Chapter 11 Going Beyond Duty Hours: A Focus on Patient Safety

Thomas Whalen, MD, FACS, FAAP
William Walsh, MD, MPH

Much of the public focus on resident hours has been in the context of a perception of long hours and fatigue as performance-shaping factors and contributing causes in errors and adverse events in teaching settings. Yet, early in the debate on duty hours and safety, it was noted that limits on resident hours cannot guarantee safety in teaching hospitals, that ''[i]t would be unrealistic to expect residents to absorb the realities of caring for their equally fragile and needy patients if their working hours were fixed according to an arbitrary schedule, however well-intended''(F. Davidoff, MD, testimony to the 1986 Ad Hoc Committee charged with the inquiry into the Libby Zion's death). As an educational accreditor, the ACGME focuses on resident duty hours in the context of the patient care environment and learning, mindful that resident education and patient safety are influenced by multiple factors. No single intervention, including the imposition of strict limits on standards for resident duty hours, by itself can ensure the safety of patients in teaching settings.

"To Err is Human"

In 1999, the Institute of Medicine's report ''To Err Is Human: Building a Safer Health System''[1] focused public attention on the findings that in the United States medical errors may be responsible for 44 000 to 98 000 deaths annually. The estimate is based on 2 studies of adverse events in hospitals in the 1980s: a study in Colorado and Utah, which showed that 2.9% of hospitalized patients experienced an adverse event (of which 8.8% were fatal), and a study in New York State, showing that 3.7% of hospitalizations were associated with an adverse event. More than one-half of the adverse events in both studies were deemed preventable, and the total cost to society of these preventable adverse events was estimated at $17 billion to $29 billion, with one-half of this total

representing health care costs.[1] The release of the IOM report prompted the ACGME to begin a process of exploring errors in teaching settings. While the report did not implicate resident hours as a cause or contributing factor, it was one factor in the ACGME's implementing duty hour limits in 2003.

The 2008 IOM report on resident hours referenced this earlier work and concluded that 8 years after the publication of ''To Err Is Human,''[1] patient safety remained a problem that went ''well beyond the subset of hospitals that train residents.''[2] In developing the ACGME duty hour standards, the Task Force applied a broad-based approach to promote safe and effective patient care, high-quality education, and resident safety. The 2011 duty hour standards include provisions for enhanced supervision and graduated responsibility, limits on patient load, improvements in the process for transitions in care, increased education about alertness management, and enhancement of teamwork in clinical settings.

Causes and Contributing Factors of Errors in Teaching Settings

To many, the advent of oversight and increasing regulation of resident hours was prompted by the 1984 death of Libby Zion in a major New York teaching hospital.[3] While much of the investigation into her death focused on the 36-hour duty periods worked by the resident physicians who had cared for her, lack of supervision by an attending physician was a key contributing factor in her death,[4,5] and the 1986 grand jury investigation into her death ultimately led to New York's state regulation establishing duty hour limits and requirements for resident supervision.[6]

Residents function in a health care system in which the financial and human costs of errors are significant. Their role as learners, with short tenure and lack of familiarity with settings, may

make them more vulnerable to errors. That efforts to explore the role of human factors in health care lag behind those in other industries becomes evident in reviews of the literature on the causes of errors and adverse events in teaching settings.[7,8] A number of studies that have analyzed long hours as a contributing factor have found a link between resident fatigue and error.[9–12] At the same time duty hours are by no means the sole or even the leading cause of errors. A study of nearly 700 residents conducted in 2004 found that one-half of respondents had cared for patients with adverse events, with the common types of events related to the procedures and drugs. Residents attributed nearly one-fourth of the adverse events to ''mistakes.'' Working more than 80 hours during the preceding week was associated with a higher likelihood of reporting an error (odds ratio 1.8).[9] The same study found that during a 1-week period, 18% of the respondents had cared for a patient who had experienced an adverse event, and 37% of the respondents in this group reported they considered themselves responsible for the error.[9] While these are important findings, there are methodologic problems with studies that associate resident self-reports of working long hours with higher rates of errors (without the ability to temporally associate incidents of errors with extended shifts). There are also more general attribution problems when individuals are asked to assign causes and contributing factors to errors they have committeed.[10,11]

