Changes in Outcomes for Internal Medicine Inpatients after Work-Hour Regulations

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Background: Limits on resident work hours are intended to reduce fatigue-related errors, but may raise risk by increasing transfers of responsibility for patients.

Objective: To examine changes in outcomes for internal medicine patients after the implementation of work-hour regulations.

Design: Retrospective cohort study.

Setting: Urban, academic medical center.

Patients: 14 260 consecutive patients discharged from the teaching (housestaff) service and 6664 consecutive patients discharged from the nonteaching (hospitalist) service between 1 July 2002 and 30 June 2004.

Measurements: Outcomes included intensive care unit utilization, length of stay, discharge disposition, 30-day readmission rate to the study institution, pharmacist interventions to prevent error, drug–drug interactions and in-hospital death.

Results: The teaching service had net improvements in 3 outcomes. Relative to changes experienced by the nonteaching service, the rate of intensive care unit utilization decreased by 2.1% (95% CI, −3.3% to −0.7%; $P = 0.002$), the rate of discharge to home or rehabilitation facility versus elsewhere improved by 5.3% (CI, 2.6% to 7.6%; $P < 0.001$), and pharmacist interventions to prevent error were reduced by 1.92 interventions per 100 patient-days (CI, −2.74 to −1.03 interventions per 100 patient-days; $P < 0.001$). Teaching and nonteaching services had similar changes over time in length of stay, 30-day readmission rate, and adverse drug–drug interactions. In-hospital death was uncommon in both groups, and change over time was similar in the 2 groups.

Limitations: The study was a retrospective, nonrandomized design that assessed a limited number of outcomes. Teaching and nonteaching cohorts may not have been affected similarly by secular trends in patient care.

Conclusions: After the implementation of work-hour regulations, 3 of 7 outcomes improved for patients in the teaching service relative to those in the nonteaching service. The authors found no evidence of adverse unintended consequences after the institution of work-hour regulations.

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Work-hour regulations, implemented in July 2003 by the Accreditation Council for Graduate Medical Education (ACGME) (1), have reportedly reduced housestaff fatigue (2), but often at the cost of increased transfers of patient care among residents (3). Each transfer of care requires the communication of patient information from the departing clinician to the arriving clinician. If this "sign-out" is performed imperfectly, with misunderstanding or loss of information, harm to patients may result (4–12). These risks of increased handoffs may mitigate the expected benefits of reduced housestaff fatigue, resulting in an uncertain net result for patients.

Literature on the impact of work-hour limits on patient outcomes is conflicting and has been hampered by small sample sizes, few clinical outcomes, and design limitations (13). Only 3 studies have included a control group to account for temporal trends in quality improvement (14–16). No study of the new ACGME regulations has included patients in an internal medicine ward, a high-volume group of complex patients.

Given the expense of this policy change (17), its broad effects on residency programs and residents (2), the statement by the ACGME that improving patient care was a "major impetus" for the regulations (18), and the lack of conclusive study before its wholesale enactment (13), the impact of the new work-hour regulations on patient outcomes is critical to evaluate. Randomized trials are not feasible because the change was mandated simultaneously for all residency programs. A simple comparison of patient outcomes in different years is subject to bias, however, because of changes in practice and quality of care over time. Lack of control for these temporal trends in outcomes is perhaps the most important limitation of most previous studies. To avoid this problem, we compared changes over time in outcomes of 2 cohorts at the same hospital, one cared for by housestaff (teaching service) and the other by hospitalists (nonteaching service). This approach allowed us to evaluate the association of work-hour regulations with changes in a broad range of outcomes for internal medicine inpatients while controlling for temporal trends by using a concurrent control group of similar patients whose caregivers were not directly affected by work-hour regulations.

See also:

Print
Editors' Notes . . . 98
Editorial comment . . . 143
Related article . . . 73
Summary for Patients . . . I-28

Web-Only
Appendix
Conversion of tables into slides

Context

Studies of resident work-hour restrictions and patient outcomes have had design limitations and inconsistent findings.

Contribution

This study compared changes in the rates of 7 clinical measures over a 2-year period for patients discharged from a teaching service that followed the ACGME work-hour rules to changes for patients discharged from a non-teaching hospitalist service. Favorable changes in rates of intensive care unit utilization, discharge to home or a rehabilitation facility, and pharmacist interventions to prevent drug error were more marked in the teaching service than in the hospitalist service.

Caution

Without a direct comparison of teaching services with and without restricted hours, this study has similar design limitations as those of previous studies.

—The Editors

METHODS

We conducted a retrospective cohort study at Yale–New Haven Hospital, comparing outcomes before and after work-hour regulations in medical patients receiving care by housestaff and those receiving care by hospitalists. Patients were assigned to the teaching or nonteaching services on the basis of time of day. Each day, admitted patients were first assigned to teaching teams until the team caps were reached, regardless of severity of illness. All subsequent admissions for the day were assigned to the nonteaching service. This policy was consistent throughout the study. Of note, patients transferred out of the intensive care unit (ICU) were usually assigned to teaching teams. Transfers between teaching and nonteaching services were unusual.

