HOD ACTION: Council on Medical Education Report 5 adopted as amended in lieu of Resolution 318 and the remainder of the report filed.

REPORT OF THE COUNCIL ON MEDICAL EDUCATION

CME Report 5-A-08

Subject: Enforcement of Duty Hours Standards and Improving Resident, Fellow And Patient Safety (Resolution 305, A-07)

Presented by: Richard J.D. Pan, MD, MPH, Chair

Referred to: Reference Committee C (David M. Lichtman, MD, Chair)

Council on Medical Education Report 4-A-06, "Enforcement of ACGME Duty Hours Standards," recommends in part that the American Medical Association "continue to monitor the enforcement and impact of the Accreditation Council for Graduate Medical Education (ACGME) duty hour standards, as they relate to the larger issue of the optimal learning environment for residents, with a report back at the 2008 Annual Meeting of the AMA House of Delegates."

Similarly, Resolution 305 (A-07), "Improving Resident, Fellow And Patient Safety," introduced by the AMA Resident and Fellow Section (AMA-RFS) and referred to the Board of Trustees, asks the AMA to urge the ACGME and American Osteopathic Association (AOA) to create an anonymous system for reporting duty hour violations and resident intimidation, as well as a system to protect whistleblowers from retaliation; work with the ACGME and AOA to develop a pamphlet on such violations; and draft a proposal for the ACGME and AOA that creates a system of incentives and disincentives for programs to comply with the requirements. This resolution was referred to the Board of Trustees.

The ACGME Duty Hours Standards

The ACGME duty hour standards went into effect in July 2003 and require:

- An 80-hour weekly limit, averaged over 4 weeks, inclusive of all in-house call activities;
- A 10-hour rest period between duty periods and after in-house call;
- A 24-hour limit on continuous duty, with up to 6 additional hours for continuity of care and education;
- No new patients to be accepted after 24 hours of continuous duty;
- One day in 7 free from patient care and educational obligations, averaged over 4 weeks, inclusive of call; and
- In-house call no more than once every 3 nights, averaged over 4 weeks.

Programs in some specialties may apply to the ACGME for an 8-hour increase in weekly duty hours. In 2004-05, 68 programs—including 42 neurological surgery programs, due to the length of cases—were functioning under the 88-hour a week limit; that number has since dropped to 42 (36 of which are neurological surgery) for the 2007-2008 academic year.

ACGME Involvement in Reporting, Monitoring, and Enforcement of Duty Hour Standards

The ACGME Subcommittee on Duty Hours was sunset in September 2004. Its successor, the ACGME Committee on the Learning Environment, is now known as the Committee on Innovation, and continues to track the impact of duty hour limits on resident/fellow training in the context of a broader agenda of innovation, improvement, and reengineering of the learning environment. The committee's September 2007 report, for example, notes the need to "[s]tudy the specific effects of the duty hour standards on resident learning and patient care in individual specialties or across specialties, and look for evidence that supports the hypotheses on any positive or negative effects of the standards through the literature, ACGME data or other relevant information."[1]

Towards this end, the committee report recommended implementation of five ACGME-supported accreditation pilots to refine duty hour standards, with ACGME review committees to select those of interest and greatest relevance to programs in their specialty: 1) Mandatory sleep or nap period through pager sign out; 2) Extend duty hours for surgical chief residents to 88 hours weekly to reflect practice after completion of residency; 3) Achieving continuity of care and education with 14-hour shifts; 4) Enhancing the educational value of night float through added debriefing and didactic activities; 5) Changing the rest requirement between duty shifts to "must be 8 hours."[2] As of the committee's February 2008 meeting, four review committees (family medicine, emergency medicine, otolaryngology, and neurological surgery) had formally expressed interest in pursuing one or more pilots, and a number of additional RRCs are considering participation.

Currently, the ACGME's principal means for collecting data on duty hours are interviews with program directors, staff, and residents during accreditation site visits and confidential Internet surveys of residents for all programs with four or more residents. ACGME site visitors annually interview some 12,000 residents. In addition, 58,602 (55 %) of residents participated in the ACGME resident survey in 2007.

Of the 2,589 programs that underwent accreditation reviews in 2006-2007, 227 (8.8%) received one or more citations related to duty hour noncompliance. This compares to 187 programs (7.9% of those reviewed), 147 (7.3%), and 101 (5.0%) in the prior three years. At the same time, while the number of citations rose, the number of complaints related to duty hours received by the ACGME declined from 53 in 2003-2004 to 16, 7, and 10, respectively, for the following three years. The 10 complaints in 2006-2007 constituted 23% of the 44 resident complaints filed during the academic year.

