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Impact of work schedules of senior resident physicians on patient and resident physician safety: nationwide, prospective cohort study

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ABSTRACT

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Received: 15 July 2022 Accepted: 15 February 2023 OBJECTIVE To determine whether long weekly work hours and shifts of extended duration (≥24 hours) are associated with adverse patient and physician safety outcomes in more senior resident physicians (postgraduate year 2 and above; PGY2+). DESIGN Nationwide, prospective cohort study. SETTING United States, conducted over eight academic years (2002-07, 2014-17).

PARTICIPANTS 4826 PGY2+ resident physicians who completed 38702 monthly web based reports of their work hours and patient and resident safety outcomes.

MAIN OUTCOME MEASURES Patient safety outcomes included medical errors, preventable adverse events, and fatal preventable adverse events. Resident physician health and safety outcomes included motor vehicle crashes, near miss crashes, occupational exposures to potentially contaminated blood or other bodily fluids, percutaneous injuries, and attentional failures. Data were analysed with mixed effects regression models that accounted for dependence of repeated measures and controlled for potential confounders. **RESULTS** Working more than 48 hours per week was associated with an increased risk of selfreported medical errors, preventable adverse events, and fatal preventable adverse events as well as near miss crashes, occupational exposures, percutaneous injuries, and attentional failures (all P(0.001). Working between 60 and 70 hours per

WHAT IS ALREADY KNOWN ON THIS TOPIC

- ⇒ Long work weeks and shifts of extended duration (≥24 hours) are associated with increased risks to physician safety and adverse patient safety outcomes
- ⇒ However, most studies have focused on resident physicians during postgraduate year (PGY) 1 (ie, interns)

WHAT THIS STUDY ADDS

⇒ When more experienced resident physicians (PGY2 and above) worked long weekly hours and shifts of extended duration, risks to them and their patients were similar in magnitude to the risks previously reported for PGY1 resident physicians

HOW THIS STUDY MIGHT AFFECT RESEARCH, PRACTICE, OR POLICY

⇒ These results could prompt policy makers in many countries, including the US Accreditation Council for Graduate Medical Education, and organisations that employ resident physicians to re-examine work hour limitations and to consider restrictions closer to those implemented through the European Working Time Directive

week was associated with a more than twice the risk of a medical error (odds ratio 2.36, 95% confidence interval 2.01 to 2.78) and almost three times the risk of preventable adverse events (2.93, 2.04 to 4.23) and fatal preventable adverse events (2.75, 1.23 to 6.12). Working one or more shifts of extended duration in a month while averaging no more than 80 weekly work hours was associated with an 84% increased risk of medical errors (1.84, 1.66 to 2.03), a 51% increased risk of preventable adverse events (1.51, 1.20 to 1.90), and an 85% increased risk of fatal preventable adverse events (1.85, 1.05 to 3.26). Similarly, working one or more shifts of extended duration in a month while averaging no more than 80 weekly work hours also increased the risk of near miss crashes (1.47, 1.32 to 1.63) and occupational exposures (1.17, 1.02 to 1.33).

CONCLUSIONS These results indicate that exceeding 48 weekly work hours or working shifts of extended duration endangers even experienced (ie, PGY2+) resident physicians and their patients. These data suggest that regulatory bodies in the US and elsewhere should consider lowering weekly work hour limits, as the European Union has done, and eliminating shifts of extended duration to protect the more than 150 000 physicians training in the US and their patients.

Introduction

Long work weeks and shifts of extended duration $(\geq 24 \text{ hours})$ have been a cornerstone of medical education in the US, and in much of the world, for more than 100 years. Given the concerns of sleep researchers, the government, the general public, and physicians themselves regarding these schedules, reformed work hour guidelines have been attempted.

The first nationwide workhour guidelines in the United States, implemented by the Accreditation Council for Graduate Medical Education (ACGME) went into effect in 2003, allowing all resident physicians to work 80-88 hours and multiple shifts of extended duration per week. In 2007, the Institute of Medicine of the National Academies—a multidisciplinary body of experts from across fields that is now known as the National Academy of Medicine was commissioned to evaluate the safety of this policy. After studying this issue for over a year, they concluded that it was unsafe for any resident physician to work for more than 16 consecutive hours without sleep.¹ Consequently, the ACGME issued new work hour guidelines that went into effect on 1 July 2011, limiting resident physicians in their first postgraduate year (ie, interns; PGY1) to work shifts of 16 hours or less. However, contrary to the advice of the National Academy of Medicine, the ACGME endorsed extended duration work shifts of up to 28 consecutive hours for more senior resident physicians (ie, in their second postgraduate year and beyond (PGY2+)); 80 hour work weeks were continued for all resident physicians.² In its impact statement, the ACGME Task Force on Quality Care and Professionalism explained: "Residents who have completed the PGY 1 year have greater preparation and increased knowledge and are therefore better prepared to make decisions and care for patients during prolonged shifts,"¹ although no data suggest that people who are more experienced on a task (eg, truck driving) are less vulnerable to the impact of sleep deprivation. Nonetheless, few data have directly evaluated the effects of work hours on patient and resident safety among PGY2+ resident physicians (ie, physicians who have more than one year of postgraduate clinical training after having completed medical school, equivalent to junior doctors in foundational year 2 and above under the Modernising Medical Careers scheme in the United Kingdom).