Teaching System before Work-Hour Regulation

A team comprised 1 resident (postgraduate year 2 or 3) and 2 interns. Before 1 July 2003, the resident and 1 intern remained in the hospital overnight on call every fourth day, during which they cared for their own patients and briefly for those of 1 other team. A resident on night-float service arrived at 8 p.m. to assume care of the patients not on the on-call intern's team. On days when no one from the team was on call, interns signed their patients out to a different team's on-call intern, who then relinquished them to the resident on night-float service at 8 p.m. Over 4 weekdays, a patient typically experienced 8 transfers of care.

Teaching System after Work-Hour Regulation

On 1 July 2003, the teaching service schedule was reorganized to better comply with work-hour limitations. There was no transition period. Residents no longer stayed overnight; they were replaced by "nocturnalists"—nonresident physicians who did the work of the night resident. This position was filled by 2 hospitalists and a large pool of moonlighting fellows. In addition, a resident on day-float service was instituted to assist with postcall care of patients so that the postcall team could leave by noon. This reorganization added 1 extra transfer of care every 4 days and increased discontinuity because of the large number of rotating nocturnalists, the new resident on day-float service, and the absence of an on-call primary resident at night. The average patient had approximately 2 physicians added to the care team; patients with long lengths of stay saw a much greater increase. However, these changes also increased the average clinical experience of those supervising nighttime patient care because all nocturnalists had completed residency. Intermittent checks of time cards completed by housestaff showed that average weekly hours were within the 80-hour limits. No physician extenders were added to reduce housestaff workload, and housestaff on the wards was not extended beyond the addition of the resident on day-float service.

Nonteaching System

The nonteaching service did not change after work-hour regulation. The primary hospitalist team for each patient (comprising a physician and 1 or more physician assistants) was present during the day. Each night, including weekends, night staff was present in the hospital for coverage of the nonteaching service. Night physicians attempted to maintain continuity by covering the same patients each night, but this was not universally achieved. Day staff signed out directly to night staff every day of the week. Over 4 days, a patient typically experienced 8 transfers of care. In the year after work-hour regulations were enacted, the nonteaching service increased in both volume and number of providers, such that the number of patients per provider remained similar. (The **Appendix**, available at www.annals.org, contains full details of work schedules before and after work-hour regulation on both services.)

Data Sources

We obtained administrative claims data for all patients discharged from the medical wards between 1 July 2002 and 30 June 2004, excluding patients discharged from HIV and oncology wards, which were restricted to teaching service teams. We derived medication error data from 2 databases kept by the hospital pharmacy. One contained all automatically generated warnings of drug–drug combinations with potential for harm. The interaction list was dynamic: 53% of the interactions (323 of 615) were added on or after 1 July 2003. The other pharmacy database recorded all direct interventions made by pharmacy staff. Pharmacists themselves generated each intervention and categorized the intent of the intervention. For this study, we restricted the database to include only those interventions made to prevent an adverse event.

Independent Variables

Patients were stratified into the teaching or nonteaching cohorts on the basis of their team assignment at discharge. The unit of analysis was hospitalization; patients admitted more than once could be included in more than 1 cohort. We collected data on age, sex, race or ethnicity, insurance status, and admission source for each patient. To account for variability in case mix over time, we grouped the principal diagnosis codes into 259 clinically similar diagnosis categories by using the Clinical Classifications Software categorization (19) and then constructed a case-mix variable that included the most common or severe 21 diagnoses plus 1 for all other diagnoses. We used the International Classification of Diseases, Ninth Revision, Clinical Modification (ICD-9-CM), secondary diagnosis codes to assign a risk severity score to each patient by using the Deyo adaptation of the Charlson comorbidity index (20, 21). Analyses using the Elixhauser method of comorbidity adjustment yielded similar results (22).

Dependent Variables

Outcome measures were ICU stay, length of hospital stay, discharge disposition, 30-day readmission rate to Yale–New Haven Hospital, pharmacist interventions to prevent adverse events, and drug–drug interactions. We dichotomized discharge disposition as discharge to home or rehabilitation facility versus discharge elsewhere (including death), and we included only patients admitted from home or through the emergency department for analysis of this outcome. We also evaluated in-hospital death, but this was an exploratory analysis because of the small number of events.

Statistical Analysis

Because this was a retrospective, single-center study, our sample size was determined by hospital volume. We compared patients' characteristics and outcomes before and after work-hour regulation within each group and between groups by using chi-square tests for categorical variables and *t* tests for continuous variables. We used the generalized linear model for length of stay, which has a long right tail. After testing several link functions and distributional assumptions, we found that a γ distribution with a logarithmic link (γ regression) best fit the data. For pharmacy interventions and medication interactions, we constructed generalized linear models by using a Poisson distribution and a logarithmic link function with an offset for log length of stay (Poisson regression).