Of the residents completing the ACGME resident survey in 2007, approximately 94% said they always or usually meet the ACGME's weekly duty hour limits. The most frequent area of noncompliance reported was the 24+6 hour limit on continuous hours, with 7% of residents reporting they meet this standard sometimes, rarely, or never.[3]

Separate from the ACGME monitoring process, a review of the 118 teaching hospitals in New York state found compliance with state duty hour limits near 90%. Noncompliance decreased from 64% in 2001 to approximately 12% for October 2004 through September 2005.[4] A 2006 study by Landrigan et al. found that over 83% of interns reported they had worked hours that were not in compliance with the ACGME duty hour standards, although monthly rates of total compliance increased from 51% in July 2003 to 62% in May 2004.[5] At the same time, 89% of pediatric residents and program directors reported that the current system is effective in ensuring appropriate working hours.[6]

Confidentiality and "Whistleblower" Protection for Residents Reporting Duty Hour Violations

The issue of confidentiality for and protection of residents/fellows who report program violations of duty hour regulations continues to be a concern, leading to the introduction of Resolution 305 (A-07). The resolution cited intimidation and pressure by attending physicians and senior residents/fellows to under-report actual duty hours and residents' fears of negative consequences for programs, program directors, and their own careers in the event of program probation or accreditation withdrawal. Furthermore, many residents are reluctant to work "on the clock" and leave tasks undone or sick and unstable patients in the care of their colleagues. In addition, true anonymity is hard if not impossible to ensure for residents in smaller programs. A May 2005 AMA-RFS survey of 2,136 AMA members (1,126 medical students and 1,010 residents) found that 50% of residents and 75% of students would be uncomfortable reporting working excessive duty hours.[7]

In addition to the possibility of under-reporting due to concerns about potential impact on one's status, it may be that the number of duty hour complaints the ACGME receives is low because of the many steps required and the time involved to report a violation. The ACGME procedure for reporting duty hours violations[8] requires filing of a formal complaint in writing (e-mail complaints are not accepted), along with evidence of the violations. Further, complaints are not accepted until the resident/fellow has attempted to resolve the issue through discussion with the program director (if not involved in the alleged violation), institutional GME committee, designated institutional official (DIO), GME office identified on the ACGME web site, or resident representative on any of these oversight groups. In addition, reporting may be impeded by a lack of understanding among residents/fellows of the complaint process, and of the ACGME itself. Finally, the ACGME is not equipped to receive and act on isolated residents complaints. Unless there are multiple complaints from the same institution/program, the ACGME simply files the complaints and provides the information to the site reviewer to look into at the time of the next site visit.

From the perspective of programs and institutions, the strongest disincentive to residents' exceeding duty hour limits is the possibility of a warning, probation, or loss of accreditation by the ACGME. A less tangible disincentive is that residents, medical students, and potential applicants may "spread the word" on which programs to avoid as having inadequate regard for work/life balance, leading to a decline in the number and quality of applicants and reduced morale among those who are in the program. Counterbalancing these concerns are the resources required to substitute other physicians (e.g., hospitalists) or nonphysicians (e.g., physician assistants and nurse practitioners) in place of residents and the essential services they perform. The expense of hiring mid-level practitioners or hospitalists to replace residents is only partially offset by increased workflow efficiencies and new technologies.[9] Further, the 80-hour work week is having a negative effect on academic faculty, particularly surgeons, with increased workload[10] and reduced job satisfaction and time for teaching,[11] which provides another institutional rationale for skirting the regulations. Additional incentives or disincentives for programmatic/institutional compliance with duty hour limits, such as longer accreditation cycles or reduced accreditation fees for compliant programs, could be explored.

Effects of Duty Hour Limits on Patient Safety and Professionalism

Recent research looking at duty hour limits vis-à-vis patient safety has shown improvements or neutral effects on clinical outcomes:

- Duty hour limits were associated with a 0.25 percent reduction in the mortality rate and a 3.75 percent reduction in the relative risk for death in a study of 1.3 million patients, saving roughly 10,000 lives annually.[12]
- Three of seven outcomes for internal medicine patients improved after implementation of duty hour limits.[13]
- ACGME duty hours reform was associated with significant relative improvement in mortality for patients with four common medical conditions in more teaching-intensive VA hospitals, but no associations were identified for surgical patients.[14]
- A related study found that duty hour limits were not associated with either significant worsening or improvement in mortality for Medicare patients in the first two years after implementation.[15]

The media has covered the issue of duty hours sporadically, usually in response to publication of research studies. With some exceptions ("Old-School Docs Frown On Shorter Hours for Residents," *Wall Street Journal*, July 23, 2007), coverage equates reduced hours with reduced medical error and increased patient safety (e.g., "Sleep-deprivation studies fail to wake up teaching hospitals," *USA Today*, December 18, 2006; "Work Rules Fail to End Danger from Tired Doctors," National Public Radio, Morning Edition, December 12, 2006). Others take a more balanced approach, examining residents' improved quality of life versus their fears of missing out on valuable learning experiences and concerns about their level of preparation for the real-world practice of medicine, for which there are only self-imposed duty hour limits, and no supervision by attendings.

