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Residency Program Alert

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Evidence for change

Two national studies aim to generate better data about duty hours

A decade after the ACGME established duty hour limits, the effects of work hour restrictions on patient safety, resident well-being, and medical education remain unclear.

Are patients safer when residents work shorter shifts, or more vulnerable to errors as their care is more frequently transitioned from one provider to another? Are residents more alert and fit for duty when their work hours are limited, or in danger of missing valuable educational experiences that prepare them for practice?

Hundreds of studies have examined duty hours, but none have produced conclusive evidence about the effects of one of the most controversial issues in medical education.

Now, two major studies aim to fill the void of meaningful data about duty hour restrictions.

The FIRST trial will test more flexible work hour arrangements at general surgery residency programs. The iCOMPARE study will examine longer shifts with protected napping periods for first-year residents in internal medicine programs.

The results of these studies, which both purport to be the first of their kind, could influence future decisions about duty hours.

"I think the results of this study will change policy," said **David A. Asch, MD, MBA,** the principal investigator of the iCOMPARE study. "It's a study that has potentially immediate policy impact in an area that's of critical importance to the development of the physician workforce of the country."

Paradox in the findings

In 2008, the Institute of Medicine released a report called "Resident Duty Hours: Enhancing Sleep, Supervision, and Safety," which called for revisions to the work hour standards the ACGME set in 2003. Among several recommendations, the report suggested shorter shift lengths for residents and better enforcement of duty hour standards.

The ACGME convened a task force in 2009 to review work hour standards. The task force held an international duty hours symposium and a national

congress, obtaining position papers and testimony from hundreds of stakeholders. The task force also commissioned three literature reviews, appointing teams of reviewers to comb through hundreds of studies related to resident duty hours and report on their findings.

The reviewers identified and analyzed hundreds of studies. The analysis resulted in what one group of reviewers called the "paradox in the findings": While research on sleep deprivation suggested that residents' performance declined when they were fatigued, there was no convincing evidence that suggested patient safety had improved as the result of duty hour restrictions.

The authors of the 2008 Institute of Medicine report wrote that the research too often came from "single-institution studies with insufficient statistical power to determine effects on patient outcomes and is often specific to one specialty, making findings difficult to generalize." The authors recommended further research on duty hours.

There was a paucity of useful literature, says **Timothy P. Brigham, PhD, MDiv,** chief of staff and senior vice president for the Department of Education at the ACGME.

"Each piece of literature led us in one direction or the other, but didn't have the power that you would want from a large multi-specialty trial," Brigham says.

The task force tried to craft the new standards in a way that made sense with the evidence available at the time, Brigham says.

More recent research has suggested duty hours have had different consequences for medical and surgical specialty programs. A 2012 review led by Ingrid Philibert, senior vice president for the ACGME's Department of Field Activities, analyzed several duty hour studies. Philibert's review identified nine studies that suggested patient safety had improved in the wake of duty hours; six of those studies were conducted in internal medicine programs. The review identified seven studies that suggested patient safety had declined; five of those studies were conducted in surgical programs.

"Some findings suggest a negative effect of the limits on quality and safety for surgical patients receiving care in teaching settings, with data showing increased complications, higher rates of patient-safety indicators, and reduced perioperative continuity," Philibert and her co-authors wrote. "The question thus is not whether there should be duty-hour limits for physicians in training,

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but where they should be set, whether they should be identical for all specialties, and what other attributes of the learning environment, particularly faculty supervision and presence in patient care settings, contribute to safe and effective care."

Increasing flexibility

One of the major changes to duty hour standards the ACGME adopted in 2011 was limiting the maximum shift length for first-year residents to 16 hours, which was one of the recommendations in the Institute of Medicine's report.

The FIRST trial and the iCOMPARE study, which will both receive some startup funding from the ACGME, could generate important evidence about the effects of the most recent changes.

"These studies are different than most of the other studies that have been done," Brigham says. "These are big, multi-centered trials that are asking fundamental questions and they would be used as part of our ongoing improvement model."

Both the FIRST trial and the iCOMPARE study will experiment with relaxing shift length requirements. However, other duty hour standard requirements—the 80-hour workweek averaged over four weeks, providing trainees one of every seven days off averaged over four weeks, and scheduling in-house call no more than every third night—will remain in place for both trials.

The FIRST trial, an acronym that stands for "Flexibility In Duty Hour Requirements for Surgical Trainees," will be conducted among 118 general surgery residency programs. **Karl Y. Bilimoria, MD,** an assistant professor at the Northwestern University Feinberg School of Medicine and the principal investigator for the trial, says 91% of eligible programs have volunteered for the trial, which indicates the high degree of interest in allowing more flexible duty hour standards.