To resolve this knowledge gap, we investigated the association between long work weeks and work shifts of extended duration in PGY2+ resident physicians and patient safety outcomes (medical errors, adverse events, patient deaths) as well as resident physician health and safety outcomes (motor vehicle crashes, near miss crashes, occupational exposures to potentially contaminated blood or other body fluids, percutaneous injuries, attentional failures).

Methods

We conducted a nationwide prospective cohort study of resident physicians in the US for eight academic years (2002-07 and 2014-17). All study procedures were approved by the Partners Human Research Committee and a certificate of confidentiality was issued by the US Centers for Disease Control and Prevention.

Data collection

With assistance from the Association of American Medical Colleges, US medical school graduates and individuals who matched to a US residency programme from 2002 to 2006 were invited by email to participate in an online study. Similarly, from 2014 to 2016, all medical school graduates who completed an application through the Electronic Residency Application Service were invited by email to participate in the study. The invitation directed potential participants to the study website

where information about the study, excluding the study hypotheses, was provided.

Those individuals who chose to enrol in the study completed an electronic consent form and provided an email address where they wanted to receive their monthly surveys. Throughout the course of the study, they had the opportunity to update their email address (eg, change from a school email address to a hospital or personal email address). At the end of each academic year, participants were invited to continue their participation into their next year of residency. On enrolment, each participant was given a unique ID enabling the linking of the surveys completed by that individual throughout the course of their participation. After their first year of participation in the study, resident physicians were invited to continue their participation as more senior resident physicians. Nominal incentives (eg, \$30 (£25.05; €28.39) for completing five monthly surveys) were provided as well as randomly drawn cash prizes.

In June of each year, unique individual links were sent via email to resident physicians who consented to participate in the study. The baseline survey collected information, on personal characteristics, including age, gender, height, weight, medical history, and specialty programme. Monthly reports collected work hour information, including total hours of work, frequency of shifts of extended duration (≥24 hours), hours engaged in patient care, and additional work related to their residency programme, using previously validated methodology.³ Hours of sleep at work and away from work were reported. In a separate section of the report, participants reported important medical errors in the past month and any patient outcomes resulting from errors. Errors resulting in patient harm were considered preventable adverse events. Participants also reported on the frequency of adverse health and safety outcomes, including motor vehicle crashes and near miss crashes. The instrument used to collect information on motor vehicle crashes has been previously validated.³ We also collected information on the frequency of occupational exposures to potentially contaminated blood or other bodily fluid and queried how many times participants nodded off or fell asleep (attentional failures) during inappropriate times (eg, surgery; rounds with attending physicians; while talking to or examining patients; and in lectures, seminars, and grand rounds). See online supplemental materials 1 for survey questions.

Statistical analysis

Given that the major components of the ACGME work hour guidelines did not differ substantially for PGY2+ resident physicians in our 2002-07 and 2014-17 study cohorts (ie, 80-88 hour work week limit, 28-30 consecutive work hour limit, including time for transitions; minimum four days off per month), we pooled the responses for our analyses,

although we controlled for cohort and other potentially confounding factors in multivariable analyses. We excluded months when participants reported ≥14 work-free days (vacation months), and when work hour information was missing or reported to exceed 168 hours of work per week. Weekly work hours were calculated as the sum of the number of hours spent physically awake in the hospital, classes, or workplace, plus the number of hours asleep in the hospital.

We examined the association among weekly work hours, shifts of extended duration, and adverse health and safety outcomes. The incidence of adverse health and safety outcomes were calculated. We tested the significance of the calculated incidence rate ratios using likelihood ratio tests in log-linear models. Sensitivity analyses used Pearson and deviance based, scaled Poisson models that accounted for overdispersion, obtaining similar results. We dichotomised rare outcomes to reflect the presence or absence of at least one outcome during the month, and estimated the risk of each outcome using generalised linear models with a binomial distribution and log-link function. Basic models for clinical outcomes were adjusted for reported hours of patient care that month. We identified potentially confounding variables a priori based on relevance to the research question and biological plausibility. Fully adjusted multivariable models controlled for age, gender, specialty programme, cohort, and an age imputation indicator variable. Analyses stratified by cohort are presented in online supplemental tables S1A and S1B.