An overarching concern among educators and residents is the effect of duty hour limits on professionalism. Some argue that improved resident well-being inherently leads to better quality of care; others counter that the regulations translate into decreased continuity of care, the "shift-work mentality," less accountability toward colleagues and reduced teamwork, and reduced time for direct patient care,[16] to say nothing of communication and compassion with patients and patients' families. Clinical faculty at internal medicine programs, for example, believe that duty hour limits have adversely affected (in descending order) residents' continuity of care, the physician-patient relationship, residents' education, professionalism (including accountability to patients), and ability to place patient needs above self-interests.[17] Another perspective is that the definition of professionalism itself has shifted: "Doctors trained under longer hours worry that residents today lack the same sense of professionalism and obligation to their patients. Their concern is legitimate and worth considering, but the definition of professionalism has changed. Today it includes knowing when someone else might take better care of your patient than you."[18]

A related issue is the ethics of under-reporting one's actual work hours in surveys, or (as a program director) encouraging one's residents to do so. Without accurate, reliable data, it will be difficult for the ACGME or other entities to make any necessary adjustments to duty hour limits.

Other Organizations Examining Duty Hours, Patient Safety

Aside from the ACGME and AMA, other organizations are looking at the intersection of GME and patient safety. The Alliance of Independent Academic Medical Centers, for example, is sponsoring a year-long national quality improvement and patient safety initiative that engages teaching hospitals in a series of substantive discussions. The Institute for Healthcare Improvement's "5

Million Lives" campaign is serving as the initiative's "backbone" for linking residents with improvements in patient care.

In addition, the Institute of Medicine (IOM) has formed a consensus committee to study resident duty hours and patient safety, sponsored by the Agency for Healthcare Research and Quality, with three meetings scheduled in 2008 and a report due by early 2009. The committee's charge is two-fold: "1) synthesize current evidence on medical resident schedules and healthcare safety; and 2) develop strategies to enable optimization of work schedules to improve safety in the healthcare work environment."[19] The committee has indicated that its recommendations "will be structured to optimize both the quality of care and the educational objectives," and has heard from a wide variety of stakeholders in its first two meetings (December 2007 and March 2008), including the ACGME, AMA-RFS, consumer advocates, medical ethicists, sleep researchers, program directors, leaders in the surgical specialties, DIOs, and CEOs of teaching hospitals. (Presentations are posted on the IOM Web site after each meeting.) The study was requested by the US House Energy and Commerce Committee, leading some observers to conjecture that the committee might recommend federal regulation of resident duty hours. Thus far, however, a common thread of testimony is the need for flexible solutions that take into account different requirements for resident experience among the specialties as well as other variables.

Emphasis Shifting From Shorter Work Weeks to Reduced Shifts

With studies showing increased fatigue and medical errors among trainees working extended shifts,[20 21] the focus of attention has moved somewhat from the 80-hour work week to calls for reductions in shift lengths to no more than 16 hours. The IOM committee described above, for example, is examining this issue as part of its deliberations. In its presentation at the December 2007 IOM committee meeting, the Committee of Interns and Residents/SEIU Healthcare called for elimination of on-call shifts greater than 16 hours.[22] Similarly, an AMA-RFS report from the 2007 Interim Meeting calls for the AMA to "encourage the voluntary reduction or elimination of extended work shifts (>16 hours) for residents and fellows by academic medical centers and teaching hospitals while opposing a new ACGME mandate at this time" and "continue to evaluate outcomes-based research on the impact of reductions in extended work shifts on (1) Patient Safety, (2) Resident Education, (3) Resident Safety, (4) Resident Quality of Life and (5) Professionalism in Transfer of Care."[23] The report also looked at the possibility of reducing the work week to 60 hours maximum, but concluded that currently available evidence does not justify such a move, and that "more research is needed to determine the potential impact of further reductions in resident work hours on resident education, especially with regard to surgical residents, and hospital expenses."

