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## Residents' working hours and patient safety: Have we finally laid the issue to rest!

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Bilimoria KY, Chung JW, Hedges LV, Dahlke RD, Love R, Cohen ME, Hoyt DB, Yang AD, Tarpley JL, Mellinger JD, Mahvi DM, Kelz RR, Ko CY, Odell DD, Stulberg JJ, Lewis FR. (Surgical Outcomes and Quality Improvement Center [SOQIC], Department of Surgery and Center for Healthcare Studies, Feinberg School of Medicine and Northwestern Medicine, Northwestern University, Evanston; the American College of Surgeons, Chicago; Department of Statistics, Northwestern University, Evanston; Department of Surgery, Southern Illinois University, Springfield; Department of Surgery, Vanderbilt University, Nashville; Department of Surgery and the Center for Surgery and Health Economics, Perelman School of Medicine, University of Pennsylvania; the American Board of Surgery, Philadelphia; Department of Surgery, University of California, Los Angeles, School of Medicine, Los Angeles, USA.) National cluster randomized trial of duty-hour flexibility in surgical training. *N Engl J Med* 2016;**374**:713–27.

### SUMMARY

Ever since the Accreditation Council for Graduate Medical Education (ACGME) introduced restrictions on resident working hours in the USA in 2003, controversy has continued to plague this issue in view of the long established and long held beliefs in the benefits of continuity of care particularly in surgical patients and the adverse effect of frequent hand-offs on resident training. Several studies have shown adverse outcomes of the new policy and some which have supported it. Evidence from large prospective randomized trials is currently lacking.

The authors did a national, cluster-randomized, pragmatic, non-inferiority trial involving 117 of 252 ACGME-accredited general surgery residency programmes in the USA in 2014. Seventy-seven programmes were excluded because of non-affiliation with the National Surgical Quality Improvement Program (ACS NSQIP), which was the intended platform for patient data collection; 77 were excluded since state regulations did not permit such a trial (state of New York); and 12 programmes were excluded due to poor standing with the ACGME.

One hundred and eighteen general surgery residency programmes which qualified for inclusion in the trial were stratified into three

strata on the basis of rates in 2012 and 2013 of a composite measure of death or serious complications and then randomly assigned as clusters within the strata into one of two groups, viz. *the standard policy group* which strictly complied with the ACGME guidelines and *the flexible-policy group* wherein the hospitals were permitted to modify four of the seven criteria of ACGME regarding residents' working hours. The institutes in the flexible policy group were allowed to permit (i) PGY1: duty periods exceeding 16 hours; (ii) PGY 2–5: duty periods exceeding 28 hours (24 hours plus 4 hours for transitions); (iii) residents not requiring to have  $\geq 8$ –10 hours between shifts; and (iv) residents not requiring to have  $\geq 14$  hours off after 24 hours of continuous duty. The remaining three guidelines, viz. (i) residents must not work more than 80 hours per week averaged over 4 weeks; (ii) residents must have 1 in every 7 days off from all educational and clinical duties averaged over 4 weeks; and (iii) residents must not be on call more frequently than every third night were the same for both groups.

Primary outcome measures studied included 30-day postoperative death rate and serious complications. Secondary outcomes studied included other complications, resident perceptions and satisfaction regarding their well-being, education and patient care. The study population was large and consisted of 4330 residents and 138 691 patients treated over the period of this study.

Results showed that flexible less-restrictive duty hour policies were not associated with an increased rate of death or serious complications (9.1% in the flexible group v. 9.0% in the standard group,  $p=0.92$ ). There was no difference in the secondary outcomes. Flexible policies did not report significantly greater dissatisfaction with overall education quality (11% in the flexible group and 10.7% in the standard group,  $p=0.86$ ) or resident well-being (14.9% and 12.0%, respectively,  $p=0.1$ ). Surprisingly, residents under flexible policies were less likely than those under the standard policies to perceive negative effects of duty hour policies on multiple aspects of patient safety, continuity of care, professionalism and resident education but were more likely to perceive an adverse effect on personal activities outside the hospital. There were no significant differences between the study groups in resident reported perception of the effect of fatigue on personal or patient safety. Residents in the flexible policy group were less likely than those in the standard policy group to report leaving during an operation (7.0% v. 13.2%,  $p<0.001$ ) or handing-off patient issues (32% v. 46.3%,  $p<0.001$ ).

The authors concluded that flexible, less restrictive resident hour policies were not inferior to standard policies in terms of resident perception or patient outcomes.

## COMMENT

The controversy about the pros and cons of restricting resident working hours in surgical fields and the consequences it may have on patient welfare, surgical outcome and quality of residents' life is continuing ever since the ACGME policy of restricting resident working hours was introduced in 2003. The initial introduction was done more for politically correct reasons rather than any strong evidence to support this restriction policy.<sup>1-3</sup> In many instances the residents may actually be working far less than 80 hours.<sup>4</sup> In Europe residents are not permitted to work for more than 48 hours/week! The absence of any level 1 evidence to suggest an abolition of the policy of curtailment of residents' working hours was responsible for its continuation with further abridgement of resident working hours. Does the present study lay to rest the controversy once and for all?