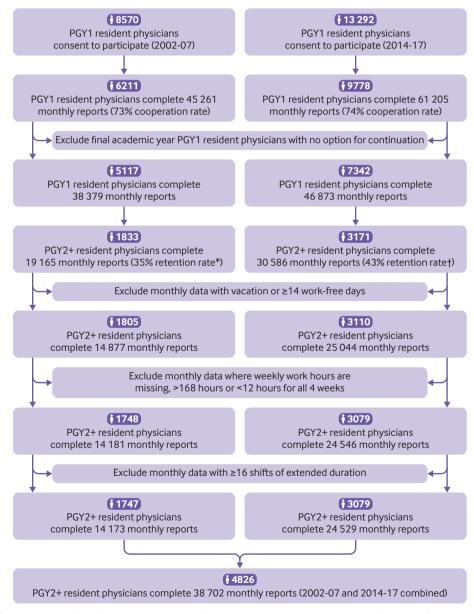


Figure 1 | Participation of resident physicians in study. PGY1=resident physicians in the first year of training after medical school graduation; PGY2+=resident physicians at postgraduate year 2 and above. *278 individuals did not participate as PGY1 resident physicians. †35 individuals did not participate as PGY1 resident physicians

For clinical outcomes (medical errors, preventable adverse events, medical errors resulting in patient death, occupational exposures, and percutaneous injuries), we also controlled for the hours of patient care reported that month. Mixed effects models were used to examine shifts of extended duration or weekly work hours as the independent variable of interest, with a random intercept for participant to control for the dependence between repeated measures. We conducted analyses with weekly work hours as a continuous variable and separately as a categorical variable with hours grouped into categories to inform policy decisions. Missing data for age (total 205 participants, 1561 person months (4% of months)) were imputed with the median age of the participant cohort, and a binary variable was created to indicate that age was imputed for that participant's observations (age imputation indicator variable).⁴ We did sensitivity analvses with and without accounting for missing data to guide the final models presented (online supplemental tables S4A-C, figure S1).

Categorical analyses used \leq 48 hours as a referent because it is the European Working Time Directive's limit. We chose additional, reasonable cut-off points (60, 70, and 80 h/week) that had sufficiently distributed data and that could be analysed and reasonably translated to meaningful policy. Further, because the ACGME limit on work weeks is 80 hours, extended routinely to 88 hours, we dichotomised the analysis (>80 $\nu \leq$ 80 hours), to evaluate the risks associated with working above the limit.

Motor vehicle crash models were limited to participants who reported a valid driver's license and who also reported driving to or from work. We limited medical error and occupational exposure models to months in which participants reported hours in patient care. SAS (version 9.4, SAS Institute, Cary, NC) was used for statistical analysis. All tests were two sided and P<0.05 was considered significant.

Patient and public involvement

We have worked extensively with public stakeholders, patient advocates, and resident physician advocacy organisations in our work on the effects of sleep deficiency on patient safety. We plan to widely disseminate the results to relevant patient and public communities, including organisations such as the Committee for Interns and Residents, Patient Safety Action Network, Agency for Healthcare Research and Quality, ACGME, National Academy of Medicine, and Royal College of Physicians. We will also post the results to the study website.

Results

We collected 14173 responses from 1747 PGY2+ resident physicians from 2002 to 2007, and 24529 responses from 3079 PGY2+ resident physicians from 2015 to 2017 (figure 1). Nearly three quarters of PGY1 resident physicians who provided informed

Table 1 Baseline characteristics of par	rticipants
Baseline characteristics	No or No (%)

Daseline characteristics	NO OF NO (76)
Total No of participants	4826
Mean (standard deviation) age (years)	29.7 (3.4)
Female gender	2612 (54)
Unknown	203 (4)
Mean (standard deviation) body mass index	23.9 (3.9)
Specialty*	
Internal medicine	1109 (24)
Family practice	559 (12)
Paediatrics	650 (14)
General surgery and surgical specialties	416 (9)
Emergency medicine	380 (8)
Obstetrics/gynaecology	249 (5)
Psychiatry	250 (5)
Anaesthesiology	215 (5)
Other (including combined)	807 (17)
Cohort	
PGY2+ residency, 2003-07	1747 (36)
PGY2+ residency, 2015-17	3079 (64)

Data are number or number (%) of participants unless stated otherwise. PGY2+ residents=resident physicians at postgraduate year 2 and above. *Column percentages might not add to 100% owing to rounding.

consent contributed monthly reports (73% and 74% cooperation rates in the 2002-07 and 2015-17 cohorts, respectively). Of these PGY1 physicians, more than one third continued participation into their more senior years of residency (35% and 43% retention rates in the 2002-07 and 2015-17 cohorts, respectively). More than half (54%) of study participants were female and mean age was 29.7 (standard deviation 3.4 years). Resident physicians from a diverse array of specialties participated in the study. The most prevalent specialty was internal medicine (24%; table 1), similar to national prevalence.⁵