Some argue that continuity of care is threatened by decreased shift length. A 2007 study found that increased complication rates in a trauma center after duty hours regulations were enacted may be due to increased handoffs necessitated by the 80-hour work week.[24] In addition, breakdowns in teamwork, from inadequate supervision by senior physicians to problems with patient handoffs, are a leading cause of medical errors among housestaff,[25] and any reduction in errors related to fatigue may be offset by errors related to decreased continuity of care.[26] Other studies, however, suggest that shorter shift lengths may lead to decreases in medical errors and improvements in patient safety. Notes one physician: "If our goal is to avoid the decrease in clinical performance related to long duty hours, it would be better to limit consecutive duty hours rather than focusing on the total hours worked per week. Limiting consecutive duty hours to 14 hours would go a long way toward eliminating the decrease in clinical performance related to the number of consecutive hours

providing clinical care. This can be achieved in all programs, leading to a healthier lifestyle for our learners and a safer environment for our patients."[27]

Summary

Problems with the ACGME complaint system for reporting duty hours violations include lack of awareness among residents about the reporting process, concerns about confidentiality, and misunderstandings about the structure and function (or very existence) of the ACGME. Such vehicles as the AMA-RFS guide to submitting a complaint,[28] or the ACGME's July 2005 letter to all residents on duty hours and the ACGME's function,[29] can help fill this gap in awareness. Because the intended audience is transitory (i.e., in residency for as few as three years), regular and systematic educational outreach is crucial.

July 2008 marks five years since the inception of duty hour limits. Continued monitoring and enforcement of the standards is required, as well as flexibility and responsiveness to emerging research on their effect. Medical organizations should work collaboratively to ensure that federal legislative action is not seen by policymakers and the public as the only effective solution. In addition, teaching hospitals should be encouraged to use the challenge of duty hours compliance as an opportunity for innovation and improvement in GME and patient safety through such strategies as night float, simulation, reduced non-educational activities, elimination of inefficiencies,[30] and enhanced emphasis on teamwork and interdisciplinary care. Further, this issue is related to medical professionalism and ethics, in that residents (and programs) must balance continuity of care and patient handoffs, service and education, and one's own needs versus the health care team's, as well as ensuring honesty and accuracy in reporting resident work hours. Finally, there is concern that some programs have changed in-house call rotations to at-home call to circumvent the intent of duty hour limits (two resolutions on this issue at the 2007 Interim Meeting of the AMA House of Delegates were referred for further study and a report, due at the 2008 Interim Meeting).

RECOMMENDATIONS

The Council on Medical Education, therefore, recommends that the following be adopted in lieu of Resolution 305 (A-07) and that the remainder of this report be filed.

1. That our American Medical Association reaffirm support of the current Accreditation Council for Graduate Medical Education duty hour standards. (Directive to Take Action)

2. That our AMA continue to monitor the enforcement and impact of the ACGME duty hour standards, as they relate to the larger issue of the optimal learning environment for residents, and monitor relevant research on duty hours, sleep, and resident and patient safety, with a report back at the 2010 Annual Meeting of the AMA House of Delegates. (Directive to Take Action)

3. That our AMA, as part of its Initiative to Transform Medical Education strategic focus, utilize relevant evidence on patient safety and sleep to develop a learning environment model that optimizes balance between resident education, patient care, quality and safety, with a report back at the 2010 Annual Meeting. (Directive to Take Action)

4. That our AMA review, evaluate, and publicize the work of the ACGME Committee on Innovation, in particular its pilot projects related to duty hours, and encourage participation

by ACGME Residency Review Committees and residency programs in these and other efforts towards innovation and improvement in graduate medical education and patient safety. (Directive to Take Action)

5. That our AMA ask the ACGME to consider offering programs/institutions additional incentives, such as longer accreditation cycles or reduced accreditation fees, to ensure programmatic and institutional compliance with duty hour limits. (Directive to Take Action)

6. That our AMA encourage publication of studies about the effects of duty hour standards, extended work shifts, hand offs and continuity of care procedures, and sleep deprivation and fatigue on patient safety, medical error, resident well-being, and resident learning outcomes, and disseminate study results to GME designated institutional officials (DIOs), program directors, resident/fellow physicians, attending faculty, and others. (Directive to Take Action)

7. That our AMA communicate to all GME DIOs, program directors, resident/fellow physicians, and attending faculty about the importance of accurate, honest, and complete reporting of resident duty hours as an essential element of medical professionalism and ethics. (Directive to Take Action)

8. That our AMA use the *GME e-Letter*, AMA Resident and Fellow Section publications, and other communications vehicles to raise awareness among residents (particularly first-year residents) of the ACGME and its role in monitoring and enforcing duty hours. (Directive to Take Action)

9. That our AMA ask its Council on Medical Education to closely monitor the progress of the Institute of Medicine (IOM) committee studying resident duty hours and patient safety and to respond, and/or assist the AMA Washington Office in responding, to any legislative or regulatory initiatives that arise from the IOM or other bodies. (Directive to Take Action)

10. That our AMA urges the ACGME and AOA to decrease the barriers to reporting duty hour violations and resident intimidation. (Directive to Take Action)

Fiscal Note: Less than $500.

Complete references for this report are available from the Medical Education Group.