THE ACCREDITATION COUNCIL FOR GRADUATE MEDICAL EDUCATION

DUTY HOUR CONGRESS SUBMISSION LETTERS

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Association of Professors of Medicine
Association of Program Directors in Internal Medicine
Association of Specialty Professors
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May 1, 2009

Thomas J. Nasca, MD
Chief Executive Officer
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Dear Dr. Nasca:

On behalf of the Alliance for Academic Internal Medicine (AAIM)—the organization that represents program directors, administrative leaders, and faculty and staff responsible for the training of over 22,000 residents and almost 10,000 fellows in the specialties of internal medicine—thank you for the opportunity to provide input as the Accreditation Council for Graduate Medical Education (ACGME) begins its five-year review of resident and fellow duty-hour standards.

As illustrated in the history of accreditation requirements for internal medicine residencies and fellowships, the specialty of internal medicine has a long history of engaging in efforts to improve patient safety and health care quality in teaching hospitals and other sites where residents and fellows learn their specialty.

In this letter, AAIM recommends ACGME:

1. Base any new or revised accreditation requirements concerning duty hours, schedules, and fatigue on evidence of interventions that yield positive results in addressing fatigue, work compression, and quality of patient care in the complex systems in which residents, fellows, and medical students are trained.
2. Ensure flexibility in the design and implementation of any new requirements that might emerge to reflect the variations among institutions and training programs. This recommendation can be accomplished, in part, by providing the Residency Review Committees (RRCs) a leading role in developing and implementing any new requirements that might emerge from this process.
3. Take every possible action, in conjunction with the training community, to maintain professional self-regulation of medical education and to sustain ACGME's role as the profession's regulatory body for graduate medical education.

Recommendations to ACGME
At the request of Congress and the Agency for Healthcare Research and Quality (AHRQ), the Institute of Medicine (IOM) convened and charged a committee to "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."[1] AAIM supports the intentions of these organizations to improve patient safety in teaching hospitals and health systems throughout the United States.

While sharing this goal, AAIM would urge caution as ACGME considers the relatively narrow issue of resident and fellow schedules among the myriad factors that influence patient safety. The competence and fatigue of physicians, nurses, and other clinicians as well as systems for documenting and transferring care from provider to provider are only a few of the many components within our extraordinarily complex systems of patient care. The interplay of these factors affects multiple outcomes, including resident and fellow fatigue; educational outcomes for all physicians-in-training; the work load and satisfaction of senior physicians and other clinicians; and near misses and errors in patient care. Changing one or more variables in this complicated calculus may have significant negative or positive effects, anticipated or not, in other segments of the system; in other words the potential for unintended consequence is high. Likewise, resident and fellow fatigue is also affected by a number of factors, including "poorer quality of sleep and greater perceived stress."[2]

Published commentary on the impact of ACGME's 2003 work hour regulations, justified in part with the statement that "promoting safe and effective patient care is a major impetus for the limits on duty hours,"[3] illustrates the complexity of addressing systems to improve patient safety. In 2008, experts in the field stated:

> There is increasing evidence that resident sleep deprivation endangers patients and residents, but studies have not shown consistent benefit from implementation of the current ACGME standards. No changes in mortality were found in national studies of surgical patients. Some reductions in mortality were observed for medical patients at Veterans Administration hospitals and in a cohort of non-Veterans Administration hospitals, although not in a larger population of medical patients covered by Medicare.[4]

In another publication, one of these experts went on to state:

> We know little about the value of staffing models using different mixes of physician assistants, nurse practitioners, residents, fellows, and attending physicians; different call and coverage schedules; or different work hour regulations. We need more and better studies to understand how to optimally structure staffing within hospitals in ways that increase the likelihood (1) that patients receive high-quality care, (2) that staffing models are sustainable and consider the well-being of the workforce, (3) that residents are

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[1] Institute of Medicine. *Resident Duty Hours: Enhancing Sleep, Supervision, and Safety.* Washington, DC: The National Academies Press, 2008.

[2] Frisen LD, Vidyarthi AR, Baron RB, Katz PP. Factors Associated with Intern Fatigue. J Gen Intern Med. 2008; 23 (12): 1981-1986.

[3] Accreditation Council for Graduate Medical Education. Statement of Justification/Impact for the Final Approval of Common Standards Related to Resident Duty Hours (September 2002). Accessed April 21, 2009, at http://www.acgme.org/DutyHours/impactStatement.pdf.

[4] Volpp KG and Landrigan CP. Building Physician Work Hour Regulations from First Principles and Best Evidence. JAMA. 2008; 300 (10): 1197-1199. (References included in original text removed here.)

