

## SPECIAL REPORT

## Residents' Duty Hours — Toward an Empirical Narrative

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It all began with a tragedy. In March 1984, a fatal error occurred in a U.S. teaching hospital. Eighteen-year-old Libby Zion died because of a lethal drug interaction. The cause was serotonin syndrome — a rather obscure condition in 1984. The residents caring for Zion diagnosed a viral syndrome with “hysterical symptoms.”<sup>1</sup> In the intense scrutiny that followed, their misdiagnosis was attributed in part to their exhaustion, since at the time they had been at work for 18 hours straight. But was exhaustion really the cause?

What if the problem stemmed from lack of supervision? What if the intern had not yet

learned to distinguish “sick” from “not sick”? On the other hand, what if the young doctor, when prescribing the fateful dose of Demerol (meperidine), had been warned by a computer alert about potential adverse interactions between Zion's inpatient and outpatient medications (which included phenelzine)? Or could Zion's death have been avoided if the intern had had a nap?

Though addressing the many potential sources of error remains relevant to both trainee education and patient safety, the regulatory changes since Zion's death have focused primarily on mitigating resident fatigue. In 1999, New York State implemented rules limiting residents to an 80-hour workweek, and in 2003, the Accreditation Council for Graduate Medical Education (ACGME) adopted a similar national standard<sup>2</sup> (see text box<sup>2-5</sup>). Still, public concern about patient safety escalated, leading Congress, in 2007, to commission a report from the Institute of Medicine (IOM) evaluating the effects of duty-hour reform and suggesting future directions. After a year-long review, the IOM recommended that interns' shifts not exceed 16 hours and that residents working up to 30 hours be allotted 5 hours for a nap (see Fig. 1 for a sample resident's schedule).

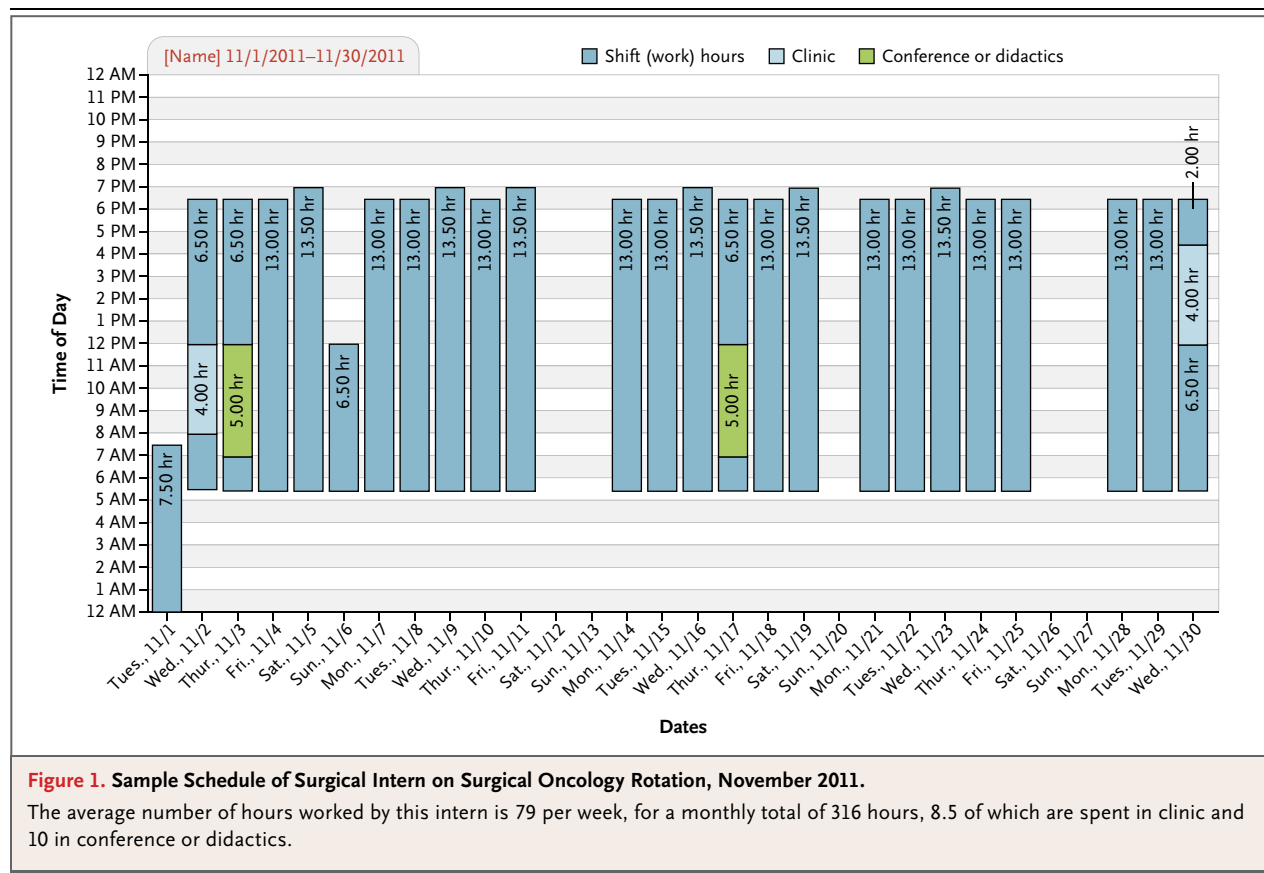
In 2010, after a 16-member ACGME task force reviewed the IOM's recommendations, along with testimony from medical organizations, sleep researchers, and patient advocates, the rules were revised (Table 1). The most notable change was that interns' shifts were not to exceed 16 hours. “Strategic napping” was strongly suggested, and programs were required to teach residents “alertness management.” These rules were implemented in July 2011, and oversight was intensified.

