Evidence and resident physician duty hours: Should scientific experiments be more suspect than universal implementation of an untested practice?

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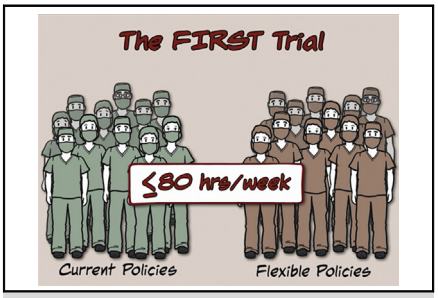

Cohorts of surgical resident physicians randomized in the FIRST trial.

Central Message

Quality studies of resident physicians' duty hours are limited and more evidence is needed. The FIRST trial is an innovative study of surgical outcomes and resident acceptance of liberalizing resident physicians' duty hours.

***Feature Editor's Note**—Duty-hour regulation draws attention to a central tension that has existed in graduate medical education for more than a century: The educational needs of resident physicians and the tendency of hospitals to use house officers as a source of inexpensive labor. Advocates for both sides have raised cogent arguments substantiating their views and devaluing those of their opponents. Advocates for regulation point to patient and trainee safety while condensing the opposition's position as simply preservation of a cheap labor source and resistance to innovative pedagogy. Opponents to regulation also point to safety issues and the fact that, despite efforts to innovate, clinical experience remains supreme in graduate medical education.*

The Institute of Medicine's spotlight on patient safety required a move from debate to action. The assessment of education quality is challenging and attempts to calculate the unique contribution of exposure to clinical material would make an already challenging task herculean. However, assessment of patient safety has received closer scrutiny and so the Flexibility In Duty Hour Requirements for Surgical Trainees trial was appropriately focused on that issue. True to its name, the trial is a first attempt at measuring the influence of a change in education format. By no means does this single trial serve as the final argument for this highly charged issue. Until now, decisions regarding work hours were made based on emotion, data from other fields, or societal/political pressure. Duty-hour regulation was the first attempt at a solution offered to address patient safety. It is understandable that society would desire change rather than preservation of the status quo. Now we are finally beginning to analyze that proffered solution and with that analysis improve our approach. Resist the temptation to remain entrenched in a single view, paint with broad strokes, or spin the findings in one direction or another. Understand all sides of the debate. Our educational system is far from homogeneously ideal and we need an open-minded approach to consider all the ways we might improve it while simultaneously enhancing patient safety.

Ara Vaporciyan, MD

In the United States, the number of hours a resident physician (hereafter referred to as resident) spends on professional duties is mandated by the Accreditation Council for Graduate Medical Education (ACGME) and fixed at 80 hours per week. Further, the minimum amount of rest between duty tours is also strictly spelled out in training paradigms from the ACGME. This limit on resident duty hours is arbitrary, lacks scientific backing, and challenges the ethical fiber of most surgical residents on a daily basis. I questioned cardiothoracic residents about the underpinnings of the 80-hour duty limits and where this mandate came from. No one knew. I even mentioned the Bell Commission and Libby Zion and the tragedy attributed to "overworked un-supervised residents" and still drew blank stares. The linkage between the story of Libby Zion and the Bell Commission built the foundation for a sweeping change in resident training and is worth repeating.[1]

In the fall of 1984, an 18-year-old girl named Libby Zion died after receiving Demerol for agitation. She was taking phenelzine (Nardill), a monoamine oxidase inhibitor prescribed for depression. She became agitated and died within

8 hours of hospital admission from a little known drug interaction between Demerol and phenelzine that caused high temperatures and ultimately cardiac arrest. Ms. Zion's father was a prominent lawyer and a former Editorialist for the *New York Times*. He brought enormous public pressure on the hospital and resident staff. Ultimately, the New York City District Attorney allowed a grand jury to consider murder charges against the residents and physicians who cared for Libby Zion. The grand jury considered whether lack of attending physician supervision or excessive resident duty hours without rest caused the death of Libby Zion. The murder charge was ultimately dropped but, with the Zion case as a catalyst, New York State empaneled the Bell Commission to investigate resident duty hours in 1987. The Panel, without much in the way of evidence, recommended that no resident should work more than 24 continuous hours and no more than 80 hours per week. Importantly, the Panel highlighted the value of resident supervision by attending staff. These recommendations subsequently became law in the state of New York, the only state in the Union with such a law.