> effectively trained, and (4) that the care we provide that meets objectives 1 to 3 is reasonably efficient and cost effective.[5]

While neither publication proposes a return to pre-2003 ACGME approaches to work hours or a lack of enthusiasm for considering additional approaches to work hours, they accurately describe the situation health care regulatory entities often face when considering interventions in care. The following *British Medical Journal* commentary provides an additional cautionary note:

> Large scale healthcare interventions are likely to improve the health of the public if the evidence clearly shows that the benefits outweigh harms and costs. Often, however, the evidence is not compelling, and well intended interventions may fail to improve health, or may even cause harm, while costing dearly. Moreover, when a large scale intervention is implemented without compelling evidence, wishful thinking may replace careful evaluation, and an unproved innovation may become an enduring but possibly harmful standard of care. Such interventions should be implemented, therefore, only when the evidence shows that expected benefits outweigh harms and costs and only when the effects of implementation will be evaluated systematically.[6]

In this vein, a lesson learned from implementation of the 2003 duty hour standards is that changes to the learning environment in which residents function can easily lead to work compression, not to better education or improved patient safety. To quote "Beyond Duty Hour Reform: Redefining the Learning Environment," the summary of recommendations from the Association of Program Directors in Internal Medicine (APDIM) Learning Environment Task Force, "There are many factors that increase resident work, including the number of hours worked per week; the number of continuous duty hours; the number of nights or transitions from night to day; the number of admissions; the acuity of the patient population; the turnover of patients; the amount of non-physician work [completed by trainees]." Geographic grouping of patients, electronic records and handover systems, and the availability of ancillary staff, clerical support, and safe transportation home after long shifts are additional elements that may cause either increases or decreases in resident work. Thus, many factors beyond work duty schedules contribute to resident work load, and these must be considered when regulating resident work schedules.

These observations cause AAIM to recommend ACGME (1) move cautiously as it further explores the realm of patient safety improvement through addressing schedules and learning environment issues and (2) approach the work at hand with the understanding that simply limiting hours without redesigning the learning environment and the entire patient care process may have untoward effects that actually reduce opportunities for learners to develop competence.

Achieving the Right Timing

AAIM recommends that any change to accreditation requirements based on the IOM report are implemented (within the bounds of flexibility noted below) only after robust pilot studies are performed to assess overall patient outcomes and validate best practices. As noted by Landrigan et al, "any systemic intervention that reduces work hours necessarily

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[5] Volpp KG. A Delicate Balance: Physician Work Hours, Patient Safety, and Organizational Efficiency. Circulation. 2008; 117: 2580-2582.

[6] Landefeld CS, Shojania KG, Auerbach AD. Should we use large scale healthcare interventions without clear evidence that benefits outweigh costs and harms? No. Br Med J. 2008; 336: 1277.

increases either providers' workload (i.e., the number of patients covered by a provider at any time) or the number of hand offs in care between medical personnel on shorter work shifts. Either can lead to increased rates of errors and adverse events."[7] The alliance is eager to participate in a discussion of the creation of such pilot projects, a substantial discussion of which should be a priority in the next stage of evolution in this arena.

AAIM strongly recommends ACGME provide a reasonable time interval, perhaps two years, between the time of finalization of new requirements and their implementation. The experiences of residency and fellowship program directors indicate that accommodating new accreditation requirements and other regulations takes time. For instance, internal medicine residencies are still adjusting schedules, handover procedures, and approaches to non-teaching services based on the 2003 ACGME requirements. Only after such accommodations have been achieved can the true outcomes of newly promulgated regulations be understood.

AAIM encourages ACGME to strongly consider incorporating review of resident and fellow duty hour and learning environment issues as part of the implementation of ACGME's strategic plan to make "ACGME an exemplary accrediting organization" by adopting and expressing values of accountability, excellence, and professionalism.[8] In particular, this review can be concurrent with ACGME's strategy to "increase efficiency and reduce burden in accreditation" by reducing "program requirements and PIF questions by 30% over the next three years."

Providing Flexibility

Because the alliance represents 382 residencies and 1,562 fellowships that are training 31,000 residents, AAIM appreciates the complexities in applying regulations to institutions that vary based on size, institutional sponsorship and ownership, geography, access to resources, longevity of leadership, research activity, and other factors. The alliance believes effective regulation should be cognizant of the variations among institutions, individuals, and the medical specialties as well as those within disciplines. **Therefore, AAIM strongly recommends ACGME provide institutions and programs the maximum flexibility possible to address concerns about patient safety vis-à-vis work schedules for residents and fellows.**

AAIM also strongly recommends providing RRCs a leading role in establishing new requirements related to duty hours. RRCs have a greater sensitivity to the specialty-specific issues facing residencies and fellowships and can craft requirements that appropriately fit their specialty. The absence of flexibility and specialty specificity would lead to a one-size-fits-all implementation of new requirements that will be neither efficient nor effective in achieving the desired outcomes for IOM, ACGME, institutions, residencies, or fellowships.

Setting and Enforcing Duty Hour Requirements

AAIM continues to strongly support the principle of professional self-regulation. **AAIM supports ACGME as the only appropriate organization within the United States to set and**

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[7] Landrigan CP, Rothschild JM, Cronin JW, Kaushal R, et al. Effect of Reducing Interns' Work Hours on Serious Medical Errors in Intensive Care Units. N Eng J Med. 2004; 351: 1838-1848. (References included in original text removed here .)

[8] Accreditation Council for Graduate Medical Education. ACGME Strategic Plan: A Roadmap to Improved Accreditation. Accessed April 21, 2009, at http://www.acgme.org/acWebsite/about/strategicplanFINAL.pdf.

enforce duty hours for residents and fellows. The alliance believes this self-regulation should be conducted transparently and should establish accountability for ACGME, training institutions, and residency and fellowship programs for adherence to reasonable duty hour standards.