The controversy surrounding work-hour reform spans decades, but a certain resignation seems to have settled over our profession. Physicians who believe that these rules are destroying our professional ethic are often perceived as curmudgeonly and have thus quieted their objections.

## Timeline of Changes in Residents' Work Hours.\*

- 1889:** Medical residency training system in the United States begins at Johns Hopkins. Residents live at the hospital and are expected not to marry.
- Early 1900s:** The American Medical Association provides listings of “approved” residency programs. House staff work every day and every other night.
- Mid-1900s:** Residents and interns are on call for 36 hours starting every other night, totaling more than 100 hours per week.
- 1975:** Residents in New York City go on strike, calling for fewer hours. They return to work after hospitals agree to reduce on-call frequency from every other night to every third night.
- 1981:** The ACGME is formed. Some specialty-specific program standards suggest that “hospital duties should not be so pressing or consuming that they preclude ample time for other important phases of the training program or for personal needs.” Work hours remain unregulated.
- 1987:** After Libby Zion's case in 1984, New York State's Bell Commission recommends an 80-hour limit on weekly resident duty hours, with no more than 24 consecutive hours on duty.
- 1990:** The ACGME sets an 80-hour workweek in four specialties (internal medicine, dermatology, ophthalmology, and preventive medicine) and limits on-call duties to every third night, with at least one 24-hour period off every 7 days.
- 2001:** Petition requests that the Occupational Safety and Health Administration regulate duty hours with the “primary intent of providing more humane and safe working conditions for medical residents and fellows.” Federal legislation is subsequently proposed to limit resident work hours with federal enforcement.
- 2003:** The ACGME announces duty-hour requirements for all specialties, including an 80-hour workweek, 1 day off in 7, and a maximum shift length of 24 hours (with 6 additional hours for education and handoffs).
- 2011:** The ACGME restricts interns to 16-hour shifts.

\* From the Accreditation Council for Graduate Medical Education (ACGME),<sup>2</sup> Gurjala et al.,<sup>3</sup> Keslar,<sup>4</sup> and Kihss.<sup>5</sup>



Trainees who would prefer fatigue to unfinished patient care must nevertheless comply, or their programs will face steep fines and loss of accreditation. And program directors who aspire to design innovative educational environments must instead direct most of their energy toward the increasing administrative burden these requirements confer.

For us, the debate is irresistible. We are both trainees and third-generation physicians. We love being doctors but enjoy lives outside the hospital. And we've watched these rules transform our educational environments. But having spent the past year as editorial fellows at the *Journal*, becoming increasingly aware of the gaps between data and practice, we were struck by the disconnect between the duty-hour limits and the evidence base to support them. We therefore seek not to debate whether these rules are right or wrong, but to figure out how their effects can be rigorously assessed.

