We would like to thank Dr Sarani and Dr Alarcon for their critique of our work, published online in Critical Care on 12 January 2005 [1]. We have reviewed the critique, and in general we think that it appropriately describes both the strengths and limitations of our studies.

We would like to make a few minor factual clarifications. First, although the study by Lockley and colleagues used a within-subjects analytical design [2], the study by Landrigan and colleagues did not [3]. A systemic-level approach rather than a within-subjects analysis was used in comparing interns’ serious medical error rates, making these analyses comparable with analyses of errors system wide (i.e. those that involved both interns and other personnel), where a within-subjects design was not appropriate. Data from 20 interns were analyzed in Lockley and colleagues’ study, as the authors note; however, data from an additional four interns contributed to the analysis in the study by Landrigan and colleagues. Our power to detect a 16% difference in serious medical errors was calculated to be 80%, not 90%. In addition, there is one error in the description of the limitations that we would like to point out. Dr Sarani and Dr Alarcon note:

“There were more patients admitted to the ICU and more ICU patient-days in the traditional arm than in the intervention arm. Although these differences were not statistically significant, it does raise the possibility that interns in the traditional arm had more opportunities to make serious errors.”

Differences in the incidence of serious errors were analyzed using rates (per patient-day), and therefore the fact that there were more patient-days in the traditional schedule cannot explain the results. On a per patient-day basis, there were no more opportunities to err in the traditional schedule. This is further confirmed by the fact that there were no more medications ordered or diagnostic tests interpreted in the traditional schedule per patient-day, and there were in fact fewer procedures performed in the traditional schedule per patient-day.

With respect to the recommendations following from our findings, we strongly disagree with Dr Sarani and Dr Alarcon’s statement that our study supports the Accreditation Council for Graduate Medical Education (ACGME) duty-hour standards:

“Based on the results of these studies, it seems that the ACGME resident work hour restrictions are warranted, at least for interns, and that efforts to reduce the number of hours worked by interns may improve patient care.”

Although we would agree that efforts to reduce the number of hours worked by interns may improve patient care, our traditional schedule was in fact compliant with the ACGME duty-hour standards. In effect, we were comparing these standards with a schedule that much more substantially reduced continuous working hours than the ACGME regulations demand, with a maximum of 16 scheduled consecutive hours. Our data support an extensive literature, derived from laboratory and field studies in other safety-sensitive industries, that 24 hours or more consecutive work are unsafe. Efforts to reduce work hours should focus first and foremost not on the frequency of extended-duration work shifts, but on the duration of consecutive work hours during such shifts. Research from laboratory and industrial settings suggests that performance deteriorates rapidly and the propensity to err rapidly increases after 16 hours of sustained wakefulness, a finding reflected in the twofold increase in interns’ attentional failures after they had been working for more than 16 hours on the traditional schedule [2].
We agree with the recommendation that further research should study the effects of sleep deprivation and work schedule interventions on the performance of upper-level residents and other medical staff across a variety of disciplines. We likewise agree that optimizing patient hand-offs, medical education, and trainees’ sense of professionalism should be priorities as interventions are developed that reduce consecutive work hours to ensure the safety of patient care. We believe, however, that development of ‘a sense of professionalism’ is not a function of whether a shift is 30 hours or is 16 hours, but is a function of the ethical priorities engendered through the medical training process; first among these is the moral obligation to ‘Do No Harm’.

Carefully controlled studies of our own systems and practices are essential to determine how best to protect patients and, ultimately, the integrity of our profession.

With respect to medical education, it is important to recognize that sleep deprivation has been found to adversely affect education as well as resident and patient safety. Recent work has demonstrated markedly impaired learning among research subjects deprived of sleep [4-6]. Whether residents exposed to recurrent acute sleep deprivation learn more or learn less than better-rested residents who spend fewer hours in the hospital remains to be tested, and should be a major focus of future work.

Authors’ response
Eric B Milbrandt, Babak Sarani and Louis H Alarcon

We would like to thank Dr Landrigan, Dr Lockley, and Dr Czeisler for their comments, including clarification of the power, sample size, and statistical approach descriptions that appeared in our recent Journal Club review [1] of their studies examining the effect of reducing interns work hours in the intensive care unit [2,3].

Our statement that “interns in the traditional arm may have had more opportunities to make serious errors” was based on the incorrect assumption that the total number of days in each schedule was the same. Under this assumption, the observation that there were more admissions and patient-days, yet the same number of interns, in the traditional arm would have meant that each intern admitted and cared for more patients. In other words, each intern would have had a heavier workload and, therefore, more opportunities to make errors. As Landrigan and colleagues correctly point out, this could not have accounted for the error differences they observed, because these data were presented as rates (errors/1000 patient-days). That the rates of medication orders and test interpretations did not differ between groups certainly suggests that the overall workload was the same in each group. However, the intensity of orders, procedures, and diagnostic interpretations is likely to be greatest at the time of intensive care unit admission. If interns did admit more patients in the traditional arm, there may have been more opportunities for each intern to err, even though this would not have been reflected in the overall observed rates. To clarify this, perhaps the authors could have presented summary measures for the number of patients admitted and cared for by interns in each study arm.

We stated that “based on the results of these studies, it seems that the ACGME resident work hour restrictions are warranted”, when instead we should have said “resident work hour restrictions in general are warranted”. Indeed, the results of these studies do suggest that the ACGME did not go far enough. But how far is enough and at what point do the increased errors associated with more frequent hand-offs offset the reduced errors associated with better-rested care providers? As noted by the authors, their intervention took place in a system that was designed to minimize the impact of hand-offs, which by definition occurred more frequently in the intervention schedule. Even with this special attention to hand-offs, at least one physician who attended the intensive care unit during the studies noted that interns in the intervention schedule “often knew very little about the patients who had been admitted the night before” and that the “intern coming on at 9 p.m. … had not considered the patient as one of his or her cases” [7]. If these studies had been conducted without extra attention to this important transition in care, perhaps the results would have been different, as other studies have suggested [8,9].

Despite these relatively minor limitations, these two studies offer the best evidence to date that sleepy interns provide bad patient care, and we applaud the authors for their excellent work. We reiterate that as we move to more restricted resident work hours, it will be crucial that we instill a sense of professionalism in our trainees, such that commitment to individual patients does not wane as work hours are curtailed and that a ‘shift-work’ mentality does not compromise care.

Competing interests
CAC was paid an honorarium to deliver a plenary address for an annual educational conference of the ACGME.
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