An average of 324.6 (standard deviation 196.0) reports per month were completed by PGY2+ resident physicians. Each resident completed an average of eight reports (standard deviation 6). Mean weekly work hours were 60.0 (standard deviation 16.1; table 2). Overall, 29 560 (76.4%) weeks exceeded 48 hours, 18 073 (46.7%) exceeded 60 hours, and 3734

Table 2 | Hours of work and sleep recorded among38702 study months

Characteristics	Mean (standard deviation) in hours
Weekly work hours	60.0 (16.1)
Hours engaged in patient care	44.2 (17.9)
Additional weekly work hours related to programme	5.2 (5.6)
Additional weekly hours moonlighting	0.60 (2.6)
Shifts of extended duration per month	1.6 (2.6)
Nightly sleep duration	6.9 (1.0)
Sleep duration on shifts of extended duration	2.5 (1.8)
Proportion (%) of extended shifts without sleep	14% (n=2068/14 319)
Days off per month	6.1 (2.2)

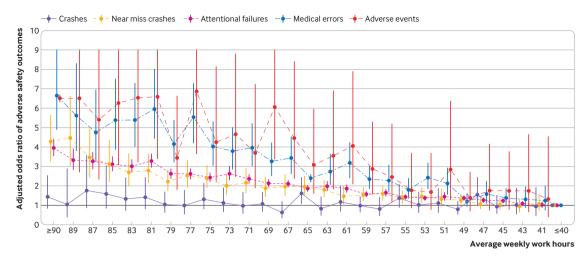


Figure 2 | Continuous analysis of adverse safety outcomes among study participants. All models are adjusted for age, gender, specialty, and cohort; medical errors and adverse events are further adjusted for hours in patient care. Estimates for near miss crashes and attentional failures are incidence rate ratios (95% confidence intervals); all other estimates are odds ratios (95% confidence intervals). Crashes=motor vehicle crashes. Referent group is ≤40 hours/ week. An odds ratio of 1 is indicated by a horizontal black line; estimates crossing 1 do not differ significantly from the referent group (≤40 hours/week)

(9.7%) exceeded 80 hours. Beyond those hours, 1024 (21%) resident physicians reported moonlighting; among those who did moonlight, the overall mean hours spent moonlighting were 0.60 (standard deviation 2.6) per week. Resident physicians reported working a mean of 1.6 (standard deviation 2.6) shifts of extended duration per month. Although daily sleep duration averaged 6.9 (standard deviation 1.0), resident physicians on shifts of extended duration reported obtaining a mean of only 2.5 hours (standard deviation 1.8) of sleep. Resident physicians reported obtaining no sleep on 14% of shifts of extended duration (table 2).

Serious medical errors and preventable adverse events

30.5% (1453/4764) of PGY2+ resident physicians reported at least one medical error; 8.3% (397/4760)

reported at least one preventable adverse event and 1.8% (85/4760) reported at least one fatal preventable adverse event. Figure 2 illustrates the relation between weekly work hours and adverse outcomes when comparing each incremental increase in weekly work hours to the referent of <40 weekly work hours. In continuous analyses, the risk of medical error increased for all hours after 50 weekly work hours.

In categorical analyses, medical errors and preventable adverse events increased significantly in a linear manner when weekly work exceeded 48 hours (table 3). Fatal adverse events also increased significantly when weekly work exceeded 60 hours. Working between 60 and 70 hours per week was associated with a more than twice the risk of reporting a medical error (odds ratio 2.36, 2.01 to 2.78, P<0.001) and almost three times the risk

Table 3 | Adjusted association between increasing weekly work hours and adverse health and safety outcomes among PGY2+ resident physicians