We then constructed multivariable models to estimate the association of time with each outcome measure within each group while adjusting for patient characteristics (age, sex, race or ethnicity, insurance status, admission source, principal diagnosis, and comorbid condition). No independent variables had a bivariate correlation greater than 0.6 or a variance inflation factor greater than 2.0. To avoid overfitting, we prespecified the multivariable models to include all patient characteristics because of their clinical importance (23). However, in our exploratory model of in-hospital death, we included only 3 covariates (age, Deyo score, and admission source) because of the small number of events in each group (24). We used logistic regression for binary outcomes, γ regression with logarithmic link for length of stay, and Poisson regression with an offset for log length of stay for medication interactions and pharmacy interventions. For death, we used a generalized estimating equation to account for the nonindependence of death in repeated admissions of the same patient. We also performed the analysis by using a random-number generator to randomly select only 1 admission per patient, and we repeated the sampling 100 times (25). Both approaches yielded similar outcomes, and we present the results of the first approach.

To determine the net association of work-hour regulations with outcomes on the teaching service, controlling for secular trends in outcomes observed in the nonteaching service, we constructed multivariable models of the general form:

$$\text{Outcome} = \alpha + \beta_1(\text{time}) + \beta_2(\text{teaching status}) + \beta_3(\text{time*teaching status}) + \beta_4(\text{covariate}_1) + \ldots + \varepsilon$$

where time and teaching status were binary indicator variables set to 1 for the post–work-hour regulation period and teaching service, respectively, and β_3 is the coefficient for the interaction between them. A statistically significant time–service interaction indicates that the change in outcome over time was different for the 2 services. However, in nonlinear models, β_3 does not reliably represent the estimate for the net change associated with the interaction (26). Consequently, we elected to show outcomes for each cohort within each time period and derived net changes and CIs directly by bootstrapping (27). We estimated the net change associated with work-hour regulations by computing the difference over time in the teaching cohort minus the difference over time in the nonteaching cohort. This analysis thus corrects for any difference between groups at baseline (before work-hour regulation).

To test whether the disproportionate inclusion of patients with ICU stays on the teaching service was responsible for any findings, we performed a sensitivity analysis that excluded all patients with ICU stays from the data set. All outcomes were similar, and none changed in statistical significance. Two authors performed statistical analyses, with review by other study members. All statistical tests were 2-tailed and used a significance level less than 0.05. We used SAS, version 9.1.2 (SAS Institute, Cary, North Carolina), for all analyses.

Role of the Funding Sources

The Human Investigation Committee at Yale University School of Medicine deemed this study exempt from review and granted a waiver of patient consent and a Health Insurance Portability and Accountability Act

Table 1. **Characteristics of Sample before and after Work-Hour Regulation, by Teaching Status**

Characteristic	Teaching Cohort			Nonteaching Cohort		
	2002–2003 (*n* = 7018)	2003–2004 (*n* = 7242)	*P* Value	2002–2003 (*n* = 2954)	2003–2004 (*n* = 3710)	*P* Value
Mean age (SD), *y*	62.9 (17.8)	62.7 (18.3)	0.63	62.5 (19.1)	62.9 (19.6)	0.42
Male, *n* (%)	3573 (51)	3603 (50)	0.166	1389 (47)	1617 (44)	0.005*
Race or ethnicity, *n* (%)			0.35			0.97†
White	4971 (71)	5031 (70)		2001 (68)	2515 (68)	
Black	1377 (20)	1480 (20)		655 (22)	823 (22)	
Hispanic	535 (8)	588 (8)		240 (8)	305 (8)	
Other	135 (2)	143 (2)		58 (2)	67 (2)	
Source of admission, *n* (%)			<0.001			<0.001*
Emergency department	4615 (66)	5102 (71)		2569 (88)	3376 (91)	
Home or other	1506 (22)	1380 (19)		257 (9)	245 (7)	
Short-term care transfer	848 (12)	753 (10)		91 (3)	87 (2)	
Insurance status, *n* (%)			0.023			0.086
Medicare	3707 (53)	3889 (54)		1574 (53)	2001 (54)	
Medicaid	872 (12)	932 (12)		393 (13)	469 (13)	
Medicare managed care	150 (2)	168 (2)		47 (1.6)	90 (2)	
Self-pay	85 (1)	121 (1.7)		47 (1.6)	72 (2)	
Other	2204 (31)	2132 (29)		893 (30)	1078 (29)	
Deyo score, *n* (%)			0.002			0.002
0	3701 (53)	3592 (50)		1629 (55)	1877 (51)	
1	1754 (25)	1956 (27)		726 (25)	997 (27)	
2	869 (12)	962 (13)		318 (11)	473 (13)	
≥3	694 (10)	732 (11)		281 (10)	363 (10)	
Principal diagnosis, *n* (%)			0.002			<0.001*
Coronary artery disease	886 (13)	858 (12)		168 (6)	141 (4)	
Dysrhythmia	547 (8)	599 (8)		189 (6)	183 (5)	
Device, implant, or graft complication	382 (5)	330 (5)		79 (3)	71 (2)	
Acute myocardial infarction	382 (5)	376 (5)		112 (4)	101 (3)	
Pneumonia	362 (5)	328 (5)		175 (6)	258 (7)	
Congestive heart failure	323 (5)	399 (6)		183 (6)	201 (5)	
Chest pain	305 (4)	359 (5)		253 (9)	312 (8)	
Asthma	224 (3)	200 (3)		85 (3)	93 (3)	
Diabetes mellitus	158 (2)	160 (2)		56 (2)	88 (2)	
Fluid or electrolyte disorder	150 (2)	187 (3)		58 (2)	113 (3)	
Acute renal failure	148 (2)	184 (3)		52 (2)	110 (3)	
Syncope	144 (2)	170 (2)		110 (4)	126 (3)	
Urinary tract infection	137 (2)	148 (2)		84 (3)	140 (4)	
Gastrointestinal hemorrhage	136 (2)	100 (1)		53 (2)	59 (2)	
Conduction disorder	110 (2)	122 (2)		12 (0.4)	10 (0.3)	
Skin infection	108 (2)	116 (2)		69 (2)	94 (3)	
Pancreatic disease	107 (2)	82 (1)		54 (2)	94 (3)	
Respiratory failure	80 (1)	103 (1)		7 (0.2)	14 (0.4)	
Malignant condition	74 (1)	66 (0.9)		24 (0.8)	51 (1)	
Sepsis	69 (1)	72 (1)		32 (1)	38 (1)	
Aspiration pneumonia	66 (0.9)	80 (1)		29 (1)	58 (2)	
Other	1979 (28)	2075 (29)		1006 (34)	1285 (35)	