In filling this role, ACGME should adopt an approach that separates duty hour enforcement from accreditation in general. For example, the alliance supports a duty hour enforcement strategy that would yield a "grade" for compliance rather than a binary yes/no determination. **At this point in time, based on the experience of New York programs, AAIM does not support routine unannounced site visits as they would prove extremely disruptive to both patient care and education at the vast majority of programs that are in compliance.**

AAIM supports public reporting of the results of regular duty hour monitoring if done appropriately. AAIM asks ACGME to be cautious in proceeding. The alliance has witnessed the growth of public reporting of "patient safety" and "quality" measures for institutions and individual physicians and has subsequently seen how such reporting can lead to misunderstandings of the data and incorrect conclusions on the part of the public and press. AAIM encourages ACGME to consider applying as much transparency as possible in public reporting so the number and type of reportable events are comparable across institutions.

Providing Leadership

Given the importance of the issues raised in the IOM report and subsequent discussions thereof, AAIM recommends ACGME extend its leadership in the field of graduate medical education by:

1. Challenging the community to prospectively study new approaches to resident and fellow duty hours and the learning environment more generally. AAIM also recommends that ACGME recruit funding organizations to support this research.
2. Convening discussions to review and improve the "system" of funding graduate medical education, including legislators, regulators, and explicit and implicit funders.
3. Working with the leading organizations representing the breadth of health care providers to discuss and potentially address the roles and responsibilities of different types of providers and the scheduling of these providers to improve patient safety and health care quality.

Responses to ACGME Requests

AAIM has carefully considered your letter dated February 20, 2009. The organization appreciates the comprehensiveness of the request as well as the recognition that this correspondence is only one part of an ongoing dialogue about possible changes to duty hour and learning environment accreditation requirements. In drafting this letter, AAIM has chosen not to replicate the work ACGME will undertake, through a third party, to exhaustively study the published medical literature on duty hours, fatigue, the learning environment, and the outcomes of regulation affecting the same.

Position on Current ACGME Duty Hour Standards

AAIM continues to support the overall 80-hour per week (averaged over four weeks) limit on resident and fellow duty hours. The alliance also supports the current, related ACGME duty-hour standards. As mentioned above, residency programs continue to adjust to these standards, reflecting continued development of best practices to meet the current requirements, new interpretations of evidence related to effective approaches to duty hour compliance, and the changing preferences of residents, fellows, and faculty.

AAIM believes the ACGME literature review will identify all published reports on the impacts of the current duty hour standards. As ACGME reviews these reports, the council should be mindful that institutions and programs vary significantly, and so too will the impact of the current and any future requirements. AAIM encourages ACGME to be particularly vigilant in understanding the effects in the following areas:

- Educational outcomes for residents and fellows as reflected in their overall development of competence to practice in the broad range of real world environments, including large health centers with an infrastructure of hospitalists to a small practice in a small community where the physician is expected to respond to patient needs day and night throughout the year.
- Improvements to patient safety and overall quality of health care, including health care outcomes and health care efficiency.
- Unanticipated effects of compliance with the duty hour standards on safety of patients and residents and overall quality of care.
- Development of competence in medical students, particularly core clerkship students and sub-interns.
- Cost for compliance and monitoring, including the development of non-teaching services to offset patient care traditionally handled by residents or fellows.
- Faculty work, job satisfaction, recruitment, and retention.

AAIM also encourages ACGME to study and learn from the experiences of other countries in regulating duty hours. The alliance encourages ACGME to continually monitor the medical literature on these and other fronts as additional relevant studies are published and we encourage ACGME to develop mechanisms to support future studies in this area so that we can better be guided by hard evidence.

Position on IOM Recommendations

The attached table provides AAIM's positions on each IOM recommendation. While AAIM agrees with the IOM recommendation to cap duty hours at 80 per week averaged over four weeks, the organization does not believe the other specific scheduling recommendations should be implemented. AAIM concurs in large part with many of the other recommendations, excepting those that would involve entities inadequately prepared to address duty hour issues—particularly the Center for Medicare & Medicaid Services and the Joint Commission—in the compliance and monitoring process.

Globally speaking, there are many possible areas of impact for the IOM recommendations. These include:

- Effects on the development of residents', fellows', and medical students' competence.
    - AAIM is concerned that implementation of some or all of the IOM recommendations may delay, curtail, or otherwise impinge on the development of physicians-in-training in some or all six of the general competencies . Faculty members in departments of

internal medicine are worried about the possible de-professionalizing impacts of close duty hour policing. Likewise, the development of communication abilities hinges on participating in a wide range of experiences to test and expand these abilities. Moreover, AAIM is concerned that limiting experiences in training generally (as will be one result of the IOM night float proposal)—and limiting night work in particular—will reduce residents' and fellows' opportunities to develop the competencies required for independent practice. AAIM believes the "good" of adequately preparing physicians for future independent practice must be prioritized during the discussion of duty hour reform.

- Effects on patient safety and quality of care.
  - Although the intention of the IOM committee was clear with regard to improving patient safety and the overall quality of patient care, AAIM does not believe that the medical education community can be confident these goals will be realized with the implementation of the IOM recommendations. As internal medicine residency directors and department chairs have presently conceptualized it, implementation of some or all of the requirements will increase patient handovers, reduce continuity in residents caring for patients during the day and at night, increase stress (and possibly fatigue) of attending physicians, and affect how patient care is orchestrated with other providers. The alliance believes implementation based on a plain reading of the recommendations will potentially worsen care.