	Weekly wor	k hours				
Outcome	≤48	>48 and ≤60	>6o and ≤7o	>70 and ≤80	>80	P value
Patient safety						
Medical errors	Reference	1.61 (1.39 to 1.87)	2.36 (2.01 to 2.78)	3.19 (2.69 to 3.78)	4.01 (3.32 to 4.84)	<0.001
Preventable adverse events	Reference	1.54 (1.06 to 2.24)	2.93 (2.04 to 4.23)	2.84 (1.93 to 4.19)	3.84 (2.51 to 5.87)	<0.001
Fatal preventable adverse events	Reference	0.66 (0.25 to 1.70)	2.75 (1.23 to 6.12)	2.51 (0.87 to 5.30)	3.67 (1.45 to 9.30)	<0.001
Resident safety						
Motor vehicle crashes	Reference	0.93 (0.74 to 1.19)	0.99 (0.76 to 1.28)	0.94 (0.72 to 1.24)	1.24 (0.92 to 1.66)	0.49
Crashes leaving work	Reference	0.96 (0.66 to 1.41)	0.96 (0.62 to 1.47)	0.92 (0.59 to 1.43)	1.78 (1.15 to 2.76)	0.13
Near miss crashes	Reference	1.41 (1.23 to 1.61)	1.77 (1.52 to 2.06)	2.11 (1.81 to 2.46)	2.97 (2.52 to 3.50)	<0.001
Occupational exposures	Reference	1.78 (1.48 to 2.16)	2.46 (2.03 to 2.98)	3.35 (2.77 to 4.06)	4.19 (3.39 to 5.17)	<0.001
Percutaneous injuries	Reference	1.71 (1.28 to 2.28)	2.59 (1.95 to 3.44)	3.49 (2.62 to 4.64)	5.80 (4.32 to 7.79)	<0.001
Attentional failures	Reference	1.33 (1.27 to 1.40)	1.80 (1.69 to 1.92)	2.29 (2.13 to 2.46)	3.06 (2.85 to 3.30)	<0.001

All models are adjusted for age, gender, specialty, and cohort. Occupational exposures, percutaneous injuries, and patient safety outcomes are further adjusted for hours in patient care. P values are obtained from likelihood ratio tests testing a linear trend through the categories. Estimates for near miss crashes and attentional failures are incidence rate ratios (95% confidence intervals); all other estimates are odds ratios (95% confidence intervals). PGY2+ residents=resident physicians at postgraduate year 2 and above.

of preventable adverse events (2.93, 2.04 to 4.23, P<0.001) and fatal preventable adverse events (2.75, 1.23 to 6.12, P<0.001; table 3). When comparing categories of weekly work hours, the odds of reporting a medical error, a preventable adverse event, and a fatal adverse event increased roughly fourfold when weekly hours exceeded 80 (4.01, 3.32 to 4.84; 3.84, 2.51 to 5.87; and 3.67, 1.45 to 9.30; respectively; table 3). Working one shift of extended duration in a month while averaging no more than 80 weekly work hours was associated with an increased risk of reporting medical errors (1.84, 1.66 to 2.03), preventable adverse events (1.51, 1.20 to 1.90), and fatal preventable adverse events (1.85, 1.05 to 3.26) compared with working no shifts of extended duration (table 4). Incidence rates are presented in online supplemental tables S2 and S3.

Motor vehicle crashes and near miss crashes

Of 580 motor vehicle crashes reported, 213 (36.7%) occurred on the commute from work. Compared with working fewer than 80 hours per week, when PGY2+ resident physicians worked 80 hours or more per week, we saw an 86% increase in the risk of a crash on the commute from work and a 99% increase in the incidence of near miss crashes (table 4). Working a shift of extended duration and 80 hours per week further increased the risk of any crash and a crash on the commute from work (odds ratios 1.44 (95% confidence interval 1.08 to 1.93) and 2.67 (1.78 to 4.01), respectively; table 4). In categorical analysis, we saw a dose dependent increase in reported near miss crashes as weekly work hours increased above 48 hours, with the incidence more than doubled with 70 or more weekly work hours (between >70 and ≤80 work hours/week, incidence rate ratio 2.11, 95% confidence interval 1.81 to 2.46; table 3). Working one or more shifts of extended duration while averaging no more than 80 hours per week in a month significantly increased the near miss crash risk (incidence rate ratio 1.47, 95% confidence interval 1.32 to 1.63, P<0.001, table 4). The combination of more weekly work hours (>80) and shifts of extended duration further increased the risk of a near miss crash (incidence rate ratio 2.54, 95% confidence interval 2.19 to 2.94, P<0.001; table 4).

Occupational exposures and percutaneous injuries

Of 663 percutaneous injuries reported on monthly surveys, 631 (95%) reported to occupational health. We saw a significant dose dependent increase in the risk of occupational exposures and percutaneous injuries when weekly work hours increased beyond 48 hours (P<0.001; table 3). Working one or more shifts of extended duration in a month was associated with an increased risk of an occupational exposure (odds ratio 1.17, 95% confidence interval 1.02 to 1.33; P<0.05 and >0.001; table 4).

Attentional failures

Of 38 702 monthly reports, attentional failures while working were reported in 2972 (8%). About a quarter of PGY2+ resident physicians (24% (1160/4826)) reported at least one attentional failure. We saw a significant dose dependent increase in attentional failures as weekly work hours increased. PGY2+ resident physicians were almost two times more likely to fall asleep at inappropriate times when working more than 60 hours per week (incident rate ratio 1.80 (95% confidence interval 1.69 to 1.92), P<0.001; table 3) Working one or more shifts of extended duration in a month was associated with a 40% increased risk of attentional failures (1.40, 1.34 to 1.48, P<0.001; table 4).