* $P < 0.001$ for nonteaching cohort compared with teaching cohort in both periods.
† $P = 0.02$ for nonteaching cohort compared with teaching cohort in the 2002–2003 period.

waiver for utilization of administrative data. At the time the study was conducted, Drs. Horwitz and Kosiborod were Robert Wood Johnson Clinical Scholars, and Dr. Horwitz was supported by the U.S. Department of Veterans Affairs. Neither source had any role in the design, analysis, or interpretation of the study or in the decision to submit the manuscript for publication.

Results

The study sample comprised 7018 patients discharged from the teaching service and 2954 patients discharged from the nonteaching service in the year before work-hour regulation, and 7242 and 3710 patients discharged from each service in the year after work-hour regulation. Admission source was missing for 95 discharges (56 teaching, 39 nonteaching); all other demographic information was available for every discharge. **Table 1** presents baseline characteristics of the cohorts. Daytime (7 a.m. to 7 p.m.) admissions to the teaching service increased from 80% before to 82% after work-hour regulation, and daytime admissions to the nonteaching service decreased from 43% to 38%.

Group Comparisons

Table 2 presents unadjusted results. In the teaching group, patients admitted after the work-hour regulation had a lower rate of ICU stay (12.4% before vs. 9.9% after;

$P < 0.001$), decreased length of stay (5.21 vs. 5.04 days; $P = 0.033$), increased 30-day rate of readmission to the study hospital (16.4% vs. 18.3%; $P = 0.004$), fewer pharmacy interventions (5.96 vs. 4.84 interventions per 100 patient-days; $P < 0.001$), and more drug–drug interactions (3.95 vs. 4.55 interactions per 100 patient-days; $P = 0.007$). The nonteaching group after the work-hour regulation had a decreased proportion of discharges to home or rehabilitation (82.0% vs. 77.2%; $P < 0.001$) and a higher 30-day readmission rate (19.1% vs. 22.9%; $P < 0.001$). The mortality analysis revealed no statistically significant changes in the teaching group (2.4% vs. 2.0%; $P = 0.105$) or nonteaching group (1.4% vs. 1.1%; $P = 0.36$).

After adjustment for age, sex, race or ethnicity, insurance status, admission source, comorbid conditions, and case mix, the decrease in deaths in the teaching service reached statistical significance (2.41% vs. 2.03%; $P = 0.047$). All other outcomes within both cohorts were similar to unadjusted outcomes. **Table 3** shows adjusted differences in outcomes over time.

Interaction Results

We found no statistically significant interaction between time period and teaching service status for adjusted length of stay, rate of 30-day readmission to Yale–New Haven Hospital, or drug–drug interactions. Three differences were statistically significant, all showing improvement in the teaching service relative to the nonteaching service after work-hour regulation: ICU utilization, discharge to home or rehabilitation versus elsewhere, and pharmacist interventions to prevent error (**Table 3**). The exploratory analysis of in-hospital death revealed no statistically significant interaction between time period and teaching service status.

Discussion

We compared outcomes in patients cared for by housestaff and those cared for by a nonteaching hospitalist service. We found that, relative to what would have been expected without the regulation, work-hour limits were associated with statistically significant improvements in 3 outcomes: ICU stay (decrease, 2%), discharge to home or rehabilitation versus elsewhere (increase, 5%), and pharmacist interventions to prevent errors (decrease, 1.9 interventions per 100 patient-days). We did not find statistically significant differences in length of stay, 30-day readmission rate to the study hospital, drug–drug interactions, or in-hospital death. Overall, the regulations were associated with neutral or positive changes in all of the outcomes we studied.