- Effects on faculty.
  - The training of residents, fellows, and medical students cannot take place without faculty. While faculty are committed to providing safe, effective patient care, most if not all faculty in departments of internal medicine are under great pressure not only to teach, but also to produce clinically, and to secure funding for and conduct research. Further restrictions on resident availability will increase clinical demands on faculty members and will force them to make painful choices between educating and mentoring physicians-in-training and fulfilling their other responsibilities. This will negatively affect recruitment and retention of the best educators, role models, and physician-scientists. Losing this core resource will negatively affect both education and the quality of patient care.

- Costs of implementation and compliance.
  - While the IOM report provided a sizable cost of compliance with its recommendations—$1.7 billion annually—the committee also acknowledged up front that "the cost projections of the model do not include the additional costs of implementing the committee's recommendations that might stem from duty hour adjustments such as the extra day off per month, safe transportation options, more detailed compliance auditing, and faculty supervision."[9] The report goes on to state that the $1.7 billion does not include local costs of compliance monitoring or research and evaluation activities. Even at the $1.7 billion level, this estimated cost for implementation is roughly $16,000 per resident and fellow in an ACGME accredited

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[9] Institute of Medicine. *Resident Duty Hours: Enhancing Sleep, Supervision, and Safety.* Washington, DC: The National Academies Press, 2008.

program or $496,000,000 annually for 31,000 internal medicine residents and fellows. AAIM believes these costs are likely underestimates but even if they are accurate, they are substantial and programs will not be able to even contemplate implementation unless support is assured.

Position on ACGME Action on IOM Recommendations

Given the dearth of gold standard evidence in support of the IOM recommendations as well as the certainty of systemic impacts of implementing the recommendations, AAIM generally recommends ACGME maintain the current standards with respect to total duty hour and scheduling issues. In essence, the present lack of a compelling case for change justifies maintenance of the present requirements.

As the impact of some of the learning environment recommendations is less burdensome, AAIM does agree that requirements already in place in the internal medicine residency accreditation standards should be implemented in July 2009. Implementation of the standards may inform future impact analyses both for internal medicine and other specialties.

AAIM's position on ACGME action in light of specific IOM recommendations is noted on the enclosed table. Given that new internal medicine residency accreditation requirements that address many duty hour and learning environment issues will be effective July 1, 2009, AAIM believes no further action on many of the IOM recommendations need occur in the immediate future. The same may be said of the internal medicine fellowship requirements that are currently undergoing revision.

Conclusion

Please accept AAIM's thanks for this opportunity to provide input. AAIM representatives are eager to attend the June 2009 congress on duty hours mentioned in your letter. Indeed, as the organization representing the educational community for the single largest specialty in graduate medical education, AAIM would encourage ACGME to consider inviting representation from AAIM and other specialties in some way reflecting the size of the disciplines.

Please contact AAIM President D. Craig Brater, MD, at (317) 274-8416 or dbrater@iupui.edu, APDIM President Donald R. Bordley, MD, at (585) 275-2874 or donald_bordley@urmc.rochester.edu, or AAIM Vice President for Policy Charles P. Clayton at (202) 861-9351 or cclayton@im.org with questions or comments about this communication or the alliance's positions on the IOM report.

Sincerely,

D. Craig Brater, MD
President

cc: AAIM Board of Directors
Charles P. Clayton
Bergitta E. Smith

IOM Recommendation	Internal Medicine Residency Program Requirement	AAIM Comment on the IOM Recommendation	AAIM Recommendation on ACGME Action
Recommendation: ACGME should adopt and enforce requirements for residency training that adhere to the following principles: duty hour limits and schedules should promote the prevention of sleep loss and fatigue; additional measures should mitigate fatigue when it is unavoidable (e.g., during night work and extended duty periods); and schedules should provide for predictable, protected, and sufficient uninterrupted recovery sleep to relieve acute and chronic sleep loss, promote resident well-being, and balance learning requirements. Programs should design resident schedules using the following parameters:		(Please see the corpus of the AAIM letter for commentary on this issue.)	
• Duty hours must not exceed 80 per week, averaged over 4 weeks.	Duty hours must be limited to 80 hours per week, averaged over a four-week period, inclusive of all in-house call activities.	AAIM strongly agrees with the IOM recommendation to cap duty hours at 80 per week averaged over four weeks.	AAIM recommends ACGME retain the cap on duty hours at 80 per week averaged over four weeks.
• Scheduled continuous duty periods must not exceed 16 hours unless a 5-hour uninterrupted continuous sleep period is provided between 10 p.m. and 8 a.m. This period must be free from all work and call, and used by the resident for sleep in a safe and sleep-conducive environment. The 5-hour period for sleep must count toward total weekly duty hour limits. Following the protected sleep period, a resident may continue the	Continuous on site duty, including in-house call, must not exceed 24 consecutive hours. Residents may remain on duty for up to six additional hours to participate in didactic activities, transfer care of patients, conduct outpatient clinics, and maintain continuity of medical and surgical care.	AAIM disagrees with the IOM recommendation as there is insufficient evidence to support this recommendation. Only one trial that has yet to be reproduced showed differences in clinical performance between residents working traditional versus shorter schedules. This study, in an intensive care unit setting, likely does not reflect the reality of most in-hospital work.	AAIM recommends ACGME retain the current internal medicine residency and fellowship requirements.