By interviewing members of the ACGME, patient advocates, program directors, educational experts, and trainees, we were exposed to both sides of the debate. Though we didn't always

agree with one another, we emerged with a fundamental shared concern: the uniform implementation of the rules has left the profession without a mechanism for adequate evaluation. Our profession would never accept a new drug or device without clinical trials delineating benefit and risk. Why assume that any less is at stake in implementing a new training system?

As Sanjay Desai, director of the internal medicine residency program at Johns Hopkins, remarked, "Everybody says we're done with duty hours and we can't go back. That's a defeatist attitude. This is the future of American medicine, and the risk is too great. Creating more regulation in the absence of data is not a tenable solution."

The path of least resistance is simply to accept the rules we've been handed. But to create delivery systems that are ultimately suited to meeting patients' diverse health needs, investigators must be able to study different approaches. Right now, such assessment is impossible. We therefore propose that the ACGME grant training programs a research exemption to permit such investigations.

**Table 1. Changes in Accreditation Council for Graduate Medical Education (ACGME) Work-Hour Requirements, and Comparison with Institute of Medicine (IOM) Recommendations.\***

| Variable                      | 2003 ACGME Requirements  | 2008 IOM Recommendations             | 2011 ACGME Requirements   |
|-------------------------------|--|--------------------------------------|---|
| Maximum hr per week           | 80   | 80                                   | 80  |
| Maximum length of duty period | ≤24 hr   | ≤16 hr unless a 5-hr nap is provided | First-year residents, ≤16 hr; PGY-2 residents and above are allowed ≤24 hr of continuous duty   |
| Additional duty hours         | Residents may remain on duty ≤6 additional hr to participate in didactic activities, transfer of care, outpatient clinics, or continuity of medical or surgical care |                                      | Residents may remain on site for periods of ≤4 additional hr to provide for the transfer of care and may not attend continuity clinics after 24 hr of duty† |
| Additional strategies         |  |                                      | Programs are to encourage residents to use “alertness management strategies”<br>Strategic napping is strongly suggested                                     |

\* PGY-2 denotes second postgraduate year.

† In unusual circumstances, residents, on their own initiative, may remain beyond scheduled hours to continue to provide care for a single patient; justifications are limited to reasons related to continuity of care required for a patient who is severely ill or whose condition is unstable, to academic importance, or to humanistic attention to the needs of a patient or family; residents cannot be compelled to continue to work these additional hours. Under those circumstances, the resident must appropriately hand over the care of all other patients to the team responsible for their continuing care, document the reasons for remaining to care for the patient in question, and submit such documentation to the program director. The program director must review each submission of additional service and track both individual residents' and programwide episodes of additional duty.

#### CURRENT INFLEXIBILITY

Seeking to better understand the justification for the uniform implementation of the current system, we visited the ACGME. Though we expected to find the organization bureaucratic, with little insight into how these rules have transformed medical culture, we instead felt sympathetic to the ACGME's dual and often conflicted mission: to accredit and to educate. Given the political mandate to improve patient safety, the threat that legislators will usurp the ACGME's regulatory power looms large. Thus, the organization's need to prove itself an adequate accreditor often trumps the imperative to educate.

The ACGME acknowledges that the need to create a uniform standard has forced the development of rules that cater to the lowest common denominator, rather than allowing each specialty to mold an environment that suits its trainees' learning needs and ambitions. “Standards are standards, and we tried to be flexible,” says Ingrid Philibert, ACGME senior vice president, “but my sense is we've created a rigid monster without flexibility.”

Had researchers established the superiority of this one-size-fits-all model to a more traditional training approach or to approaches meeting each specialty's distinct needs, implementing the sys-

tem in all programs and specialties would be logical. Given the absence of a mechanism for prospective analysis, however, we must rely on previous research. So do we know enough to accept this system as the model for training future physicians?

The short answer is no. But the longer answer, which has contributed to the long-running controversy, is that there are data to support every opinion.