The effect size of the improvements was substantial for pharmacy interventions and was more modest for ICU admissions and discharge disposition. In terms of the number needed to treat for benefit, we would need to admit 10 patients for a typical 5-day hospital stay to avert 1 pharmacy intervention, 20 patients to avert 1 adverse discharge disposition, and 50 patients to prevent 1 ICU admission. Most important, we did not observe unintended negative consequences for patients after work hours were reduced. Further study would be necessary to confirm the presence and magnitude of benefit associated with the institution of work-hour regulations.

There are several possible mechanisms by which work-hour regulations might have improved patient outcomes. First, reduced fatigue among housestaff may have made a real difference to clinical care. Second, the increase in discontinuity may not have been substantial enough to affect outcomes. Third, clinical involvement by more senior physicians—such as fellows and attending physicians—may have increased to compensate for discontinuity of care and frequent turnover of housestaff. Fourth, the use in the teaching service of nocturnalists with more clinical experience than residents may have improved outcomes even though they had less knowledge of the patients. Finally, the dramatic changes to workflow may have—at least tempo-

Table 2. **Unadjusted Outcomes before and after Work-Hour Regulation, by Teaching Status***

Variable	Teaching Cohort			Nonteaching Cohort		
	2002–2003 ($n = 7018$)	2003–2004 ($n = 7242$)	P Value	2002–2003 ($n = 2954$)	2003–2004 ($n = 3710$)	P Value
Admitted to ICU, *n (%)*	867 (12.4)	720 (9.9)	<0.001	93 (3.2)	104 (2.8)	0.41
Mean length of hospital stay (SD), *d*	5.21 (9.3)	5.04 (9.2)	0.033	4.51 (6.6)	4.62 (5.9)	0.25
Discharged to home or rehabilitation facility, *n (%)*†	4947 (80.8)	5281 (81.5)	0.35	2316 (82.0)	2796 (77.2)	<0.001
Readmitted to Yale–New Haven Hospital within 30 d, *n (%)*	1152 (16.4)	1323 (18.3)	0.004	563 (19.1)	848 (22.9)	<0.001
Mean pharmacist interventions per 100 patient-days (SD), *n*	5.96 (16.7)	4.84 (16.9)	<0.001	3.33 (12.6)	3.73 (14.0)	0.066
Mean medication interactions per 100 patient-days (SD), *n*	3.95 (16.46)	4.55 (17.64)	0.007	3.69 (15.11)	3.72 (15.17)	0.54
In-hospital mortality, *n (%)*	170 (2.4)	147 (2.0)	0.105	40 (1.4)	41 (1.1)	0.36

* ICU = intensive care unit.
† Of patients admitted from home or through the emergency department (6121 from teaching cohort, 2002–2003; 6482 from teaching cohort, 2003–2004; 2826 from nonteaching cohort, 2002–2003; 3621 from nonteaching cohort, 2003–2004).

Table 3. **Changes in Adjusted Outcomes in Teaching Service Compared with Nonteaching Service***

Variable	Mean Adjusted Change (after vs. before) (95% CI)		Mean Net Adjusted Change (Teaching vs. Nonteaching) (95% CI)	*P* Value
	Teaching Service	Nonteaching Service		
ICU stay, %	−2.35 (−3.36 to −1.31)†	−0.23 (−1.09 to 0.57)	−2.11 (−3.27 to −0.73)	0.002
Length of hospital stay, *d*	−0.05 (−0.29 to 0.19)‡	0.10 (−0.18 to 0.38)	−0.16 (−0.53 to 0.19)	0.37
Discharge to home or rehabilitation facility, %	0.62 (−0.76 to 2.21)	−4.67 (−6.46 to −2.84)‡	5.29 (2.58 to 7.61)	<0.001
Readmission to Yale–New Haven Hospital within 30 d, %	1.87 (0.65 to 3.12)§	3.86 (1.92 to 5.92)‡	−1.99 (−4.35 to 0.49)	0.097
Pharmacist interventions per 100 patient-days, *n*	−1.50 (−2.12 to −0.86)†	0.42 (−0.13 to 0.97)	−1.92 (−2.74 to −1.03)	<0.001
Medication interactions per 100 patient-days, *n*	0.45 (0.10 to 0.81)§	0.14 (−0.31 to 0.61)	0.31 (−0.25 to 0.87)	0.30
In-hospital mortality, %‖	0.06 (−0.49 to 0.60)§	0.31 (−0.23 to 0.85)	−0.25 (−1.0 to 0.56)	0.50

* The adjusted 95% CIs were obtained from bootstrapping and were adjusted for age, sex, race or ethnicity (black, Hispanic, other vs. white), insurance type (Medicare, Medicaid, managed Medicare, self-pay vs. other), admission source (home or other, transfer vs. emergency department), principal diagnosis, and Deyo score (1, 2, 3 vs. 0) unless otherwise indicated. ICU = intensive care unit.
† $P < 0.001$ for comparison of 2003–2004 vs. 2002–2003.
‡ $P < 0.01$ for comparison of 2003–2004 vs. 2002–2003.
§ $P < 0.05$ for comparison of 2003–2004 vs. 2002–2003.
‖ Adjusted for age, admission source, and Deyo score only.

rarily—prompted more attention to patient safety and clinical care. More work is needed to distinguish between these possible effects and to test the sustainability of the results in future years.