IOM Recommendation	Internal Medicine Residency Program Requirement	AAIM Comment on the IOM Recommendation	AAIM Recommendation on ACGME Action
extended duty period up to a total of 30 hours, including any previous work time and the sleep period.			
• Residents should not admit new patients after 16 hours during an extended duty period.	No new patients may be accepted after 24 hours of continuous duty.	AAIM does not concur with the IOM recommendation as there is insufficient data to fix a specific time applicable to all residents in all circumstances.	AAIM recommends ACGME retain the current requirement.
• Extended duty periods (e.g., 30 hours that include a protected 5-hour sleep period) must not be more frequent than every third night with no averaging.	In-house call must occur no more frequently than every third night. (While ACGME allows averaging of call over four weeks, the Residency Review Committee for Internal Medicine does not allow averaging for internal medicine residencies.)	AAIM concurs with the recommendation pertaining to frequency but, as stated, not the recommendation related to napping during a work period.	AAIM recommends ACGME retain the current requirement.
• After completing duty periods, residents must be allowed a continuous off-duty interval of o A minimum of 10 hours following a daytime duty period that is not part of an extended duty period, o A minimum of 12 hours following a night float or night shift work that is not part of an extended duty period, and o A minimum of 14 hours following an extended duty period; and residents should not return to service earlier than 6 a.m. the next day.	Adequate time for rest and personal activities must be provided. This should consist of a 10-hour time period provided between all daily duty periods and after in-house call.	AAIM disagrees with the IOM recommendation as it essentially curtails the ability of programs to implement rational schedules.	AAIM recommends ACGME retain the current requirement.

IOM Recommendation	Internal Medicine Residency Program Requirement	AAIM Comment on the IOM Recommendation	AAIM Recommendation on ACGME Action
• Night float or night shift duty must not exceed four consecutive nights and must be followed by a minimum of 48 continuous hours off duty after three or four consecutive nights.	Residents must not be assigned more than two months of night float during any year of training, or more than four months of night float over the three years of residency training. Residents must not be assigned to more than one month of consecutive night float rotation.	AAIM strongly disagrees with this recommendation. Without signification restructuring and addition of personnel, implementation of this recommendation would require internal medicine residency programs to maximize night float rotations for all residents, effectively eliminating valuable elective experiences. AAIM's disagreement also stems from the conflicting evidence related to this recommendation. For instance, published papers illustrate acclimatization of workers to night shifts if the length of night work is seven days or longer.[10]	AAIM recommends ACGME refrain from changing requirements based on this recommendation.
• At least one 24-hour off-duty period must be provided per 7-day period without averaging;	Residents must be provided with one day in seven free from all educational and clinical responsibilities, averaged over a four-week period, inclusive of call.	AAIM disagrees with the IOM recommendation. Allowances for averaging provide residents flexibility in scheduling to meet their personal needs. Averaging also provides programs the opportunity to create schedules that reflect local opportunities.	AAIM recommends ACGME retain the current requirement.
• one additional (consecutive) 24-hour period off duty must be provided to ensure at least one continuous 48-hour period off duty per month.		AAIM disagrees with the IOM recommendation. The IOM report cites no evidence to support this recommendation and does not take into consideration those rotations residents experience when duty hours are significantly less than when on call.	AAIM recommends ACGME refrain from changing requirements based on this recommendation.

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[10] Lamond M, Dorrian J, Burgess H, et al. Adaptation of performance during a week of simulated night work. Ergonomcs. 2004 Feb 5; 47 (2): 154-165.

IOM Recommendation	Internal Medicine Residency Program Requirement	AAIM Comment on the IOM Recommendation	AAIM Recommendation on ACGME Action
• In exceptional circumstances requiring the resident's physical presence to ensure patient safety or to engage in a critical learning opportunity, program faculty may permit, but not require, residents to remain on duty beyond the scheduled time; programs must record for ACGME review the nature of each exception allowed. These exceptions are not to become routine practice. Residency Review Committees should determine at the time of program reaccreditation whether the documented exceptions to scheduled duty hours warrant citation.		(Please see the corpus of the AAIM letter for commentary on this issue.)	
• The ACGME should develop criteria for granting individual programs waivers from one or more of the above scheduling parameters; such criteria should be formulated *only* to accommodate rare, well-documented circumstances in which patient safety and/or educational requirements of specific programs outweigh the advantages of full compliance with the committee's recommendations and cannot be addressed by means other than the requested waiver(s); programs that are granted waivers (if any) and the nature of those waivers should be posted on the public access		(Please see the corpus of the AAIM letter for commentary on this issue.)	

