



Perspective

Resident Duty Hours and Medical Education Policy — Raising the Evidence Bar

David A. Asch, M.D., M.B.A., Karl Y. Bilimoria, M.D., M.S.C.I., and Sanjay V. Desai, M.D.

On March 10, 2017, the Accreditation Council for Graduate Medical Education (ACGME) issued revised common program requirements for residents that go into effect this July.

The revisions emphasize the importance of teamwork, flexibility, and physician welfare during training, but all the attention has been (and will no doubt remain) focused on the changes in duty hours. The new rules maintain an 80-hour-per-week cap on residents' work, averaged over 4 weeks, but extend the permissible work shifts for first-year residents from 16 hours to 24 — limits already in place for residents in year 2 and beyond — and permit more within-shift flexibility as long as weekly duty-hour limits are met. What makes this policy change so important is that it seems to reverse direction on the basis of a new approach to developing and using evidence to inform education policy.

For a public largely used to 8-hour workdays and 40-hour workweeks, the old rules seemed stressful enough. Public interest in the topic has been strong since 1984, when an 18-year-old college freshman named Libby Zion died at New York Hospital, ostensibly because she was cared for by overworked and undersupervised residents.¹ A New York State grand jury investigating the case looked beyond the involved physicians and hospital and essentially indicted U.S. graduate medical education for its long hours and lax supervision. Resident duty hours became a focus of the ACGME, and duty-hour policies were introduced, shaped, and reshaped over the subsequent three decades, at first on the basis of opinion,

and later supplemented by bits and pieces of evidence.

At the heart of this debate is the concern that residents working longer hours might get less sleep and that sleep-deprived residents might make errors that hurt patients or themselves. Competing concerns are that shorter work hours mean more patient hand-offs, which are themselves dangerous, and might also mean less education, or socialization into a kind of “shift mentality” that reduces professionalism — either of which might result in less competent and less committed doctors for patients in the future.

The debate has been colored by concerns that academic medicine is holding on to tired and abusive traditions akin to the hazing of cadets, or that what is really at stake is money, since resident physicians are such a captive and elastic source of cheap labor. Critics of restrictive rules have countered that one can regulate

work hours but not sleep, and that resident fatigue may be caused more by the compression of a large volume of clinical work, which may be exacerbated by duty-hour limits. At times, the debate has seemed like a shouting contest, rooted in opinion rather than evidence.

But science has had a place, including a National Academy of Medicine report.² A large literature reveals that sleep deprivation causes errors, and physicians are just as susceptible to these effects as anyone else. Alertness and performance vary with the point in one's circadian rhythm. Observational studies reveal that changes in resident duty-hour rules have not been associated with changes in patient mortality or other clinical outcomes.³ Varying call schedules or providing protected nap times affects the amount of sleep on a given day but not sleep time averaged over a few days. There has been no consistently observed relationship between duty hours and education, socialization, or physician burnout or well-being.

Contrast this level of evidence with what we expect before launching a new drug. A pharmaceutical compound prescribed to 20,000 patients per year would be subjected to a sequence of prospective studies assessing safety and effectiveness, and in the end, randomized trials would be used to judge its value as compared with placebo or alternatives. Resident physicians touch millions of patients each year, and the independent physicians they become touch us all. Physicians practice for decades, whereas a new pharmaceutical might have a useful life less than half that long. Despite the broad and enduring effects on patients of medical edu-

cation policy, we haven't subjected it to anywhere near the same rigor required to put a single drug on the market.⁴

What is meaningful about the recent ACGME rules is that they are based on stronger evidence and on a more disciplined approach to developing the kind of evidence that ought to inform policy of such reach. The Flexibility in Duty Hour Requirements for Surgical Trainees (FIRST) trial ran from July 2014 to June 2015, and the Individualized Comparative Effectiveness of Models Optimizing Patient Safety and Resident Education (iCOMPARE) trial for medical residents ran from July 2015 to June 2016. These pragmatic randomized trials — in which we are investigators — test policy in its natural context. In both studies, U.S. residency programs, the organizational level at which duty-hour standards apply, were randomly assigned to adhere to either standard ACGME duty-hour rules or flexible rules under which limits on shift lengths and time off between shifts were waived. Both are noninferiority trials in which the primary trial measure is patient outcome, and multiple other outcomes are measured simultaneously. The FIRST trial included 119 surgical residency programs, and its main results have been published, revealing no inferiority of patient outcomes in the surgical programs using the flexible duty-hour standards.⁵ The iCOMPARE trial included 63 medical residency programs, and its analyses await the availability of Medicare data for the intervention period.

It is in this context that the ACGME has reset its duty-hour rules, maintaining the 80-hour-a-week limit that both trials had

retained, but moving to more flexible rules within that cap. The ACGME took advantage of the substantial increase in the level of evidence that the FIRST trial delivered. But the timing was no doubt awkward for the accrediting organization. The ACGME had caught a tiger by the tail. Surgical programs were clamoring for the more flexible duty-hour standards, and the ACGME's own study revealed that the new standards would be no worse than the old, but the publication of results from iCOMPARE in internal medicine programs was more than a year away.

It's likely that residency programs will use this new flexibility only for selected clinical rotations and, even then, only some of the time. One reason is that today's residency program directors are more informed about the science of fatigue than their predecessors were 30 years ago. A second reason is that residents' expectations have changed: residents' perceptions in the FIRST trial favored the more flexible duty-hour standards that allowed longer shifts, but that doesn't mean that residents would welcome a return to 1984. Programs that are out of touch with current resident expectations are likely to find themselves without residents. Indeed, a central value of pragmatic trials is that they reveal the incremental impact of policy in the context of other changes in norms or expectations.

Despite the fact that the ACGME made its revisions while another trial was on deck, we believe the main story is that until now medical education hasn't been able to rely on any large-scale, randomized trials. From that perspective, acting now isn't a prob-

lem, because there is always yet another trial waiting to be done. Randomized trials are outstanding ways to test narrow questions, such as the effects of one drug as compared with another or the impact of shift length for residents. FIRST and iCOMPARE were designed to answer the kind of narrow questions that are relevant to today's policy discussion. There are many other questions that can be tested with future studies of the training environment. In the meantime, the ACGME has rec-

ognized that far-reaching health policies deserve to be based on the same kind of science as far-reaching health treatments.

Disclosure forms provided by the authors are available with the full text of this article at NEJM.org.

From the University of Pennsylvania and the Philadelphia VA Medical Center — both in Philadelphia (D.A.A.); Northwestern University, Chicago (K.Y.B.); and Johns Hopkins University, Baltimore (S.V.D.).

This article was published on April 5, 2017, at NEJM.org.

1. Asch DA, Parker RM. The Libby Zion

case: one step forward or two steps backward? *N Engl J Med* 1988;318:771-5.

2. Ulmer C, Wolman DM, Johns MME, eds. Resident duty hours: enhancing sleep, supervision, and safety. Washington, DC: National Academies Press, 2009.

3. Philibert I, Nasca T, Brigham T, Shapiro J. Duty-hour limits and patient care and resident outcomes: can high-quality studies offer insight into complex relationships? *Annu Rev Med* 2013;64:467-83.

4. Asch DA, Weinstein DF. Innovation in medical education. *N Engl J Med* 2014;371:794-5.

5. Bilimoria KY, Chung JW, Hedges LV, et al. National cluster-randomized trial of duty-hour flexibility in surgical training. *N Engl J Med* 2016;374:713-27.

DOI: 10.1056/NEJMp1703690

Copyright © 2017 Massachusetts Medical Society.