Does it matter how much physician trainees work anymore?

Kathlyn E Fletcher,[1,2] Sumant R Ranji[3]

[1]Department of Internal Medicine, Clement J. Zablocki VAMC, Milwaukee, Wisconsin, USA
[2]Department of Internal Medicine, Medical College of Wisconsin, Wisconsin, USA
[3]Division of Hospital Medicine, University of California San Francisco, San Francisco, California, USA

Correspondence to
Dr Kathlyn E Fletcher, Medical College of Wisconsin and Milwaukee Veterans Affairs Medical Center, 5000 W. National Ave, Milwaukee, WI 53295, USA; kfletche@mcw.edu

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The restriction of working hours for physicians in training was one of the earliest and most far-reaching interventions of the patient safety movement. The US Accreditation Council for Graduate Medical Education (ACGME) implemented rules in 2003 restricting residents to 80 h of work per week and no more than 30 h of continuous duty. Subsequent regulations implemented in 2011[1] limited the maximum shift length for first-year trainees to 16 h and reduced continuous duty for all residents to 28 h. Other countries have implemented significantly stricter rules—the European Working Time Directive[2] has limited European trainees to 48 working hours per week since 2009. These regulations directly affect >118 000 residents in the USA[3] and about 40 000 junior doctors in the UK yearly, with major consequent effects on the workforce and finances of teaching hospitals and clinics.

Yet a decade of rigorous evaluation has failed to demonstrate any improvement in patient safety or clinical outcomes associated with restricting duty hours. Systematic reviews of studies of the 2003 US duty hour regulations,[4] as well as well-designed studies[5] of the 2011 regulations, have consistently shown that reducing duty hours did not improve patient outcomes at teaching hospitals (compared with non-teaching hospitals). The effect on education and resident well-being has been mixed at best—although some studies indicate resident perception of their education has improved, rates of burnout and depression among residents appear unaffected.[6]

One explanation for this finding could be that residents are still working past the point of fatigue—that is, duty hours simply have not been restricted enough or regulations have not been adequately enforced. However, no European study has demonstrated positive benefit for patients of the 48 h work week (although few studies have been performed). Another explanation could be that since outcomes such as adverse events and inpatient death are rare, relatively small changes in resident duty hours (such as those implemented in the USA) may not be sufficient to affect these outcomes, especially when many other interventions to improve safety and quality were also implemented simultaneously. While outcomes are clearly important, sometimes it makes sense to assess the processes that precede them. Processes are of particular importance if the outcome is rare or if the outcome is likely to be influenced by so many factors that it becomes difficult to assess the relative contribution of any single factor. The downside of measuring processes is that there is no guarantee that if the process is followed that the outcome will be improved. It is therefore important to choose processes that have a demonstrated or a strong theoretical link to the outcomes of interest.

In this issue of *BMJ Quality and Safety*, the study by Rajaram *et al*[7] examines the relationship between the 2011 US duty hour regulations and the outcome of patient satisfaction alongside several process measures, including whether or not patients with heart failure were given discharge instructions, whether or not patients with pneumonia had blood cultures drawn before they were given their first dose of antibiotics and whether or not urinary catheters were removed within 2 days of surgery. They did not find an association between implementation of duty hour rules and improvement in any of these (or other) process measures.

This study addresses an important gap in the duty hour literature. The theoretical argument for examining the effect of duty hour regulations on process measures is that they may be more under the control of residents than outcomes such as mortality and adverse events.

However, there are issues with using these metrics to detect the effect of duty hour regulations on safety and quality.

The overall emphasis on improving safety and quality over the past 15 years has yielded many interventions that likely attenuate the effect of resident staffing and duty hours on clinical processes of care. As a result, most of the process measures examined by Rajaram *et al* may not be under residents' direct control. This is especially true for the measures assessed in this study, which are publicly reported in the USA. This external pressure results in hospitals putting extra resources into ensuring high performance, corroborated by the finding that all process measures were achieved at a median of at least 93% both pre intervention and post intervention. For example, obtaining blood cultures before antibiotics in patients with pneumonia is often accomplished by having emergency department nurses draw blood cultures on all patients with suspected infections, sometimes even before a physician has evaluated them. Prompt removal of urinary catheters postoperatively is often carried out via nursing protocols that do not require input from physicians. For protocol-driven processes such as these, at worst residents could get in the way. At best, they have no effect.