Discussion

Principal findings

Senior resident physicians (PGY2+) work long weekly hours, with three quarters of work weeks including over 48 hours and nearly half exceeding 60 hours. PGY2+ resident physicians working more than 48 hours per week had a significantly increased risk of making a medical error and injuring a patient. The risk of a medical error resulting in death significantly increased when weekly work hours exceeded 60 hours. Additionally, work shifts of extended duration significantly increased risk to patient safety. Further, the combination of long weekly work hours and shifts of extended duration had a synergistic effect, amplifying the risks to patient safety. Importantly, motor vehicle crashes, near miss crashes, percutaneous injuries, and attentional failures showed similar patterns of worsening with long work weeks and work shifts of extended duration, suggesting that these two factors pose a danger not only to patients, but also to resident physicians. These increased risks associated with long weekly work hours and shifts of extended duration by PGY2+ resident physicians were similar in magnitude to the risks we previously reported in PGY1 resident physicians.^{6–8}

Comparison of results with previous studies

Our results are consistent with and build on previous literature, providing multispecialty, US wide data for experienced (PGY2+) resident physicians. A previous US report found an increased risk of medical errors resulting in adverse patient outcomes for first and second year resident physicians who worked more than 80 weekly hours.⁹

Data from the UK have also shown a relation between work hours and patient safety. A large retrospective review showed no increase in mortality, average length of stay, or readmission rate in regions of England that were adherent to the 48 hour weekly work limit, as compared with other regions of the country that had not yet implemented that limit.¹⁰ A similar large trial in the US found that the change in hospital level mortality was not inferior as defined 6

Table 4 Adjusted a	ssociat	Table 4 Adjusted association between weekly work hours, shifts of	work hour.	s, shift:	s of extended duration	on, and adverse he	alth and saf	ety outcom	extended duration, and adverse health and safety outcomes among PGY2+ resident physicians	esident physicians		
	Week	Weekly work hours		Shifts c	Shifts of extended duration			Combined o	categorical weekly wor	Combined categorical weekly work hours and shifts of extended duration	ttended duration	
Outcome	≤80	>80	P value	None 1-4	1-4	Ş	P value	≤80 work h/week, no shifts	≤80 work h/week, ≥1 shifts	>80 work h/week, no shifts	>80 work h/week, no >80 work h/week, ±1 shifts	P value
Patient safety												
Medical errors	Ref	1.59 (1.41 to 1.79)	P<0.001	Ref	1.56 (1.41 to 1.73)	2.25 (1.99 to 2.53)	P<0.001	Ref	1.84 (1.66 to 2.03)	2.12 (1.70 to 2.64)	2.30 (1.99 to 2.66)	P<0.001
Preventable adverse events	Ref	1.52 (1.17 to 1.98)	P=0.001	Ref	1.28 (1.01 to 1.63)	1.70 (1.29 to 2.25)	P<0.05 and P>0.001	Ref	1.51 (1.20 to 1.90)	2.35 (1.50 to 3.69)	1.82 (1.30 to 2.53)	P<0.001
Fatal preventable adverse events	Ref	2.32 (1.36 to 3.96)	P<0.05 and Ref P>0.001	Ref	1.57 (0.89 to 2.76)	1.99 (1.04 to 3.81)	I	Ref	1.85 (1.05 to 3.26)	3.36 (1.15 to 9.78)	2.62 (1.23 to 5.56)	P<0.001
Motor vehicle crashes	Ref	1.29 (1.00 to 1.66)	Ι	Ref	1.15 (0.93 to 1.42)	1.17 (0.92 to 1.49)	I	Ref	1.09 (0.89 to 1.32)	0.91 (0.48 to 1.73)	1.44 (1.08 to 1.93)	Ι
Crashes leaving work	Ref	1.86 (1.28 to 2.69) P=0.001	P=0.001	Ref	1.51 (1.09 to 2.07)	1.92 (1.35 to 2.74) P<0.05 and P>0.001	P<0.05 and P>0.001	Ref	1.42 (1.05 to 1.93) 1.07 (0.39 to 2.96)	1.07 (0.39 to 2.96)	2.67 (1.78 to 4.01)	P<0.05 and P>0.001
Near miss crashes	Ref	1.99 (1.74 to 2.27) P<0.001	P<0.001	Ref	1.37 (1.22 to 1.53)	2.06 (1.83 to 2.33)	P<0.001	Ref	1.47 (1.32 to 1.63) 1.64 (1.27 to 2.12)	1.64 (1.27 to 2.12)	2.54 (2.19 to 2.94)	P<0.001
Occupational exposures Ref	s Ref	1.42 (1.19 to 1.69) P<0.001	P<0.001	Ref	1.27 (1.11 to 1.45)	1.54 (1.32 to 1.79) P<0.001	P<0.001	Ref	1.17 (1.02 to 1.33)	1.23 (0.85 to 1.77)	1.42 (1.17 to 1.73)	P<0.05 and P>0.001
Percutaneous Injuries	Ref	1.66 (1.33 to 2.07) P<0.001	P<0.001	Ref	1.24 (1.02 to 1.50)	1.35 (1.08 to 1.68) P<0.05 and P>0.001	P<0.05 and P>0.001	Ref	1.16 (0.96 to 1.40)	1.34 (0.83 to 2.15)	1.91 (1.47 to 2.48)	P<0.001
Attentional failures	Ref	1.85 (1.74 to 1.96) P<0.001	P<0.001	Ref	1.29 (1.23 to 1.35)	1.95 (1.82 to 2.09)	P<0.001	Ref	1.40 (1.34 to 1.48)	1.75 (1.57 to 1.96)	2.30 (2.14 to 2.47)	P<0.001
All models are adjusted for weekly work hours and shi near miss crashes and atte	r age, ger fts of exte intional fe	All models are adjusted for age, gender, specialty, and cohort. Occupational exposures, percutaneous injuries, and patient safety outcomes are further adjusted for hours in patient care. P values are obtained from likelihood ratio tests. Linearity was assumed for weekly work hours and shifts of extended duration was tested across the categorical variables using likelihood ratio tests than tested for a linear trend across categories. Estimates for neekly work hours and shifts of extended duration was tested across the categorical variables using likelihood ratio tests that tested for a linear trend across categories. Estimates for near miss crashes and attentional failures are incidence rate ratios (95% confidence intervals), all other satimates are odds ratios (95% confidence intervals), all other satimates are odds ratios (95% confidence intervals). Ref=reference group; PGY2+ residents physicians at postgraduate year 2 and above.	Occupational e of increasing tios (95% con	exposure: g work we. fidence in	s, percutaneous injuries, an ekly hours and shifts of ext itervals); all other estimate	nd patient safety outcom ended duration was test s are odds ratios (95% co	es are further ad ed across the cat onfidence interva	justed for hou egorical varial als). Ref=refere	s in patient care. P values oles using likelihood ratio ence group; PGV2+ resider	s are obtained from likeliho tests that tested for a line nts=resident physicians at l	od ratio tests. Linearity was r trend across categories. E oostgraduate year 2 and ab	assumed for stimates for ove.