Participants in the FIRST trial, which launches this year, will randomly be assigned to one of two groups. One group will follow current duty hour standards. Programs in the other group will only be required to adhere to the following duty hour standards:

- The 80-hour workweek (averaged over four weeks)
- One day free from duty per week (averaged over four weeks)
- In-house call scheduled no more frequently than every third night

By waiving other duty hour requirements, including maximum shift lengths, participants in the second group will be able to design more flexible schedules for trainees.

The researchers will use data submitted through the American College of Surgeons National Surgical Quality Improvement Program to analyze how more flexible work hour arrangements affect patient safety, considering outcomes such as:

- Death or serious morbidity composites
- Individual complications
- Reoperations
- Length of hospital stays
- Readmissions
- Failure to rescue from a complication of an underlying illness or a complication caused by medical care

They'll also consider information that could suggest how duty hours affect resident education, including programs' case volumes, American Board of Surgery In-Training Exam scores for residents, and resident and program director surveys.

"Are [these studies] the end of this? Probably not. But they will certainly push us toward where we can at least have a conversation with the community and with America based on real data and information rather than just anecdotes."

—Timothy P. Brigham, PhD, MDiv

Testing new strategies

The iCOMPARE study, which will be conducted among first-year residents in internal medicine programs, is expected to launch in July 2015, says Asch, who is a professor at the Perelman School of Medicine and the Wharton School at the University of Pennsylvania.

Currently, the team of researchers leading the study is applying for funding and seeking applications from participants through its website, *www.icomparestudy.com*.

The study, which loosely pulls its name from the words "Comparative Effectiveness of Models Optimizing Patient Safety and Resident Education," will compare current duty hour standards with 28-hour shifts that include a four-hour protected napping period.

"There is some scientific basis to arguing for napping as a fatigue mitigation approach," Asch says. "The challenge is to find something that's successful in mitigating fatigue [and] feasible for programs to deploy."

The study employs a two-year crossover design, which means all participants will test both approaches. Whether participants test the longer shift during the first or second year of the study will be assigned at random.

The crossover design essentially allows programs to act as their own control, Asch says. The environment at most training programs is fairly similar from one year to the next—they serve the same patient populations, are roughly the same size, and have mostly the same attending physicians. By having programs test both approaches, researchers can be more certain that changes observed during the study are related to the intervention.

The research team will analyze 30-day patient mortality rates based on Medicare and Veterans Health Administration claims data to gain insight into how residents' work hours affect patient safety. They'll also consider prolonged hospital stays and hospital readmissions within 30 days.

To understand how work hours affect sleep, they'll use wrist actigraphy, a method for measuring sleep and activity patterns using a device worn on the wrist. To consider the effects on education, researchers will review residents' in-training exam scores.

Using the data

The ACGME's role in the studies will be limited to providing "seed funding" and waivers to allow participants to deviate from some duty hour requirements, **CEO Thomas J. Nasca, MD, MACP,** wrote in a recent open letter posted on the ACGME's website. The organization will not be involved with designing or implementing the studies or interpreting the data from the studies, Nasca wrote.

However, the results of the FIRST trial and iCOMPARE study could influence policy on resident duty hours in the future.

Frank R. Lewis Jr., MD, executive director of the American Board of Surgeons, which is also providing funding for the FIRST trial, says the board will ask the ACGME to relax some of its standards if the results demonstrate that more flexible work hours don't harm patient safety.

Brigham says the ACGME plans to seriously consider the findings, although "they would not be the sole determinants" of whether the ACGME kept the current duty hour standards. To change the standards, it's likely the ACGME would initiate a process similar to the one it employed in 2009, engaging the community and hearing testimony from experts and stakeholders.

"Are [these studies] the end of this?" Brigham says. "Probably not. But they will certainly push us toward where we can at least have a conversation with the community and with America based on real data and information rather than just anecdotes."

Who's behind the trials

Two large trials on the effects of duty hours are about to launch.

The FIRST trial, which stands for the "Flexibility In Duty Hour Requirements for Surgical Trainees," is a collaboration between the American Board of Surgery, the American College of Surgeons, and the Surgical Outcomes and Quality Improvement Center at Northwestern University. At last count, 118 general surgery residency programs plan to participate, according to **Karl Y. Bilimoria, MD,** an assistant professor at the Northwestern University Feinberg School of Medicine and the principal investigator for the trial. A list of enrolled hospitals is available at the trial's website, *www.thefirsttrial.org.*

A team of researchers from the University of Pennsylvania in Philadelphia, Brigham and Women's Hospital in Boston, and Johns Hopkins Medicine in Baltimore, are currently recruiting internal medicine programs for the iCOMPARE study, says **David A. Asch, MD, MBA,** the principal investigator. Programs interested in enrolling can request details through the study's website, *www.icomparestudy.com.*