Our finding of 1.9 fewer pharmacy interventions per 100 patient-days after work-hour regulation is remarkably similar to that of a recent study, which found 1.7 fewer medication errors per 100 patient-days in the ICU with reduced work hours (16). The similar degree of improvement is particularly notable because our study included ward patients, whose care is often transferred overnight to physicians with many responsibilities and little knowledge of the patients. Two studies with similar study designs were set in New York after the state enacted work-hour regulation in 1989 (28). One reviewed mortality in internal medicine patients in the early 1990s (14) and the other examined safety in surgical patients in the late 1990s (15); neither found substantive changes. Both studies were limited by the assignment of teaching status to the hospital as a whole, possibly obscuring effects in hospitals that have both teaching and nonteaching services, such as the one in our study. Many before–after studies without a nonteaching control have yielded conflicting results (10, 29–35). Our study was larger and broader than these studies, and the nonteaching control allowed us to draw more robust conclusions.

An important feature of our study design is that both teaching and nonteaching patients within the same hospital environment were included, allowing us to distinguish effects of time from effects of work-hour regulation. For example, medication interactions increased statistically significantly in the teaching group after work-hour regulation. With the benefit of the nonteaching service comparison, we found that medication interactions had increased over this period for all medical patients, as expected because of the addition of interaction rules to the database. Thus, the increase in these errors did not provide evidence of harm associated with work-hour regulation, an inference that might have been made without a comparison group.

Additional strengths of this study include our detailed knowledge of schedule changes and implementation at the hospital and the use of data sources beyond traditional administrative data. However, our study has several limitations to consider in its interpretation. The nonrandomized design limits conclusions about causality. Nonetheless, our inclusion of a control group and the consistent direction of the findings lend credence to the conclusions. Second, this was a single-institution study, although this institution's schedule changes were very similar to those made nationally (3). Third, we relied largely on administrative data, which may contain inaccuracies or omissions; do not provide sufficient information to determine whether care was appropriate, patient-centered, humane, technically proficient, efficient, or timely; and cannot provide a complete picture of adverse events (36). Fourth, our study was not powered to detect mortality effects because of the relatively small number of events. Fifth, we were able to examine only a limited number of outcomes. Other outcomes, such as diagnostic delays, might have been more affected by increased discontinuity. Finally, the design of our study assumes that without the work-hour regulation, teaching service patients would have had the same changes in outcomes as nonteaching service patients did. However, because patients were consistently assigned to teaching teams earlier in the day and nonteaching teams later in the day, some systematic bias in patient population may have caused outcomes on one service to change differently than the other over time, even without regulation. It is reassuring that when we removed the most notable bias—patients with ICU stays, who were primarily assigned to the teaching service—the results were essentially unchanged.

In summary, we found that a major reorganization of patient care to reduce resident work hours was implemented without evidence of harm to patients, despite concern about possible adverse effects of discontinuity. These findings demonstrate the importance of rigorously evaluating policy changes implemented without previously proven benefit or harm.

From the Center for Outcomes Research and Evaluation, Yale–New Haven Hospital, and Yale University School of Medicine, New Haven, Connecticut, and Mid America Heart Institute and University of Missouri, Kansas City, Missouri.