#### KEY DATA

For the public, the most compelling data are those suggesting that practicing medicine while sleep-deprived is akin to working while drunk.<sup>6</sup> For instance, a 2004 study comparing reduced work hours with standard schedules showed that interns working longer hours had higher rates of “attentional failures,” as defined by the “intrusion of slow-rolling eye movements” on continuous electrooculographic monitoring while awake.<sup>7</sup> Being tired, of course, is something everyone understands, so data on harms wrought by sleep deprivation make sense intuitively. Indeed, a recent study showed that 80% of Americans surveyed would want to see a different doctor if they knew theirs had been working more than 24 consecutive hours.<sup>8</sup>

But it's one thing to show that people get tired when they don't sleep much; it's another to prove that fatigue impairs judgment in a way that results in patient harm. Christopher Landrigan, of Harvard Medical School, a leading investigator behind work-hour reform, has devoted his academic life to studying this link. Motivated by his own memory of an ICU call night when he slept through an urgent page regarding a decompensating patient, Landrigan led the only randomized trial to date on work-hour reform — a single-center study of medical interns in an intensive care setting. Interns were randomly assigned to a standard every-third-night schedule, a schedule in which 30-hour shifts alternated with 10-hour shifts, or an intervention schedule limiting interns to a maximum of 16 consecutive hours of work. The interns whose work hours did not exceed 16 did make fewer “serious medical errors,” but there were no differences among groups in total rates of adverse events.<sup>9</sup>

Kevin Volpp, of the University of Pennsylvania, and his colleagues published tandem studies in 2007, based on Medicare and Veterans Affairs claims data. They too found that, overall, duty-hour limitations have not reduced medical errors. Recognizing ubiquitous quality-improvement efforts as potential confounders, the investigators used a difference-in-differences approach to compare rates of change in medical error among teaching and nonteaching hospitals.<sup>10</sup> Despite this adjustment, Volpp acknowledges the limitations of observational data. He notes that “a number of factors make it difficult to discern cause and effect” because the reform itself may induce behavioral responses that have offsetting positive or negative effects. For example, “any patient admitted to the hospital might have 20 to 25 people taking care of them. Who is assigned responsibility of care? It gets very complicated.”

Given the complexity of a systemwide intervention such as work-hour reform, this type of attribution bias is not unique to observational data. Indeed, after the publication of Landrigan's randomized trial, three residents from the intervention group wrote a letter questioning the study's conclusions.<sup>11</sup> They wrote: “Worried residents and attending physicians, aware that the interns on the intervention schedule were poorly informed, took a more active role in patient care, making the majority of decisions and

more closely supervising the interns' actions. This hypervigilance may have strongly biased the study toward a positive result.” Physicians who, in recent years, have increasingly assumed the work once performed by interns know that such concerns regarding this potential study bias are not unfounded.

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#### AN OSTENSIBLY FLEXIBLE SYSTEM

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Nevertheless, the only way to move beyond our observations and mitigate biases such as heightened oversight would be to conduct more and larger randomized trials, with data collected over a longer period of time. Instead, the results of Landrigan's trial are now seen as a major justification for further work-hour restrictions, and no subsequent randomized trials have been undertaken to study this issue. Why is that?

The reasons are many, but the most salient factor is the lack of flexibility to allow such trials to be conducted. Robust analysis depends on the existence of adequate controls so that different approaches to residents' shift lengths and total work hours can be compared over time.

Ostensibly, the ACGME recognized this need for ongoing analysis. Indeed, the wording of the current regulations suggests that such flexibility is possible, but this option has proved to be an empty promise. The 2011 restrictions state that programs may apply for exemptions for “experimentation and innovation” and note that “requests for . . . projects that may deviate from the institutional, common, and/or specialty-specific program requirements must be approved in advance by the Review Committee.”

But no program has been approved for such an exemption for duty hours, Philibert says. She notes that although one request for exemption was received, from a group of program directors in internal medicine, the ACGME “had to turn it down” because of a prior decision that it wouldn't grant any duty-hour exemptions for 2 years under the “innovation rule.”

The program directors had proposed the exemption after the approval of the 2010 duty-hour limits but before implementation. The exemption would have allowed them to delay uniform implementation of the new standard for 1 to 2 years while they conducted a comparative assessment of the 2003 and 2010 standards, focused on the length of intern shifts, with patient safety as the prespecified principal outcome measure.