IOM Recommendation	Internal Medicine Residency Program Requirement	AAIM Comment on the IOM Recommendation	AAIM Recommendation on ACGME Action
portion of the ACGME website. Included in the application for waiver should be a long-term plan that articulates how the program will work to avoid a permanent need for the requested waiver. All waivers should be monitored and reviewed on an annual basis to determine suitability for renewal.			
• Programs should provide annual formal education for residents and staff on the adverse effects of sleep loss and fatigue and on the importance of and means for their prevention and mitigation.	Faculty and residents must be educated to recognize the signs of fatigue and sleep deprivation and must adopt and apply policies to prevent and counteract its potential negative effects on patient care and learning.	AAIM concurs with the recommendation.	AAIM recommends ACGME retain the current requirement.
• Sponsoring institutions and programs should ensure that their practices promote and ensure that residents take the required sleep during extended duty periods.		(See above comments pertinent to the IOM recommendation regarding on-duty sleep.)	
Recommendation: The ACGME should immediately amend its current requirements on moonlighting by • Requiring that any internal and external moonlighting for patient care adhere to the duty hour limits listed above (e.g., 80 hours and all other limits), even if the program has received an exception to schedule longer hours; and	Internal moonlighting must be considered part of the 80-hour weekly limit on duty hours.	AAIM believes the IOM recommendations represent an unenforceable burden on programs, institutions, and faculty. Additionally, the recommendations, if implemented, may well create unintended barriers to dialogue between residents and faculty about clinical moonlighting as well as the myriad non-clinical external activities residents and fellows engage in that may affect their ability to be well rested during the course of clinical activities.	AAIM recommends ACGME retain the current requirements.
• Requiring that sponsoring institutions, if they choose to permit	Moonlighting must not interfere with the ability of the resident to achieve		

IOM Recommendation	Internal Medicine Residency Program Requirement	AAIM Comment on the IOM Recommendation	AAIM Recommendation on ACGME Action
moonlighting, include provisions in resident contracts that (1) a resident must request prospective, written permission from the program director for moonlighting, and (2) resident performance will be monitored to ensure that there is no adverse effect of moonlighting on resident performance.	the goals and objectives of the educational program.		
Recommendation: ACGME and residency programs should ensure adherence to the current limits now, and to any new limits when implemented, by strengthening their current monitoring practices.		AAIM believes that overly stressing the monitoring of duty hour limits de-professionalizes physicians-in-training, a strictly negative outcome. The alliance believes adherence can best be achieved by providing rational regulations with appropriate flexibility.	AAIM recommends ACGME move cautiously as it considers implementing new monitoring practices that might de-professionalize training and create a significant cost and compliance burden on institutions and programs.
To provide additional support, the Centers for Medicare and Medicaid Services and the Joint Commission should take an active oversight role:		AAIM strongly opposes this recommendation.	AAIM recommends ACGME aggressively resist any efforts to remove its authority over the setting or monitoring of duty hour standards.
• ACGME should maintain responsibility for duty hour monitoring and		AAIM strongly concurs with this recommendation.	AAIM recommends ACGME aggressively resist any efforts to remove its authority over the setting or monitoring of duty hour standards.
• [ACGME] should enhance its procedures by *including unannounced visits for monitoring duty hours*		AAIM disagrees with this recommendation. The alliance notes that the New York experience with unannounced site visits illustrates many negative impacts, including severe disruptions to educational and patient care activities.	ACGME should not implement this recommendation.

IOM Recommendation	Internal Medicine Residency Program Requirement	AAIM Comment on the IOM Recommendation	AAIM Recommendation on ACGME Action
• [ACGME] should enhance its procedures by including…*regular collection of sufficient data to understand when and why limits are violated.*		AAIM disagrees with this recommendation as implementation of it would seem to impose a significant, unfunded burden on institutions and programs. Approaches to implementation of this recommendation that would eliminate such a burden could be supportable.	ACGME should not implement this recommendation.
• Sponsoring institutions should provide for confidential, protected reporting of duty hour violations by residents through their compliance office or by an entity above the program level that does not have direct responsibility over the residency programs.		AAIM concurs with this recommendation.	As this recommendation is not directed at ACGME, no action is required.
• ACGME should strengthen its complaint procedures to provide more confidentiality and protection to persons reporting violations of duty hours, as well as other violations of residency rules.		AAIM concurs with this recommendation.	ACGME should implement this requirement.
• The Centers for Medicare and Medicaid Services should assess the reliability of ACGME procedures and data and should sponsor periodic independent reviews of ACGME's duty hour monitoring to determine the characteristics of and reasons for violations.		AAIM strongly opposes this recommendation. ACGME alone should have the authority and responsibility for setting duty hour standards and enforcing those standards.	AAIM recommends ACGME aggressively resist any efforts to remove its authority the setting or monitoring of duty hour standards.
• The Joint Commission should seek to ensure that duty hour monitoring is linked to broader activities to		AAIM strongly opposes this recommendation. ACGME alone should have the authority and	AAIM recommends ACGME aggressively resist any efforts to remove its authority the setting or

