Patient Safety in the Era of the 80-Hour Workweek

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OBJECTIVE: In 2003, duty-hour regulations (DHR) were initially implemented for residents in the United States to improve patient safety and protect resident's well-being. The effect of DHR on patient safety remains unclear. The study objective was to evaluate the effect of DHR on patient safety.

DESIGN: Using an interrupted time series analysis, we analyzed selected patient safety indicators (PSIs) for 376 million discharges in teaching (T) vs nonteaching (NT) hospitals before and after implementation of DHR in 2003 that restricted resident work hours to 80 hours per week. The PSIs evaluated were postoperative pulmonary embolus or deep venous thrombosis (PEDVT), iatrogenic pneumothorax (PTx), accidental puncture or laceration, postoperative wound dehiscence (WD), postoperative hemorrhage or hematoma, and postoperative physiologic or metabolic derangement. Propensity scores were used to adjust for differences in patient comorbidities between T and NT hospitals and between discharge quarters. The primary outcomes were differences in the PSI rates before and after DHR implementation. The PSI differences between T and NT institutions were the secondary outcome.

SETTING: T and NT hospitals in the United States.

PARTICIPANTS: Participants were 376 million patient discharges from 1998 to 2007 in the Nationwide Inpatient Sample.

RESULTS: Declining rates of PTx in both T and NT hospitals preintervention slowed only in T hospitals postintervention ($p = 0.04$). Increasing PEDVT rates in both T and NT hospitals increased further only in NT hospitals ($p = 0.01$). There were no differences in the PSI rates over time for hemorrhage or hematoma, physiologic or metabolic derangement, accidental puncture or laceration, or WD. T hospitals had higher rates than NT hospitals both preintervention and postintervention for all the PSIs except WD.

CONCLUSIONS: Trends in rates for 2 of the 6 PSIs changed significantly after DHR implementation, with PTx rates worsening in T hospitals and PEDVT rates worsening in NT hospitals. Lack of consistent patterns of change suggests no measurable effect of the policy change on these PSIs. (J Surg 71:551-559. © 2014 Association of Program Directors in Surgery. Published by Elsevier Inc. All rights reserved.)

KEY WORDS: patient safety, duty hours, internship and residency, quality indicators

COMPETENCIES: Patient Care, Practice-Based Learning and Improvement, Systems-Based Practice

INTRODUCTION

Now a decade into the era of work-hour regulations for all resident physicians in the United States, with initial national regulations enacted in 2003 and additional mandates in 2011, the effect of these policies on patient safety remains unclear. Duty-hour regulations (DHR) were initially implemented for U.S. medical trainees by the Accreditation Council on Graduate Medical Education (ACGME) in July 2003 as a result of public pressure to achieve greater safety for both patients and residents.[1,2] Responding to continued concerns and specifically to the Institute of Medicine's report "Resident Duty Hours: Enhancing Sleep,

This study was supported by AHRQ Health Services Training Grant #T32 HSO 13833-08. B.K.P. and J.S. had full access to all the data in the study and take responsibility for the integrity of the data and the accuracy of the data analysis.

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 1931-7204/$30.00 http://dx.doi.org/10.1016/j.jsurg.2013.12.011

Supervision, and Safety," the ACGME proposed additional requirements for resident duty hours in 2009, which were implemented in 2011, stating "patient safety always has been, and remains our prime directive."[3,4] This was explicitly defined as the safety of patients being cared for by physicians in training and the safety of future patients who will be cared for by physicians after they complete their residency training.[4]

It is not apparent, however, that the duty-hour reform has achieved the ACGME's primary goal of improving patient safety. Existing literature describes potential benefits of improvements in resident lifestyle, sleep, mood, operative case volume for surgical residents, and higher in-service testing scores.[5-8] Data regarding effects of work-hour regulations on patient safety are equivocal. A systematic review by Fletcher noted no significant difference in patient safety–related outcomes for most of the included studies.[9] It is noteworthy that most studies included in that review were limited by study size and inability to adequately control for comorbid conditions in their patient populations. Our group previously used time series analyses with adjustment for comorbidities to evaluate the effect of New York State resident's work-hour regulations on surgical patient safety indicators (PSIs) and found increased rates in 2 out of the 6 surgical PSIs after the intervention in teaching (T) hospitals, which were not observed in the control group of nonteaching (NT) hospitals.[10] Historically, New York State has implemented patient safety–oriented policies much earlier and more readily than other states, including mandatory reporting of outcomes after coronary artery bypass grafting in 1989 and the previously studied resident work-hour restrictions, which were also enacted in 1989, so the patient safety culture in New York may differ from the national culture. A nationwide study examined the effect of DHR on selected PSIs in a population of Medicare patients and Veterans, finding no difference in composite PSIs.[11] Although these results may be more generalizable, they are limited by the inherent older age and greater comorbidity burden of its study population. We sought to evaluate the long-term effect of DHR on a nationally representative sample of inpatients using these standardized measures of patient safety. We examined nationwide trends in standardized PSIs among adult inpatients associated with the 2003 DHR. We hypothesized that the 2003 DHR would result in decreased rates of selected PSIs in T hospitals, but no change in the PSI rates in NT hospitals would be observed.

METHODS

Design Overview

To assess effects of the national 2003 implementation of resident work-hour regulations in T hospitals, we used weighted discharges from the Nationwide Inpatient Sample (NIS) 1998 to 2007[12] and selected PSIs as objective outcome measures. We performed an interrupted time series analysis that included 5 years before and 5 years after the initial duty-hour mandates. Interrupted time series analysis is a suitable method for examining both the immediate effects of policy change, as well as the effects of the intervention over time.[13,14] NIS NT hospitals served as a concurrent control group.

Data Sources and Study Groups

NIS data were obtained from the Agency for Healthcare Research and Quality (AHRQ) Healthcare Cost and Utilization Project for the years 1998 to 2007. The NIS provides a large, publicly available database from which investigators can derive patient safety data. The NIS is comprised of discharge data on 6 to 8 million discharges per year from approximately 1000 hospitals (Table 1). This represents 20% of all nonfederal inpatient discharges, which are then weighted to produce national estimates.[12] We defined the study group as weighted discharges from those hospitals categorized as "T hospitals" and the control group as weighted discharges from "NT hospitals" based on American Hospital Association survey data. The NIS defined T hospitals based on the following criteria: American Medical Association–approved residency programs, hospitals with a ratio of full-time equivalent interns and residents to beds of at least 0.25, or those with a membership in the Council of Teaching Hospitals.[12] PSI data were compiled for study and control groups by discharge quarter.

Intervention

Full compliance with DHRs was expected by July 1, 2003 across the nation. These DHRs limited resident work hours to a total of 80 hours per week (averaged over a 4-week period) with several stipulations. In-house call was limited to 24 hours plus an additional 6-hour period to allow for transfer of patient care, didactics, or other educational activities. Residents were expected have 10 hours of rest

TABLE 1. Summary Statistics for Teaching and Nonteaching Hospitals From 1998 to 2007

Variable	Teaching	Nonteaching	p Value
Total weighted discharges (million)	171.6	204.9	n/a
Hospitals (mean no. sampled/y)	181.8	825.5	n/a
Propensity scores (mean, 95% CI)			
Preintervention	0.44 (0.43-0.46)	0.44 (0.43-0.46)	0.997
Postintervention	0.46 (0.45-0.48)	0.46 (0.45-0.48)	0.998