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by the investigators (a difference of more than 1% in absolute mortality rate between the groups), although mortality was substantially higher when restrictions to PGY1 resident physicians' work hours were temporarily lifted compared with programmes that maintained work hour restrictions.^{11–13}

Further, in a clinical trial reviewing medical records of more than 1700 admissions of 19 resident physicians, there were approximately a third fewer medical errors when residents worked fewer than 48 hours per week had about a third fewer medical errors than those who worked fewer 56 work hour limit per week.¹⁴ Although the number of adverse events has fallen in the past decade, their frequency remains unacceptable.¹⁵ Based on estimates during a month in 2018, 25% of Medicare patients in hospital experience harm.¹⁶

Strengths and limitations of the study

Strengths of our study included its wide geographical representation and cross specialty make up, its focus on PGY2+ resident physicians, an understudied group, and the consistent findings of dose-response associations observed among long work weeks, shifts of extended duration, and important health and safety outcomes.

Our study had several limitations. Despite the large amount of monthly data collected from resident physicians across specialties and geographical regions, and the similarity of our cohort to that of the US national resident population,⁵ those who chose to participate had specific interest in work hours, thus raising the potential of participation bias. However, potential participants were not informed of the specific study hypotheses. Although response bias is always possible in survey studies, we deliberately chose a shorter, consistent monthly time frame and the questions relating to our independent variables and primary outcome measures were distributed among questions regarding secondary outcome measures such as sleep, caffeine use, and physical activity.

Further, questionnaire data rely on self-reports. Questions regarding work hours, motor vehicle crashes, and percutaneous injuries were previously validated.^{3 7} Although patient safety data were not independently validated and the definition of what incidents constituted a important error or adverse patient outcome might have varied from participant to participant, it is unlikely to have varied within each participant between survey months. Additionally, the consistency of the results when the outcome of the error resulted in a death-a tragic but unambiguous outcome-provides a common metric of severity. Voluntary self-report can also contribute to missingness. We imputed observations with missing age using the median value for each cohort. This imputation was necessary for 4% of the observations. The pattern of missingness was characterised

as missing at random. We did not perform multiple imputation because of the lack of data to inform a multiple imputation approach, limited variability of age in the sample, and the minimal effect of varied approaches on results. Results of sensitivity analyses using only complete information and analyses that omitted age from the models were similar to analyses using single imputation (online supplemental tables S4A-C, figure S1). Although self-reported outcomes have inherent limitations, they also have advantages: resident reported outcomes reflect a more proximal, direct connection between resident individual performance under a discrete set of working conditions and outcomes, compared with studies looking at hospitalwide outcomes of systemic interventions that are downstream of resident physicians and subject to confounding due to concurrent safety interventions and other factors.^{11 13} Moreover, perceived medical errors that result in an injury or death to a patient under the care of a resident physician, which can only be derived from self-reports, have been associated with adverse mental health outcomes.¹⁷