IOM Recommendation	Internal Medicine Residency Program Requirement	AAIM Comment on the IOM Recommendation	AAIM Recommendation on ACGME Action
improve patient safety in hospitals, including the use of ACGME's adherence data as part of the Joint Commission's hospital surveys and accreditation actions.		responsibility for setting duty hour standards and enforcing those standards.	monitoring of duty hour standards.
Recommendation: The committee recommends that sponsoring institutions immediately begin to provide safe transportation options (e.g., taxi or public transportation vouchers) for any resident who for any reason is too fatigued to drive home safely.		AAIM concurs with this recommendation.	AAIM recommends ACGME facilitate the sharing of best practices with regard to providing transportation to residents who feel too fatigued to drive safely. AAIM also recommends ACGME reconsider its position that residents in the hospital after their duty time ends but who would rather sleep in the hospital than wait for transportation be allowed to do so without this time counting toward the 80-hour limit.
Recommendation: To ensure that residency programs fulfill their core educational mission, ACGME should require that institutions sponsoring residency programs appropriately adjust resident workload by		AAIM strongly concurs with the IOM recommendation.	
• Providing support services and redesigning healthcare delivery systems to minimize the current level of residents' work that is of limited or no educational value, is extraneous to their graduate medical education program's educational goals and objectives, and can be done well by others; and	Inpatient and outpatient systems must be in place to prevent residents from performing routine clerical functions, such as scheduling tests and appointments, and retrieving records and letters;	AAIM strongly concurs with the IOM recommendation.	As the related internal medicine residency program requirement is about to be implemented, AAIM recommends ACGME ask RRC-IM to track and report on compliance with the new standard. If additional action seems necessary, changes or additions to the requirements can occur as part of the regular review process.

IOM Recommendation	Internal Medicine Residency Program Requirement	AAIM Comment on the IOM Recommendation	AAIM Recommendation on ACGME Action
• Providing residents with adequate time to conduct thorough evaluations of patients and for reflective learning based on their clinical experiences. ACGME should require each Residency Review Committee to define and then require appropriate limits on the caseload (e.g., patient census, number of admissions, number of surgical cases to assist per day, cross-coverage) that can be assigned to a resident at a given time, taking into consideration the severity and complexity of patient illness and the level of residents' competency.	(a) a first-year resident must not be assigned more than five new patients per admitting day; an additional two patients may be assigned if they are in-house transfers from the medical services; (b) a first-year resident must not be assigned more than eight new patients in a 48-hour period; (c) a first-year resident must not be responsible for the ongoing care of more than 10 patients; (d) when supervising more than one first-year resident, the supervising resident must not be responsible for the supervision or admission of more than 10 new patients and four transfer patients per admitting day or more than 16 new patients in a 48-hour period; (e) when supervising one first-year resident, the supervising resident must not be responsible for the ongoing care of more than 14 patients; (f) when supervising more than one first-year resident, the supervising resident must not be responsible for the ongoing care of more than 20 patients.	AAIM strongly concurs with the IOM recommendation.	As the related internal medicine residency program requirement is about to be implemented, AAIM recommend ACGME ask RRC-IM to track and report on compliance with the new standard. If additional action seems necessary, changes or additions to the requirements can occur as part of the regular review process. As ACGME considers extending this recommendation in other specialties, AAIM encourages ACGME to be mindful of the gaps and seams among programs that may occur on the local level. ACGME could address this issue by charging sponsoring institutions to report on overall work shifts in response to implementation of this recommendation.
Recommendation: To increase patient safety and enhance education for residents, the ACGME should ensure that programs provide adequate, direct, onsite supervision for residents. The ACGME should require:	Second- or third-year internal medicine residents or other appropriate supervisory physicians (e.g., subspecialty residents or attendings) with documented experience appropriate to the acuity, complexity, and severity of patient	AAIM concurs with this recommendation in general.	(See below for AAIM recommendations to ACGME on specific IOM recommendations.)

IOM Recommendation	Internal Medicine Residency Program Requirement	AAIM Comment on the IOM Recommendation	AAIM Recommendation on ACGME Action
	illness must be available at all times on site to supervise first-year residents. **For fellows:** The program must ensure that qualified faculty provide appropriate supervision of fellows in patient care activities.		
• The Residency Review Committees, in conjunction with teaching institutions and program directors, to establish measurable standards of supervision for each level of doctor in training, as appropriate to their specialty; and		AAIM concurs with this recommendation.	AAIM recommends ACGME implement this recommendation.
• First-year residents not to be on duty without having immediate access to a residency program-approved supervisory physician in-house.[11]		AAIM concurs with the general sentiment of this recommendation and the statement elsewhere in the IOM report that supervision should be provided by at least a PGY-3 resident. AAIM concurs with this recommendation because supervision is an important component of the overall system of providing safe patient care.	As stated above, AAIM recommends ACGME charge RRCs with consideration and implementation of potential new or revised specialty-specific accreditation requirements.
Recommendation: Teaching hospitals should design, implement, and institutionalize structured handover processes to ensure continuity of care and patient safety.		AAIM concurs with this recommendation in general.	As the accrediting agency for graduate medical education programs and their sponsoring institutions, ACGME should play a limited role in implementing this recommendation. ACGME should refrain from inserting its requirements into the clinical care processes of the sponsoring institutions. Doing so would risk the council's legitimacy as an organization to accredit educational programs.

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[11] The IOM report specifically mentions a PGY-3 in the specialty or attending. It is unclear if the attending physician can be from a related specialty (e.g., emergency medicine for internal medicine residents).