In 2003, the ACGME implemented codified work-hour restrictions, largely in response to a number of troubling factors, including escalating resident work demands, increased public concern, the possibility of government intervention, and published research on the consequences of sleep deprivation. The Libby Zion case and the subsequent Bell Commission report were the seminal events that triggered the ACGME mandated 80-hour duty limits. These resident work-hour restrictions were adopted without any ethical or scientific investigation and they persisted for almost 30 years without any attempt at proving, in a scientific manner, how resident duty hours should be managed.

EVIDENCE—THE INSTITUTE OF MEDICINE WEIGHS IN

Arguably, the above facts constitute the evidence base for restricted resident duty hours and shift limits. There are plenty of other opinions, observational studies, and even systematic reviews[2-4] that address the rationale and effects of limiting resident duty hours. The most recent systematic review[4] suggests that focusing on duty hours alone has not resulted in improved patient care or resident well-being. There are problems with measuring resident duty hours, especially those duty shifts that are self-reported.[5,6] Evidence suggests that sleep loss dulls judgment, impairs visual sensory processing, amps up anger mechanisms, increases calorie consumption, and actually damages brain cells to the point of cell death.[7] How these deficits associated with sleep deprivation influence resident performance is uncertain, are untested, and are subject to diverse opinions and enormous political pressures. There is ample research that addresses the effect of sleep deprivation, but almost all deal with the effects on animals. When humans are the subject of these experiments the cognitive abilities studied tend to be basic skills such as math and comprehension, so their direct applicability to a resident's functions are not available.

The closest thing to a rigorous evidence-based approach to the effects of resident duty hours on performance is summed up in an open-access book published by the Institute of Medicine (IOM) in 2009.[8] This book summarizes multiple efforts to characterize resident duty-hour problems and describes interventions aimed at improving outcomes and limiting resident-related errors. There is a surprising lack of controlled trial data, or just plain good science, to back up the recommendations and assertions developed by the IOM. Despite the evidence generated in the IOM report, there is no good scientific reason for picking 80 hours as the magic limit for resident duty in a week. Indeed, resident workweeks are mandated at much lower levels in Europe.

FIRST TRIAL TO THE RESCUE

Although the politically charged case of Libby Zion and the Bell Commission report were drivers for limiting tours of duty to 80 hours per week and mandating improved supervision by attending physicians, it is astonishing that it took nearly 30 years for surgeons to treat the question of resident duty hours like a problem that can be addressed with good science. The Flexibility In Duty Hour Requirements for Surgical Trainees (FIRST) trial is the initial, and only, published prospective randomized study of the effect of liberalizing surgical resident duty-hour restrictions on surgical outcomes and on resident satisfaction.[9] This study is good science. The authors, with the support of the ACGME, randomized general surgical programs to either conventional resident duty-hour restrictions or liberalized duty hours that essentially retained the 80-hour limit but did away with the 24-hour tour limit and the 8-hour rest period between shifts. The results suggested that liberal duty hours were noninferior to conventional restricted duty hours with regard to patient safety and surgical outcomes. The authors did a commendable job of assessing residents' perceptions of these 2 duty-hour patterns. Residents under flexible duty-hour policies were less likely to perceive negative effects on patient safety, continuity of care, professionalism, and education but were more likely to perceive negative effects on personal activities, including time with family and friends, compared with standard restrictive duty hours.

FIRST TRIAL CONTROVERSY—SCIENCE VERSUS UNTESTED PRINCIPLES

The results of the FIRST trial appeared in print in early 2016 amidst controversy. Public Citizen, a consumer advocacy organization, drafted a letter to the Office of Human Research Protection of the Department of Health and Human Services.[10] This letter asked for an immediate