Correspondence

QJM

Cappuccio response to correspondence

Sir,

In reply to *Dr Dobson's* comments, the Traditional rotas in each individual doctor reflect common practices across the country, that do not always comply with the non-binding guidelines cited. We state in the paper that a 56-h working week is based on an average calculated over 6 months, as permitted by the European Working Time Directive (EWTD), and make the point very clearly that the ranges are more informative, revealing extremes of bad practices. We agree that the differences in the rotas would have contributed to the differences seen in error rates, which was the objective of the study. We did analyse data in the former 6 weeks and the latter 6 weeks and found no differences in error rates, although statistical significance was not achieved due to reduced power in sub-groups (data not shown but referred to in the text). We would have preferred not to have incurred a schedule change mid-way but this was a pragmatic real-world trial and we felt obliged to address the concerns raised. We are reasonably confident, however, that these small changes have not introduced any bias. Given the problems in the first 6 weeks, we would have expected, if anything, higher error rates in the intervention, leading to an underestimate of the true benefit on errors. We did not measure at what time of the day the errors occurred and when they were intercepted (if indeed they were). We agree and recognize in the paper that for a full implementation of our rota in future iterations of the schedule, these changes should be synchronized with normal hospital practices and that there is a need for a wider reengineering of shift systems and hospital processes. We have stated that our study was not designed to measure educational opportunities and we would welcome robust studies addressing those outcomes. We detected the same self-reported beliefs as reported in other surveys but they were not associated with compromised patients' safety, as directly measured. There is no evidence that doctors are more resistant to the effects of sleep loss than other individuals and no data to show that an individual can learn to go without sleep during their training. Indeed, recent studies[1] have shown that the ability to learn simple motor skills, or more complex executive functioning and insight, is impaired if sleep does not occur shortly after learning, questioning the traditional view in graduate medical education that long hours facilitate training. These concerns, and concerns about the impact of long working hours on patient safety, require a fundamental evidence-based review of the structure of medical education. Restructured programs that remove the unnecessary work that junior doctors currently do and focus on educational requirements will enhance quality of learning and reduce wasted time.

In response to *Dr Mann*, the sample size is not an issue as we detected significant differences in error rates due to sufficient statistical power; the two groups were comparable for patients' characteristics, hospital episodes and health outcomes as shown in Table 1; units of randomization (and analysis) were firms, not individual doctors. It would have been wrong to randomize doctors when in real life doctors are arranged in firms and work as a unit. The differences in specialties between the two groups is an important point that, whilst do not invalidate the results, call for a more definitive, longitudinal multicenter randomized controlled trial of implementing 2009 EWTD rotas to address this concern. The assessment of medical errors used is a well validated method.[2] We do not understand what profound effect it is envisaged, though. Blinding assessors of outcomes is what matters as in any modern clinical trial. If we were to use a drug, we would be happy with the PROBE design. Finally, it was not the objective of our study to measure perceptions.

In response to *Dr Waterman and colleagues*, we accept that this is a pilot study and open to improvements. We indeed recognize several

limitations to it. The comparison of error rates between groups is robust and valid, however. We considered the possibility of a cross-over design. It was excluded on several grounds: (i) it would have been extremely difficult to implement as it would have required a change in the rota 'within' the 3-month assignment of junior doctors to their rotation (not considering that the study coincided with the Medical Training Application Service scheme), with risk of reduced compliance; (ii) the length of follow-up would have been halved (from 12 to 6 weeks) to be able to complete the study with the same cohort within their 3-month rotational assignment; (iii) to exclude a possible carry-over effect on the likelihood of an incident we would have had to extend the period of observation with a wash-out period over the 3-month assignment and would have run out, again, of their rotational assignment.

While much discussion continues on the implementation and impact of the EWTD, our pilot study is one of the first to provide objective data to inform that debate. We would welcome more definitive, longitudinal multicenter randomized controlled trials of the impact of the EWTD on patient safety, graduate medical education and doctors' health. In the meantime, our study shows that, notwithstanding the limitations we reported, an EWTD-compliant rota in general medical wards in the NHS does not compromise patients' safety.

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