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References

1. Common Program Requirements, Section VF. Chicago: Accreditation Council for Graduate Medical Education; February 2004. Accessed at www.acgme.org/acWebsite/dutyHours/dh_Lang703.pdf on 20 January 2007.
2. **Fletcher KE, Underwood W 3rd, Davis SQ, Mangrulkar RS, McMahon LF Jr, Saint S.** Effects of work hour reduction on residents' lives: a systematic review. JAMA. 2005;294:1088-100. [PMID: 16145030]
3. **Horwitz LI, Krumholz HM, Green ML, Huot SJ.** Transfers of patient care between house staff on internal medicine wards: a national survey. Arch Intern Med. 2006;166:1173-7. [PMID: 16772243]
4. **Arora V, Johnson J, Lovinger D, Humphrey HJ, Meltzer DO.** Communication failures in patient sign-out and suggestions for improvement: a critical incident analysis. Qual Saf Health Care. 2005;14:401-7. [PMID: 16326783]
5. **Center for Safety in Emergency Care.** Profiles in patient safety: emergency care transitions. Acad Emerg Med. 2003;10:364-7. [PMID: 12670851]
6. **Vidyarthi AR.** Triple handoff. AHRQ WebM&M. September 2006. Rockville, MD: Agency for Healthcare Research and Quality; 2006. Accessed at http://webmm.ahrq.gov/case.aspx?caseID=134 on 20 January 2007.
7. **Bollschweiler E, Krings A, Fuchs KH, Pistorius G, Bein T, Otto U, et al.** Alternative shift models and the quality of patient care. An empirical study in surgical intensive care units. Langenbecks Arch Surg. 2001;386:104-9. [PMID: 11374042]
8. **Chassin MR, Becher EC.** The wrong patient. Ann Intern Med. 2002;136:826-33. [PMID: 12044131]
9. **Gandhi TK.** Fumbled handoffs: one dropped ball after another. Ann Intern Med. 2005;142:352-8. [PMID: 15738454]
10. **Lofgren RP, Gottlieb D, Williams RA, Rich EC.** Post-call transfer of resident responsibility: its effect on patient care. J Gen Intern Med. 1990;5:501-5. [PMID: 2266432]
11. **Petersen LA, Brennan TA, O'Neil AC, Cook EF, Lee TH.** Does housestaff discontinuity of care increase the risk for preventable adverse events? Ann Intern Med. 1994;121:866-72. [PMID: 7978700]
12. **Sutcliffe KM, Lewton E, Rosenthal MM.** Communication failures: an insidious contributor to medical mishaps. Acad Med. 2004;79:186-94. [PMID: 14744724]
13. **Fletcher KE, Davis SQ, Underwood W, Mangrulkar RS, McMahon LF Jr, Saint S.** Systematic review: effects of resident work hours on patient safety. Ann Intern Med. 2004;141:851-7. [PMID: 15583227]
14. **Howard DL, Silber JH, Jobes DR, Silber JH.** Do regulations limiting residents' work hours affect patient mortality? J Gen Intern Med. 2004;19:1-7. [PMID: 14748854]
15. **Poulose BK, Ray WA, Arbogast PG, Needleman J, Buerhaus PI, Griffin MR, et al.** Resident work hour limits and patient safety. Ann Surg. 2005;241:847-56; discussion 856-60. [PMID: 15912034]
16. **Landrigan CP, Rothschild JM, Cronin JW, Kaushal R, Burdick E, Katz JT, et al.** Effect of reducing interns' work hours on serious medical errors in intensive care units. N Engl J Med. 2004;351:1838-48. [PMID: 15509817]
17. **Nuckols TK, Escarce JJ.** Residency work-hours reform. A cost analysis including preventable adverse events. J Gen Intern Med. 2005;20:873-8. [PMID: 16191130]
18. Statement of Justification/Impact for the Final Approval of Common Standards Related to Resident Duty Hours. Chicago: Accreditation Council for Graduate Medical Education; September 2002. Accessed at www.acgme.org/acWebsite/dutyHours/dh_impactStatement.pdf on 20 January 2007.
19. **HCUP CCS.** Healthcare Cost and Utilization Project (HCUP). Rockville, MD: Agency for Healthcare Research and Quality; February 2007. Accessed at www.hcup-us.ahrq.gov/toolssoftware/ccs/ccs.jsp on 20 January 2007.
20. **Charlson ME, Pompei P, Ales KL, MacKenzie CR.** A new method of classifying prognostic comorbidity in longitudinal studies: development and validation. J Chronic Dis. 1987;40:373-83. [PMID: 3558716]
21. **Deyo RA, Cherkin DC, Ciol MA.** Adapting a clinical comorbidity index for use with ICD-9-CM administrative databases. J Clin Epidemiol. 1992;45:613-9. [PMID: 1607900]
22. **Elixhauser A, Steiner C, Harris DR, Coffey RM.** Comorbidity measures for use with administrative data. Med Care. 1998;36:8-27. [PMID: 9431328]
23. **Harrell FE.** Regression Modelling Strategies: With Applications to Linear Models, Logistic Regression, and Survival Analysis. New York: Springer; 2002.
24. **Peduzzi P, Concato J, Kemper E, Holford TR, Feinstein AR.** A simulation study of the number of events per variable in logistic regression analysis. J Clin Epidemiol. 1996;49:1373-9. [PMID: 8970487]
25. **Garnick DW, DeLong ER, Luft HS.** Measuring hospital mortality rates: are 30-day data enough? Ischemic Heart Disease Patient Outcomes Research Team. Health Serv Res. 1995;29:679-95. [PMID: 7860319]
26. **Ai C, Norton EC.** Interaction terms in logit and probit models. Econ Lett. 2003;80:123-9.
27. **Efron B, Tibshirani RJ.** An Introduction to the Bootstrap. New York: Chapman & Hall; 1993.
28. Medical Staff. N.Y. Comp. Codes R. & Regs. tit. 10, §405.4(b) ¶6. Accessed at www.health.state.ny.us/nysdoh/phforum/nycrr10.htm on 20 January 2007.
29. **Mycyk MB, McDaniel MR, Fotis MA, Regalado J.** Hospitalwide adverse drug events before and after limiting weekly work hours of medical residents to 80. Am J Health Syst Pharm. 2005;62:1592-5. [PMID: 16030369]
30. **Bailit JL, Blanchard MH.** The effect of house staff working hours on the quality of obstetric and gynecologic care. Obstet Gynecol. 2004;103:613-6. [PMID: 15051548]
31. **Schenarts P, Bowen J, Bard M, Sagraves S, Toschlog E, Goettler C, et al.** The effect of a rotating night-float coverage scheme on preventable and potentially preventable morbidity at a level 1 trauma center. Am J Surg. 2005;190:147-52. [PMID: 15972189]
32. **Kaafarani HM, Itani KM, Petersen LA, Thornby J, Berger DH.** Does resident hours reduction have an impact on surgical outcomes? J Surg Res. 2005;126:167-71. [PMID: 15919415]
33. **Daigler GE, Welliver RC, Stapleton FB.** New York regulation of residents' working conditions. 1 year's experience. Am J Dis Child. 1990;144:799-802. [PMID: 2356800]
34. **Mann FA, Danz PL.** The night stalker effect: quality improvements with a dedicated night-call rotation. Invest Radiol. 1993;28:92-6. [PMID: 8425860]
35. **Laine C, Goldman L, Soukup JR, Hayes JG.** The impact of a regulation restricting medical house staff working hours on the quality of patient care. JAMA. 1993;269:374-8. [PMID: 8418344]
36. **Iezzoni LI.** Assessing quality using administrative data. Ann Intern Med. 1997;127:666-74. [PMID: 9382378]