The 2008 IOM Committee on Resident Duty Hours reported that the percentage of errors attributed to long hours and fatigue varied by type of study. It found that error rates in self-attribution studies ranged from 19% to 41%, with data for the lower percentage collected in 2003,[11] shortly after the implementation of the ACGME common duty hour limits, and the higher estimate resulting from a study of internal medicine residents in 1989.[10] In contrast, there are much lower percentages of work hours and fatigue in root cause analyses. Root cause analyses of errors in Veterans Affairs hospitals mention fatigue as an associated factor

in 4.5% and a cause in 0.7% of serious errors.[13] A comparable analysis for less serious safety incidents mentioned fatigue as a contributing factor in 1.0% to 3.3% of the cases.[13] In addition to methodologic differences, the self-report studies assessed solely residents, while the Veterans Affairs studies include all types of providers (including those who work hours much below the weekly and continuous duty hour limits worked by residents), as the Veterans Affairs does not routinely identify resident status in its analyses.[13]

Nonduty Hour Causes of Errors in Teaching Settings

A study of closed malpractice claims data between 1979 and 2001 found higher error rates in teaching than nonteaching settings, but it does not allow the calculation of a percentage of patients that experienced an error during their care.[14] The study found 240 errors in teaching settings during the 22-year period.[14] Of these, the most prevalent contributing factors were errors in judgment in 72% of the 240 cases, problems with teamwork in 70%, and lack of technical competence in 58%.[14] Lack of supervision and handoff problems were the most prevalent teamwork problems, and both were disproportionately more common among errors that involved residents than those that did not.[14] Studies based on resident self-reports also find that factors such as ''job overload'' and suboptimal working conditions contribute to errors and adverse events.[10–12,15] In a large study of residents and errors, residents offered inadequate supervision ahead of duty hours, problems with handoffs, large patient loads, and cross-covering patients as common causes or contributing factors to error, along with long work hours.[9] A cross-sectional survey of 125 internal medicine residents immediately before the implementation of the ACGME 2003 duty hour limits found that suboptimal working conditions (fatigue and work compression and errors during handovers) were the most common contributing conditions reported by the residents.[12] Personal factors and lack of support for noneducational and administrative tasks also played a role, with

residents who felt overwhelmed with work ($P = .02$) and who reported spending more than 50% of their time in nonphysician tasks ($P = .002$) more likely to report suboptimal care practices, which was associated with a higher self-reports of errors.[12]

The most common event during which failures of technical competence or attention occurred involved diagnostic decision making and monitoring of the patient.[14] This is consistent with studies of instances of ''failure to rescue'' as a cause or contributing factor in adverse outcomes, and with publicized errors in settings where residents participate in care, such as the death of a live liver donor in a New York teaching institution after the state implemented limits on resident hours,[16] or the postoperative death of a young patient from a perforated ulcer due to a high dose of pain medication.[17] An analysis of closed malpractice claims found that errors involving residents also were more complex than errors for other practitioners (with a mean of 3.8 contributing factors versus 2.5 [$P < .001$]), suggesting that 1 factor may be complexity of the teaching environment.[14]

Impact of the 2003 Duty Hour Limits

Data collected soon after the 2003 implementation of the ACGME common standards found resident self-reports of factors contributing to errors for programs did not differ for residents in programs that had made significant reductions in weekly hours and those that had made no changes under the new limits.[15] Both groups implicated poor handoff practices, caring for too many patients, and inadequate supervision, though all percentages were somewhat lower for residents in programs that reduced duty hours.[15] A study that explored the effect of duty hour limits on patient safety implicated problems with handoffs in a slight increase in errors in the pediatrics inpatient setting,[18] and a systematic review found that effort to reduce resident hours failed to have a clear positive effect on patient safety indicators, with some unchanged and others worsening.[19] However, many were single-site studies with

interventions entailing informal schedule changes, and the analysis was limited by study factors, small sample sizes, and the range of interventions included in the analysis.[19]

