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### On Patient Safety: Have The ACGME Resident Work Hour Reforms Improved Patient Safety?

Michael J. Lee MD

t has been 12 years since the Accreditation Council for Graduate Medical Education (ACGME) mandated the first of its two sets of major reforms for US residents. The first initiative focused on restricting resident duty hours, including: (1)

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M. J. Lee MD (🖂)

University of Chicago Medical Center, 5841 S Maryland Ave, MC 3079, Chicago, IL 606037, USA e-mail: jihoon2000@hotmail.com Averaging no more than 80 hours a week during a 4-week period, (2) a maximum of 24 hours of on-site clinical duty, and (3) a minimum of 10 hours between all daily duty periods and after in-house calls [2]. In 2011, the ACGME implemented additional work restrictions for residents, namely: (1) Reducing the work hour limit to 16 hours for first-year residents and (2) providing more standards for faculty supervision limitations during night float duties [2].

Since its implementation, there has been extensive study on the effects of these reforms on resident education, resident quality of life, cost, and most importantly, patient safety [3, 5, 10– 12, 14–18, 20, 22–24]. After 12 years, two to three generations of surgical trainees, and four generations of internal medicine trainees, we must ask: What is the net effect of these reforms as they relate to patient safety?

#### Literature Overview

When we review how these reforms came about, it is clear that patient safety was the driving factor. However, we must not ignore other motivations possibly at play, such as winning over the court of public opinion. High-profile cases, like the Libby Zion case, where a woman died while being treated by a fatigued resident [13], focused our attention on resident hours and fatigue. It was argued that physician fatigue led to mistakes, and ultimately, patient harm. Reforms are all-but inevitable once a story of this magnitude hits the mainstream media.

Whatever the motivation, common sense suggests reforms were needed anyway. It certainly seemed intuitive that long resident hours would be linked to patient safety issues. Truck drivers and pilots are limited in their work hours for safety purposes [8, 9]; it seemed completely reasonable to do at least the same for physicians. Surely, by reducing resident hours and resident fatigue, the safety of patient care would improve.

Critics of these reforms, particularly surgical groups, have suggested that these reforms were actually detrimental to patient care, arguing that patient care does not fall neatly into the ACGME's parameters. As such, the need for more frequent handoffs and sign outs would only increase the likelihood of errors. This sentiment was certainly expressed among orthopaedic surgeons—when the new 2011

Note from the Editor-in-Chief: We are pleased to publish the next installment of "On Patient Safety" in Clinical Orthopaedics and Related Research<sup>®</sup>. The goal of this quarterly column is to explore a broad range of topics that pertain to patient safety. We welcome reader feedback on all of our columns and articles; please send your comments to eic@clinorthop.org.

restrictions were enacted, the large majority of orthopaedic residents and program directors felt that more handoffs would be detrimental to care [14]. Several reports in the neurosurgery literature suggested that these reforms have actually been harmful to patient care [5, 11, 15]. In 2005, following the implementation of New York State resident hour restriction, Poulouse and Colleagues [19] observed a worsening trend for complication rates. In 2013, Hoh and colleagues [11] analyzed the data of 107,000 patients from the Nationwide Inpatient Sample and observed a statistically significant increase in the rate of complications after the ACGME reform. In 2014, a systematic review [3] concluded that resident duty hour restrictions have had an overall negative impact on patient outcomes and safety.

However, other studies [18, 23] suggest that there was no difference in the rate of complications before and after the ACGME reforms. Using the Medicare database and examining readmission and mortality, Patel and colleagues [18] concluded that there is no statistical association of worsening complication rates with these reforms. Similarly, Volpp and colleagues [23] concluded that "concerns of worsening outcomes seem unfounded" after a similar analysis of Medicare patients.

Though the vast majority of studies suggest no effect or even a worsening effect on patient safety, there have been studies that have suggested a possible improvement with the ACGME measures. One study did report a trend for reduced mortality among Medicare patients in the 4th and 5th years after the reform went into place [23]. Another study by the same authors demonstrated reduced mortality among patients with myocardial infarction, congestive heart failure, gastrointestinal bleeding or stroke at acute care Veterans Affairs hospitals since the reform [22]. However, these studies were published in 2007. In 2014, the same authors also reported that "the goals of improving the quality and safety of patient care ...were not being achieved" with the ACGME reform [18].

#### **Did The Reforms Work?**

The ACGME reforms should also be examined in its proper context. It is a challenging subject to examine. There have been several concurrent patient safety initiatives that were realized since these mandates entered the landscape [4, 6, 7, 21], including The National Surgical Quality Improvement the Joint Program, and Commission's Surgical Care Improvement Project. With all these reforms and initiatives being implemented during roughly the same time period, it is difficult to ascertain what effect, if any, is attributable to which policy or reform. Furthermore, it is going to be increasingly challenging to study the effect of the ACGME reform in the future, as additional quality and safety issues will certainly be initiated.

One of the larger challenges in implementing these reforms has been cost. In reducing work hours for residents, several mechanisms have been used to account for the shortfall-all involving additional cost to the system. The ACGME website [1] references two studies that have estimated the costs of these reforms. It was estimated that the 2003 reform would incur USD 673 million to USD 1.1 billion a year in additional cost [22]. To maintain cost neutrality to society, complications would have needed to decrease by 5.1% to 8.5% [17]. Similarly, it was estimated that the 2011 reform would cost an additional USD 177 million to USD 982 million a year [16]. To maintain cost neutrality for the 2011 reform, complications needed to decrease by an additional 7.2% to 25.8% [16]. No study to date has suggested that the ACGME reforms have achieved these thresholds. Even if there had been a slight improvement in safety metrics during the past 12 years (though the majority of evidence does not support this), it is hard to

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imagine that we have even come close to these thresholds of societal cost neutrality.

Based on the literature in aggregate, it seems that the ACGME reforms have, at best, maintained the status quo in patient safety. But the driving push for these reforms was not to simply maintain the status quo, but to improve overall patient safety. While it may be debatable if patient safety has worsened overall, the vast majority of studies clearly show that patient safety has not demonstrably improved since these reforms were mandated. The fact that we have not observed a significant improvement in patient safety metrics after 12 years suggests to me that these reforms are not likely to improve patient safety.

The ACGME reforms will ultimately be judged by their impact on all aspects of healthcare, including resident quality of life, which is an important topic that this essay does not address. However, regarding the most important aspect of healthcare—patient safety, it is a sad observation that after 12 years, all the extensive changes, and cost to academic medicine, not much has really improved.

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