In December 2010, Thomas Nasca, the ACGME's chief executive officer, responded to this request in a letter to one of the program directors. After mentioning the 2000 comments received during the regulations' vetting period and the fact that various advocacy groups had petitioned the Occupational Safety and Health Administration (OSHA) to limit all residents to 16-hour shifts, he wrote: "Although I realize that there is interest in pursuing an experiment to compare 16 hours to 28 and 30 hours, given the current sociopolitical milieu, including the interest in having OSHA assume ownership and oversight of compliance of duty hours, I do not believe that the ACGME Board would be inclined to consider a proposal to waive the new requirement for 16 hours."

Philibert told us that the phased implementation of the Next Accreditation System, scheduled for July 2013, will be accompanied by a revised policy-and-procedure manual that may offer high-performing programs some added flexibility to innovate. Though this manual is still under review, our understanding is that it will not permit innovation in the realm of duty-hour limits, which remains a core requirement. Nevertheless, Philibert emphasizes that the ACGME carefully balances "the desire and need for flexibility for programs and residents" against demands for "rigorous" management of duty-hour limits voiced by parties purporting to speak for the public. She adds, "Both [sides] have legitimate, strong arguments."

#### A PROPOSAL

Though the ACGME must be accountable to both the public and the profession, the public's voice has often been louder than ours. When a patient dies after a medical error, the emotional salience of the event often trumps the imperative to accurately discern cause and effect, leaving us more receptive to anecdote than hard data. Cases such as Libby Zion's have captivated the public's imagination. As Susan Day, cochair of the ACGME task force, notes, "Increasingly, the public feels that it has a right to understand, and in a way direct, how people are trained as physicians."

Undoubtedly, both proponents and opponents of work-hour reform believe they are doing the right thing for our system. But without a robust evidence base, it is too easy to justify our intuiti-

ve beliefs by relying on fragmentary data. Though we can't change human nature, we can conduct investigations that allow a more evidence-based narrative to emerge.

To inform this understanding, the ACGME must grant programs a research exemption. A research consortium could then be created to pool data on a prespecified set of outcomes, fostering both small-scale innovation and an understanding of more widespread trends. Research efforts should consider not only the effects of hours worked, but also the relative importance of such factors as supervision, the structure of clinical teams, handoffs, simulator-based learning, and the amount of direct patient care. As noted by John Ioannidis of Stanford University School of Medicine, such a consortium would enable several randomized trials to occur simultaneously while ultimately informing a prospective meta-analysis.

Both short-term and long-term outcomes should be considered. For instance, when assessing work hours, do we look at safety within the confines of a 16-hour shift, or can we examine the effects of a bad handoff 6 months after the fact? Equally critical, how do we understand what will happen 5 years down the road, when today's trainee is suddenly facing 100-hour workweeks because that's what it takes to get the work done?

Given the complexity of the underlying questions and the diversity of outcomes to be assessed, the ACGME should take the lead in ensuring that such research is encouraged and rewarded. By spearheading this investigative undertaking, the organization would be given an opportunity to truly fulfill its dual roles as accreditor and educator.

Finally, convincing the ACGME to permit research exemptions is partly predicated on convincing the public that a more sophisticated understanding of medical education requires formal research. In a recent editorial describing the need for rigorous research on resident education and work-hour reform, Volpp and Vineet Arora acknowledged methodologic challenges but noted that an important hurdle will be making such investigations a national research priority.<sup>12</sup> In our political system, trainee education, which is not disease-specific, lacks a powerful lobby. The ACGME alone cannot change public sentiment. As a profession, we must not only develop



methods for evaluating our educational systems, but also convince the public that informing this understanding is critical to their health.

#### FUTURE DIRECTIONS

As invested as the public may be in enhancing hospital safety, patients are also increasingly disenchanted with their relationships with their physicians. Creating safe hospitals, training competent physicians, and preserving the sanctity of the physician–patient relationship need not be mutually exclusive goals, but it is naive to assume that rules in pursuit of one aim don't also affect the other aims.

We believe we must question the assumptions that have polarized the profession and left us with a system we cannot evaluate. Each assumption — that sleep deprivation makes for bad doctors, that ours will become a generation of shift workers, that one standard of training suits all trainees — is distinct in substance. But they all similarly lack substantiation. To continue implementing changes without rigorous data is simply not safe.

The current chapter of the work-hour story need not be the last. But to best serve the public and the profession, the next chapter should begin with data.

Disclosure forms provided by the authors are available with the full text of this article at [NEJM.org](http://NEJM.org).

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