In an important research article about the patient safety benefits of limits on residents' continuous duty period, Landrigan and colleagues[20] reported on error rates for 21 first-year residents in an intensive care unit. The study compared error rates across first-year residents and unit-wide, as well as residents working a 14-hour shift versus a schedule pattern that included overnight call, and found that errors per 1000 patient-days unit-wide were 193 for serious errors and 39 for preventable adverse events. First-year residents working on call every third night accounted for a substantial portion of the reported errors (136 serious errors and 20 preventable events per 1000 patient-days). Working a schedule limited to no more than 16 continuous hours reduced errors and adverse events involving first-year residents.[20] A third-party observer collected errors, increasing the methodologic robustness of this study. However, although unit-wide collection of information on errors was within the range identified by other studies, the ''data on interns were more detailed due to the presence of the observers.''[21] It is important to note that none of the studies answer the question of whether there is an increased prevalence of errors in teaching hospitals, as none compare error rates for teaching and nonteaching hospitals. A single analysis of the classic studies of adverse event rates for Utah and Colorado, which underlie the estimates of errors in the 1999 IOM report,[1] found adverse event rates of 4.0% for major teaching hospitals, 3.9% for minor teaching hospitals, and 2.5% for nonteaching and private hospitals, though the data are not adjusted for differences in severity of illness or intensity of service among the 3 types of hospitals.[22]

The 2011 Standards and Safety as a Systems Property

Experts have estimated that 80% of medical errors occur as a result of systems failures.[23,p. 5]

This suggests that the resolve of individuals—residents, faculty physicians, and other professionals—to work harder and avoid errors will be insufficient to improve the quality and safety of care. The IOM's 2008 report on resident hours noted that a culture of safety in hospitals and enhanced teamwork in patient care can also contribute to safety, and the examples of this culture of safety exist from high-reliability organizations.[2] High-reliability organizations function in high-risk domains and produce ''nearly accident-free performance''[24] or function in a ''nearly error-free fashion.''[25] Examples include flight deck operations on aircraft carriers, the US air traffic control system, and nuclear power plants. All of these settings emphasize teamwork and training in and for teams.[26,27] The IOM's 2001 report ''Crossing the Quality Chasm'' emphasized coordination across multiple professionals responsible for the care of the patient, stating that ''[c]linicians and institutions should actively collaborate and communicate to ensure an appropriate exchange of information and coordination of care.''[28]

The 2011 standards address various aspects of patient safety, including (1) efforts to enhance the quality and safety of care through residents' participation in interprofessional quality improvements teams; (2) enhancements to the handover process; (3) promotion of patient safety as an element of physician professionalism; and (4) residency program and sponsoring institution commitment to creating an environment and systems focus on patient safety.

> [Residents are expected to] work in interprofessional teams to enhance patient safety and improve patient care quality.

> The program must be committed to and responsible for promoting patient safety and resident well-being in a supportive educational environment.

> The program director must ensure that residents are integrated and actively participate in interdisciplinary clinical quality improvement and patient safety programs.

> The program director and institution must ensure a culture of professionalism that supports patient safety and personal responsibility.

> Residents and faculty members must demonstrate an understanding and acceptance of their personal role in…[the] assurance of the safety and welfare of patients entrusted to their care.

> Sponsoring institutions and programs must ensure and monitor effective, structured handover processes to facilitate both continuity of care and patient safety.

Collectively, these standards promote a focus on patient safety as a property of the learning and patient care environment in which residents function. Safety as a systems property is important because individuals, including residents and faculty, can positively influence practices and processes to promote safe practices and a focus on safety and quality. Studies across a range of industries show that the most important marker of safety is an organizational effort to create a culture of safety at the system level,[29–31] and that an organizational culture of safety is associated with fewer adverse events. The focus on safety at the systems level includes research on a safety focus at the level of the clinical microsystem.[32] Finally, such an organizational focus on patient safety requires the commitment of the organizational leadership by setting expectations, ensuring organizational focus and, as needed, providing resources to enhance the safety of patient care.[30,33,34]

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