Policy implications

Although long work hours have remained part of the cultural norm for resident physicians in the US, the general public does not approve of them. In a nationally representative sample, 81% of participants indicated that patients should be informed if a treating resident physician had been working for 24 or more hours, and 80% would want a different doctor.¹⁸

The World Health Organization and International Labour Organization recognise that working more than 55 hours per week is an occupational risk factor.¹⁹ Other countries have successfully limited work hours of physicians in training.^{20 21} The European Working Time Directive led to junior doctors in the UK being restricted to 56 weekly hours in 2004, which was further reduced to 48 hours per week (averaged over 26 weeks) in 2009. The shorter work weeks were associated with a maintenance or improvement in patient safety.^{10 14} Despite an optout clause that allows for additional work, European Working Time Directive rules include a minimum of 11 hours of rest every 24 hours, one day off each week, and four weeks of annual leave. By contrast, over the past two decades, the US's policy on shifts of extended duration has vacillated, particularly for PGY1 resident physicians. Current ACGME policy allows for 28 hour shifts and 80-88 hour work weeks for all resident physicians, fundamentally unchanged from 2003. Our data reveal that PGY2+ resident physicians are just as vulnerable to the impact of long work weeks and work shifts of extended duration as PGY1 resident physicians, supporting the notion that clinical experience and advanced training do not mitigate their effects. Policies consistent with the European Working Time Directive's limits for all physicians could potentially mitigate these risks and

could be extended to other healthcare workers and all those in safety sensitive occupations.

As efforts are made to safely reduce work hours, it is important to recognise that patient and resident safety is multifactorial. The ROSTERS trial recently found that increased workload likely confounded efforts to implement a safer work schedule.²² Schedule design is also critical, as attempts to reduce consecutive working hours can result in other undesirable changes such as increased consecutive night shifts, reduced number of hours off between work shifts, or unfavourable rotation schemes. Additional research is required to study the interaction between shift duration, weekly work hours, workload, handoffs, and teamwork in order to craft appropriate policies and operationally effective schedules to minimise risks to patients and resident physicians. Creative solutions, such as the use of physician extenders in intensive healthcare settings, and best methods to sway the cultural norms might need to be explored.

Conclusions

We found that the current ACGME work hour guidelines could pose considerable hazards to patients and resident physicians. Other nations have been successful in providing patient care with more limited work hours for physicians in training. Resident physicians throughout the European Union are limited by the European Working Time Directive to 48 hours of work per week.²⁰ The province of Quebec in Canada limits physicians in training to shifts no longer than 16 consecutive hours; New Zealand has imposed such limits for more than 30 years.²¹ Our data suggest that lower work hour limitations would reduce risks for PGY2+ resident physicians and their patients in the US, although workload and other factors will need to be concurrently investigated as efforts are made to implement safer work schedules.

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Contributors LKB, CPL, and CAC proposed the design of the study, LKB, MDW, JPS, SQ, CPL, and CAC conducted the study; SQ prepared the database; MDW conducted the analyses; LKB, MDW, JPS, CPL, and CAC interpreted the results; LKB drafted the manuscript; and LKB, MDW, JPS, SQ, CPL, and CAC provided critical revisions to the manuscript. LKB is guarantor. The corresponding author attests that all listed authors meet authorship criteria and that no others meeting the criteria have been omitted. Transparency: The lead author (the guarantor) affirms that the manuscript is an honest, accurate, and transparent account of the study being reported; that no important aspects of the study have been omitted; and that any discrepancies from the study as planned (and, if relevant, registered) have been explained.

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Ethics approval This study involves human participants and was approved by Partners Human Research Committee (2002-P-000202). Participants gave informed consent to participate in the study before taking part.

Provenance and peer review Not commissioned; externally peer reviewed.

Data availability statement Data are available upon reasonable request. We will make the datasets available to other investigators following publication of the final study results, in accordance with National Institutes of Health policy and the policies of the institutional review board of Mass General Brigham. Any investigator

or entity requesting the data must request the data in writing in an agreement outlining how the data will be used, protected, and maintained, for example, through a formal data use agreement (DUA) negotiated by a Partners office or a template letter agreement signed by the sharing and receiving principal investigators. The policy includes a requirement that for outgoing data with information on human participants or protected health information, institutional research board approval must be received before DUA execution.

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