The study design was meticulous and involved a large group of hospitals and residents randomly assigned to two groups on the basis of working hour policy or so it appears. The outcome parameters were strictly defined as per established criteria. However, there are some deficiencies. Although 136 residency programmes qualified for inclusion in the trial, only 118 were included. The paper provides no information on why 18 other programmes were excluded. Would their inclusion have modified the results? The second major issue is that three of the ACGME criteria, viz. mandatory work hours/week, mandatory time free of duty and frequency of on-call duty were not allowed to be modified in the flexible policy group. The study is incomplete and weak without assessing the effect of exceeding 80 hours/week or violation of the 1 in 7 days off policy or increased frequency of calls. The flexible policy group may permit maximum shift length or minimum time off between shifts to vary but has to compensate with greater time off overall to keep within the mandate of the 80 hour rule per week or the off day in 7 or the on-call frequency. Also, the study does not mention whether patients' opinions were collected about frequent hand-offs or whether consultants' opinion were collected on residents handing off during operative procedures. These are important considerations in assessing the change due to restriction of work hours on the healthcare system and not only on patient outcomes and residents' perceptions.

Long and unpredictable work hours have been a staple of medical training for centuries. In fact, the term 'resident' is a relic of times when physicians in postgraduate training literally lived at the hospital.<sup>5</sup> Little attention was paid to potential patient safety effects of fatigue among residents until March 1984, when 18-year-old Libby Zion died at a New York Hospital due to a medication-prescribing error while under the care of residents in the midst of a 36-hour shift. The subsequent investigation into her death led to the formation of the Bell Commission, which passed regulations in 1987 mandating that residents at New York hospitals should work no more than 80 hours per week and no more than 24 consecutive hours. Another study confirmed this in relating reduction in medical errors in ICU to reduced resident working hours.<sup>6</sup> The study found nearly 36% more serious medical errors and 5.6 times more serious diagnostic errors among interns working a traditional schedule (more than 24 hours in a row) than among interns working shorter shifts.

A systematic review of the effect of physician duty hour regulations found that the regulations were associated with improved resident well-being, but had mixed effects on resident educational outcomes and clinical outcomes.<sup>7</sup> What is the opinion of faculty to the change in resident duty hours? In one study it was found that faculty were concerned that duty hour restrictions led

to a loss of educational opportunities, decreased continuity of care, and worsened resident-patient relationships and although faculty felt that the residents' quality of life had improved, attending physicians reported spending more time in direct patient care, but less time mentoring or evaluating residents.<sup>8</sup> A 2014 systematic review found that surgical residents had lower case volumes and scored more poorly on certification examinations after implementation of duty hour restrictions.<sup>9</sup>

If duty hour restrictions in surgeons were essential for patient and resident welfare it would be interesting to compare the quality of patient care and quality of life of practising surgeons and relate it to their working hours since in many instances they work much more than 80 hours/week.<sup>10</sup> However, there is no evidence to show that physician sleep deficits affect the safety of surgical care. One case-control study found no increase in complications in elective procedures performed by surgeons who had operated the night before compared to those with no overnight responsibilities,<sup>11</sup> and another population-based study found no differences in mortality, complications or re-admissions between procedures performed by surgeons with sleep loss compared to those without sleep loss.<sup>12</sup>

The authors themselves acknowledge some issues. These are (i) limiting the study to hospitals affiliated only to ACS NSQIP, thus limiting the ability to generalize their findings; (ii) restricting the study to general surgery residents alone and hence not being in a position to apply it to other surgical specialties; (iii) restricting the study to one year and not the entire duration of the residency period, thus excluding the possibility of any conclusions on long-term long duty hours restrictions; (iv) considering patient outcomes captured only by the ACS NSQIP, thus raising the possibility of missing adverse outcomes that are not listed; and (v) not collecting evidence of effect on educational outcomes of residents related to their working pattern. Some additional issues are mentioned in the comments regarding ignoring patient perceptions about frequent hand-offs on their care and ignoring faculty perceptions on training and educational outcomes.

The study does fulfil a long felt need of a prospective randomized trial of the effects of restricted working hours of residents. However, by covering only one year of a resident's training period and permitting flexibility in only four of seven norms of the ACGME criteria, it does not provide answers to all the questions. Incidentally, a *BMJ* blog has questioned whether the study review meets ethical guidelines since patients' consent was not taken. For unknown reasons, the study was classified by the concerned institutional review board (IRB) as a non-human subject research, thus obviating the need for informed consent from patients for their data to be included in the analysis. The authors have stoutly defended their decision but the controversy has not ended.<sup>13</sup> However, this controversy is not very relevant to the contents of the paper or its analysis.

Is the ACGME policy on restricting residents' working hours justified or not?—the jury is still out.

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