REVIEW

The Interventional Arm of the Flexibility In Duty-Hour Requirements for Surgical Trainees Trial: First-Year Data Show Superior Quality In-Training Initiative Outcomes

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PURPOSE: With the implementation of strict 80-hour work week in general surgery training, serious questions have been raised concerning the quality of surgical education and the ability of newly trained general surgeons to independently operate. Programs that were randomized to the interventional arm of the Flexibility In duty-hour Requirements for Surgical Trainees (FIRST) Trial were able to decrease transitions and allow for better continuity by virtue of less constraints on duty-hour rules. Using National Surgical Quality Improvement Program Quality In-Training Initiative data along with duty-hour violations compared with old rules, it was hypothesized that quality of care would be improved and outcomes would be equivalent or better than the traditional duty-hour rules. It was also hypothesized that resident perception of compliance with duty hour would not change with implementation of new regulations based on FIRST trial.

METHODS: Flexible work hours were implemented on July 1, 2014. National Surgical Quality Improvement Program Quality In-Training Initiative information was reviewed from July 2014 to January 2015. Patient risk factors and outcomes were compared between institutional resident cases and the national cohort for comparison. Residents' duty-hour logs and violations during this period were compared to the 6-month period before the implementation of the FIRST trial. The annual Accreditation Council for Graduate Medical Education resident survey was used to assess the residents' perception of compliance with duty hours.

RESULTS:

	Institution Resident Cases = 379 (%)	National Resident Cases = 49,064 (%)	p Value
Cases with 3 risk factors	15.57	8.04	<0.01
Cases with 4 risk factors	5.54	3.06	<0.01
Cases with 5+ risk factors	5.80	2.12	<0.01
Unplanned readmissions in 30 d	5.01	7.26	N.S.
Death within 30 d	1.58	1.30	N.S.

With respect to the postoperative complications, the only statistically significant measures were higher prevalence of pneumonia (3.4% vs. 1.5%, $p < 0.05$) and lower prevalence of sepsis (0% vs. 1.5%, $p < 0.05$) among cases covered by residents with flexible duty hours. All other measures of postoperative surgical complications showed no difference. The total number of duty-hour violations decreased from 54 to 16. Had the institution not been part of the interventional arm of the FIRST trial, this number would have increased to 238. The residents' perception of compliance with 80-hour work week from the Accreditation Council for Graduate Medical Education survey improved from 68% to 91%.

CONCLUSIONS: Residents with flexible work hours on the interventional arm of the FIRST trial at our institution took care of a significantly sicker cohort of patients as compared with the national dataset with equivalent

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outcomes. Flexible duty-hour policy under the FIRST trial has enabled the residents to have fewer work-hour violations while improving continuity of care to the patients. Additionally, the overall perception of resident compliance with the duty-hour requirements was improved. (J Surg Ed ▮:▮▮▮-▮▮▮. © 2016 Association of Program Directors in Surgery. Published by Elsevier Inc. All rights reserved.)

KEY WORDS: ACGME, resident's duty hours, QITI, NSQIP, FIRST trial

COMPETENCIES: Patient Care, Medical Knowledge, Practice-Based Learning and Improvement, Interpersonal and Communication Skills, Professionalism, Systems-Based Practice

INTRODUCTION

Resident work (duty) hours have been a source of increased debate since 1984 when a college freshman in New York died due to a medical error determined, after a 2-year investigation, to be related to resident fatigue and poor resident supervision. This prompted increasing scrutiny about the relationship between sleep deprivation and its effects on both patient and resident health. Thus, the concept of regulating resident duty hours was born. In July 1992, the Accreditation Council for Graduate Medical Education (ACGME) implemented the General Requirements pertaining to resident duty hours and supervision. However, the creation and the execution of specific policies satisfying these requirements were left to the discretion of the individual programs and specialties.[1]

Nine years later, it was difficult for both the ACGME to explain and the public to conceptualize residency program adherence to the duty-hour requirements owing to a variety of specialty-specific implementations. Furthermore, the rise in compliance violations reported in 2001 compared with 2000 was not attributed to more diligent monitoring, but to increasing laxity in the ACGME's enforcement of the requirements. This prompted formal requests that the regulation and enforcement of resident duty hours become the responsibility of the federal government instead.[1] The ACGME's Work Group on Resident Duty Hours and the Learning Environment was formed to investigate and develop common requirements for resident education and resident and patient safety that would be implemented across all specialties without compromising the qualities and standards previously established by each program.[2] In July 2003, the Common Program Requirements went into effect and with it the Common Duty-Hour Standards.[2] These hours were further restricted when the common program requirements were updated in 2011.[3]

Critiques of the new restrictions included the increased handoffs because of the 16-hour maximum shift limit for interns, decreased professionalism from residents learning to focus more on hours worked than patient care, and the ethical dilemma residents face choosing between duty-hour violations and continuity in patient care. A significant concern from general surgery programs was the detrimental effects of decreased operative exposure because of increased duty-hour restriction. These concerns seemed validated by the significant decline seen in board pass rates from 2006 to 2012, and in survey results from program/fellowship directors expressing concern that newly trained surgeons were not prepared to perform independently in the operative and perioperative phases of patient care.[4] Noting the lack of prospective data and the inconsistencies of the retrospective findings, the Institute of Medicine called for research studies to investigate. From July 2014 to June 2015, Drs. Bilimoria et al.[5] conducted what would become a landmark study in resident duty hours: the Flexibility In duty-hour Requirements for Surgical Trainees (FIRST) Trial.

This study was a prospective, cluster-randomized, noninferiority trial comparing the effects of the current duty-hour policy (standard policy) and a more flexible duty-hour policy on patient outcomes and resident satisfaction.[5] First-year data not only demonstrated noninferiority of the interventional arm compared to the national cohort but also demonstrated superior outcomes in some cases. The study methodology also provided programs on its interventional arm the ability to independently compare their data with the national cohort, as was the purpose of our study.

In this study, we hypothesized that residents under more flexible duty hours can engage in more complex operations and have equal or better outcomes. Therefore, our primary objective was to compare the complexity and complication profile along with the outcomes of procedures performed. Secondary objectives included comparing our institution's work-hour violations and residents' perception of compliance to the weekly work hours before (i.e., standard policy duty hours) and after the implementation of the flexible duty hours.

METHODS

Study Design

In this retrospective study, National Surgical Quality Improvement Program Quality In-Training Initiative (QITI) information was reviewed from July 2014 to January 2015. This period was selected because of the uninterrupted institutional availability of collected QITI data. The data included all cases performed in general surgery training programs nationwide. Procedures logged without the participation of residents or with the participation of residents and mid-level providers were excluded from the study. The data were divided into 2 categories: cases performed by residents with flexible duty hours at a single university-affiliate community teaching institution and cases performed by residents at other general surgery training sites. Comparison to a less heterogeneous cohort