Even for processes that remain under physician control, closer supervision by senior physicians likely ameliorates the impact of reduced resident presence. Teaching faculty increasingly face pressure to 'micromanage'—closely monitor relatively minor resident decisions in order to ensure quality metrics are met.[8] This phenomenon is particularly relevant for the publicly reported metrics analysed by Rajaram *et al*. Another mechanism that teaching hospitals have used to respond to the duty hour regulations is to create direct care services where care is provided by faculty physicians without trainees, thereby decreasing the proportion of patients with residents involved in their care. Improvement in quality metrics at teaching hospitals may therefore represent both indirect and direct faculty involvement. This may help achieve quality goals, but results in negative educational consequences as residents gain less independent clinical experience during training. Finally, in 2011 the ACGME also implemented curricular requirements for residents to receive formal training in patient safety and quality improvement. This requirement may have improved resident skills at handoffs and increased resident awareness of quality metrics, contributing to improved performance despite decreased duty hours.

In light of these systematic changes, the results of the recent FIRST trial[9] are not surprising. This cluster-randomised trial (led by the senior author of the study by Rajaram *et al*[7]) compared patient outcomes in surgical residency programmes allocated to 'flexible' duty hours, in which specific aspects of the regulations were waived but the overall 80 h work week was retained, with programmes adhering to the 2011 regulations. The study found similar rates of 30-day postoperative death and serious complications in the two groups, confirming non-inferiority of the flexible schedule. A similar trial, the iCompare study,[10] is currently being conducted in internal medicine residency programmes. Given the results of the FIRST trial and the decade of preceding duty hour research, the iCompare study is almost preordained to show no difference in clinical outcomes between duty hour schedules.

This evidence prompts two important questions for policymakers. First, does the presence of trainees still endanger patient safety? Second, should duty hour regulations be relaxed?

Trainees are at the front line in teaching hospitals, usually the first physicians to see a patient and make decisions about initial triage, diagnosis and management. These interactions and decisions are crucial for patient care—but are also among the most difficult to quantify. It is tempting to conclude that teaching hospitals have (perhaps despite themselves) managed to construct safe systems for care independent of residents, but studies of the 'July Effect', the academic year-end changeover where experienced residents are replaced by new graduates, belie this conclusion. A systematic review of these data[11] shows that patients hospitalised early in the academic year are at increased risk of mortality and adverse events. The mechanism for this effect is not clearly defined, but likely indicates gaps in our ability to measure the influence of residents on patient outcomes. The safety field still lacks accurate measures of diagnosis or triage decisions, and measures of high-value care (another area directly influenced by resident decision-making) are still in their infancy. More progress has been made in measuring the patient experience, but as the findings of Rajaram *et al* indicate, existing measures may not adequately discriminate between the specific aspects of communication influenced most by residents. Adequate definitions of effective supervision or even consensus on what constitutes effective supervision in different clinical settings are also lacking. Teaching institutions may have adapted appropriately to duty hour regulations by devising systems of care that minimise the effect of clinician fatigue, but patients are still vulnerable to harm caused by inexperienced or inadequately supervised trainees. This harm may be difficult to measure, but still exists.

The answer to the second question is more straightforward. It is true that patient outcomes do not improve when residents work less—but they do not worsen either. Given that rates of burnout and depression among trainees remain alarmingly high, we think that a closer look into the causes of these problems is warranted. Certainly, duty hour regulations should be optimised in order to maximise resident educational and psychological outcomes while preserving patient

safety. Affording training programmes more flexibility in constructing schedules and using data-based approaches to optimise resident workload would likely help more than further blanket reductions in duty hours.

The continuing saga of resident duty hour regulations holds important lessons for the patient safety field. It is one of several examples where a 'common sense' intervention has turned out to have vastly different effects than predicted.[12] The failure of duty hour regulations to improve patient safety does not mean that the rules themselves were misguided; instead, the data demonstrate that the relationship between medical education and the quality of care is complex and dynamic, and that errors committed by trainees may not be primarily due to fatigue. Further studies of duty hours need not assess high-level clinical outcomes such as inpatient mortality or readmissions. Instead, they should focus on process measures that are under the control of residents and could plausibly be influenced by fatigue, supervision or clinical experience, and should include formal assessments of educational outcomes and levels of burnout and psychological distress. Some studies directly comparing teaching and direct care services have been published,[13] and more (ideally multicentre) research of this format would greatly help identify safety and quality issues unique to teaching services. Finally, rigorous studies of the European Working Time Directive are also urgently needed as these much stricter restrictions likely have a more profound effect on both clinical metrics and educational outcomes compared with the relatively modest US regulations.

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