:1453–1461.
- Patel MS, Volpp KG, Small DS, et al. Association of the 2011 ACGME resident duty hour reforms with mortality and readmissions among hospitalized Medicare patients. JAMA 2014; 312:2364–2373.
- Prasad M, Iwashyna TJ, Christie JD, et al. Effect of workhours regulations on intensive care unit mortality in United States teaching hospitals. Crit Care Med 2009;37:2564–2569.
- 14. Volpp KG, Rosen AK, Rosenbaum PR, et al. Mortality among patients in VA hospitals in the first 2 years following ACGME resident duty hour reform. JAMA 2007;298: 984–992.
- **15.** Volpp KG, Rosen AK, Rosenbaum PR, et al. Mortality among hospitalized Medicare beneficiaries in the first 2 years following ACGME resident duty hour reform. JAMA 2007; 298:975–983.
- 16. Volpp KG, Rosen AK, Rosenbaum PR, et al. Did duty hour reform lead to better outcomes among the highest risk patients? J Gen Intern Med 2009;24:1149–1155.
- Fabricant PD, Dy CJ, Dare DM, Bostrom MP. A narrative review of surgical resident duty hour limits: where do we go from here? J Grad Med Educ 2013;5:19–24.
- Richardson JD. Workforce and lifestyle issues in general surgery training and practice. Arch Surg 2002;137:515–520.
- Wagner AK, Soumerai SB, Zhang F, Ross-Degnan D. Segmented regression analysis of interrupted time series studies in medication use research. J Clin Pharm Ther 2002;27: 299–309.

- Brown SE, Ratcliffe SJ, Halpern SD. Assessing the utility of ICU readmissions as a quality metric: an analysis of changes mediated by residency work-hour reforms. Chest 2015;147: 626-636.
- Denson JL, McCarty M, Fang Y, et al. Increased mortality rates during resident handoff periods and the effect of ACGME duty hour regulations. Am J Med 2015;128: 994–1000.
- **22.** Desai SV, Feldman L, Brown L, et al. Effect of the 2011 vs 2003 duty hour regulation-compliant models on sleep duration, trainee education, and continuity of patient care among internal medicine house staff: a randomized trial. JAMA Intern Med 2013;173:649–655.
- 23. Roshetsky LM, Coltri A, Flores A, et al. No time for teaching? Inpatient attending physicians' workload and teaching before and after the implementation of the 2003 duty hours regulations. Acad Med 2013;88:1293–1298.
- 24. Singh H, Thomas EJ, Petersen LA, Studdert DM. Medical errors involving trainees: a study of closed malpractice claims from 5 insurers. Arch Intern Med 2007;167:2030–2036.

# **Invited Commentary**



Lenworth M Jacobs Jr, MD, MPH, FACS Hartford, CT

The authors have addressed an area of interest for patients, surgeons, educators, regulatory agencies, and parties interested in public policy. There is considerable interest in the impact of duty hour restrictions on patient care and resident education.

The original tenant was that tired, fatigued residents are more prone to clinical and cognitive mistakes having substantial consequences. These events can result in increased patient morbidity and mortality. The sentinel case in New York City, in which a patient's death was linked to a fatigued resident, resulted in regulatory changes that dramatically changed resident education. These changes have resulted in significant complaints from senior surgeons, who are seeing residents who graduated from programs that have instituted these duty hour restrictions.

There have also been significant reports that residents are less comfortable with practicing independently after graduating from residency programs attesting to their successful completion of the cognitive and psychomotor requirements for taking the qualifying and certifying examinations of the American Board of Surgery.

These findings should not be a surprise because residents are expected to be competent to practice independently in two-thirds the amount of time (80 to 120 hours per week) and have significantly fewer operative caseloads on completion of their training.

The authors have selected the domain of trauma to evaluate the impact of the residency duty hour reform on clinical care. Trauma should be a good surrogate for this evaluation because it requires immediate attention to a patient with an emergent problem. This is particularly important because the event can occur at any time of the day or night. The new duty hour reforms were implemented in response to increasing pressure placed on surgical educators to implement strategies to prevent fatigued residents from managing patients.

The authors used a pre- and post-event model to evaluate resident patient care over 4 years in a level I trauma center. This is a busy center, so large numbers of patients were accrued to the study. They used sophisticated statistical methods to analyze the test variables and concluded that although most outcomes were unaffected, the quality of care may still have changed after the reform. There was increased resource use both in performing bedside procedures and in operating room visits. There was 1 major confounding variable of onsite attending surgeons, where the state may have insulated major outcomes from change.

It is unfortunate that the study design did not address resident and attending attitudes regarding these new changes. There are 2 unanswered questions. First, do these educational regulatory changes enhance patient care, and second, do they ultimately produce a resident who is competent and confident to practice surgery independently at the completion of their training?

The radical changes in surgical education implemented more than a decade ago to address perceived problems of resident fatigue thought to result in perceived diminished patient care cannot be allowed to overturn decades of surgical education that produced excellent surgeons. There has to be complete commitment to fulfill the twin requisites of enhanced patient safety and excellent patient care. The new resident education process must result in a generation of confident and competent residents who are comfortable in independently providing excellent clinical care upon completion of their residency. This was the expected and routinely attained outcome before the attenuation of resident work hours. Surgical educators should guarantee this outcome because patients expect no less.

# Journal of the American College of Surgeons 159 Country Netherlands -SIR Ranking of Netherlands H Index Subject Medicine Area and Surgery Category Elsevier BV Publisher Publication Journals type ISSN 10727515 1994-ongoing Coverage The Journal of the American Scope College of Surgeons (JACS) is a monthly journal publishing peer-reviewed original contributions on all aspects of surgery. These contributions include, but are not limited to, original clinical studies, review articles, and experimental investigations with clear clinical relevance. In general, case reports are not considered for publication. As the official scientific journal of This website uses cookies to ensure you get the Got it! best experience on our website