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Appendix: Work Schedule for Teaching and Nonteaching Teams

Teaching System before Work-Hour Regulation

A general medical team comprised 1 resident (postgraduate year 2 or 3) and 2 interns. Before 1 July 2003, the resident and 1 intern remained in the hospital overnight on call every fourth day, during which they cared for their own patients and briefly for those of 1 other team. While on call, an intern could admit up to 6 new patients; the overall caseload cap for interns was 12 patients. A resident on night-float service arrived at 8 p.m. to assume care of the patients who were not on the on-call intern's team. If a patient without a private attending physician arrived before 1 a.m. and the on-call team had already reached their caseload cap, the resident on night-float service admitted the patient as a holdover for the on-call team for the following day. Each on-call team was allowed 1 holdover patient.

On the postcall day, the team members remained until they had completed their work for the day and were then free to sign out and leave. On days when no one from the team was on call, interns remained in the hospital until approximately 5 p.m. and then signed their patients out to that day's on-call intern. The on-call intern then relinquished the patients to the resident on night-float service at 8 p.m.

Over 4 weekdays, a patient typically experienced 8 transfers of care.

Teaching System after Work-Hour Regulation

On 1 July 2003, the teaching service schedule was reorganized to better comply with work-hour limitations. There was no transition period. The call cycle remained 4 days long, and on-call interns continued to stay overnight as they had under the old system. However, residents no longer stayed overnight, and they were asked to leave by 8 to 10 p.m. Their place was taken by "nocturnalists"—nonresident physicians who did the work of the night resident. The position of nocturnalist was filled by 2 hospitalists and a large pool of moonlighting fellows.

The cap for on-call admissions to interns was reduced from 6 to 5 patients; the total caseload cap remained at 12. If the team had not yet reached their caseload cap by the time the resident left, the nocturnalist admitted any further patients with the on-call intern. Patients arriving after 1 a.m. or after the teams had reached their cap were no longer held over for the following morning's on-call team, but they were sent directly to the nonteaching service. The only exceptions were patients who had just been discharged from the teaching service; if the team that had cared for the patient during his or her first admission were still on the wards, the patient was returned to the teaching service in the morning as a "bounce back." In addition to admitting with the on-call intern, the nocturnalist assisted with the care of the team's patients and cross-coverage of patients belonging to teams that were not on call.

On the postcall day, the resident returned and spent a full day in the hospital, but interns were asked to leave by noon. To facilitate this, a resident on day-float service was instituted to assist with postcall care of patients.

There was no addition of physician extenders to reduce housestaff workload nor any expansion of housestaff on the wards besides the resident on day-float service.

Intermittent checks of time cards completed by housestaff showed that average weekly hours were within the 80-hour limits.

Nonteaching System

Patients admitted after the teaching teams had reached their caseload cap were sent directly to a large nonteaching service staffed by physicians and physician assistants. This service had no contact with housestaff, and patients were not transferred between services. There was no attempt made to distribute patients among teaching and nonteaching services according to illness severity, "teaching value," or any criteria other than time of day.

The nonteaching service did not change schedules after work-hour regulation. The primary hospitalist team for each patient (comprising a physician and 1 or more physician assistants) was present during the day. Each night, including weekends, night staff was present in the hospital for coverage of the nonteaching service. Night physicians attempted to maintain continuity by covering the same patients each night, but this was not universally achieved. Day staff signed out directly to night staff every day of the week. Over 4 days, a patient typically experienced 8 transfers of care.

In 2002–2003, the year before work-hour regulation, the day staff was composed of 4 physician hospitalists and 6 physician assistants. In 2003–2004, the year after work-hour regulation began, 2 medical doctors and 4 physician assistants were hired onto the day staff to offset an increase in patient volume on the nonteaching service.