IOM Recommendation	Internal Medicine Residency Program Requirement	AAIM Comment on the IOM Recommendation	AAIM Recommendation on ACGME Action
• Programs should train residents and teams in how to hand over their patients using effective communications.		AAIM concurs with this recommendation.	As the educational aspect of this skill is already addressed within the internal medicine residency requirements related to competence in patient care, professionalism, and interpersonal and communication skills, AAIM does not believe additional program requirements at the specialty level are necessary. ACGME should assess its institutional requirements for information systems to ensure that support for effective transitions in care is provided.
• Programs should schedule an overlap in time when teams transition on and off duty to allow for handovers.		While AAIM agrees with the need for effective handovers, this recommendation presupposes certain approaches will be used for this process. Therefore, AAIM does not concur with this recommendation as written.	AAIM recommends ACGME refrain from changing requirements based on this recommendation.
• The process should include a system that quickly provides staff and patients with the name of the resident currently responsible in addition to the name of the attending physician.		While AAIM agrees with the need for effective handovers, this recommendation presupposes certain approaches will be used for this process. Therefore, AAIM does not concur with this recommendation as written.	AAIM recommends ACGME refrain from changing requirements based on this recommendation.
Recommendation: Graduate medical education-sponsoring institutions should fully involve residents in their safety reporting, learning, and quality improvement systems, and this should become an important part of the residents' educational experience.		AAIM concurs with this recommendation.	As the current internal medicine residency and fellowship requirements adequately address the development of competencies in systems-based practice and practice-based learning and improvement, AAIM recommends ACGME take no action on this recommendation.

IOM Recommendation	Internal Medicine Residency Program Requirement	AAIM Comment on the IOM Recommendation	AAIM Recommendation on ACGME Action
Recommendation: All financial stakeholders in graduate medical education, such as the Centers for Medicare and Medicaid Services, Department of Veterans Affairs, Department of Defense, Health Resources and Services Administration, states and local governments, private insurers, and sponsoring institutions, should financially support the changes necessitated by the committee's recommendations to promote patient safety and resident safety and education, with special attention to safety net hospitals. • An independent convening body should bring together all the major funders of graduate medical education to examine current financing methodologies and develop a coordinated approach to generate needed resources.		AAIM concurs with this recommendation.	AAIM recommends ACGME facilitate the development of this process.
Recommendation: To gather the data necessary to monitor implementation of these recommendations and to prepare for future adjustments as needed to achieve the desired objectives, ACGME should convene a meeting of stakeholders and potential funders to set priorities for research and evaluation projects. The Centers for Medicare and Medicaid Services, Agency for Healthcare Research and Quality, National Institutes of Health, Department of Defense, Department of Veterans Affairs, and other funders should support this work as a high priority.		AAIM concurs with this recommendation.	AAIM recommends ACGME move expeditiously to develop this process.

For the position of the

Association of Program Directors in Internal Medicine,

please refer to the letter behind Tab 1.

ACP
AMERICAN COLLEGE OF PHYSICIANS
INTERNAL MEDICINE | *Doctors for Adults*

April 26, 2009

Thomas J. Nasca, M.D., MACP
Chief Executive Officer
Accreditation Council for Graduate Medical Education
515 N. State Street
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Chicago, IL 60654

Dear Dr. Nasca:

I am writing on behalf of the American College of Physicians (ACP) to provide formal feedback to the ACGME about the recommendations outlined in the Institute of Medicine (IOM) Report on Resident Duty Hours. We appreciate the opportunity to comment on these recommendations, which have generated significant discussion among the various constituencies represented by the ACP. The following comments are based upon input from ACP's Education Committee, the Council of Young Physicians, the Council of Associates (which is composed of residents and subspecialty fellows), the Board of Governors, and the Board of Regents. The views stated below were formally approved by ACP's Board of Regents on April 20, 2009.

ACP is fully supportive of trying to optimize residency training in a way that best balances the following three goals:

1) Assuring patient safety and the highest quality of care provided to patients
2) Providing the best possible educational experience for trainees to enhance their professional growth and prepare them for their ultimate career
3) Protecting residents from work expectations that do not best meet their personal and educational needs

We believe that establishing regulations that help achieve these goals is important, i.e. work hours that are detrimental to patient care, resident education, and resident satisfaction should be avoided. However, we also believe that the regulations need to focus on the principles that the regulations are trying to achieve, without being overly prescriptive or proscriptive. Some degree of flexibility is important to allow balancing these three goals, whereas rigid guidelines may unduly prohibit creativity in program design, strip residents of their ability to make the best decisions that impact them as well as their patients, and actually be counterproductive in achieving one or more of the goals.

Although the current duty hour requirements certainly have some positive aspects, we feel they are not yet providing the optimal model for meeting the above goals. At the same time, although we applaud the IOM's intention to improve upon the current duty hour regulations, the sentiments provided by both resident and faculty members of ACP are that the recommendations do not clearly improve the framework for meeting the above goals. The remainder of this position statement will amplify these general comments about duty hour regulations, and then provide our thoughts about several of the specific IOM recommendations that propose change from the 2003 ACGME duty hour limits.

First, both the current and the proposed duty hour regulations are applying micro-management and inflexibility to a process of program design and patient care that should allow for creative approaches, local solutions, and sufficient flexibility to accommodate specialty-specific patient care and educational needs. At the same time the ACGME has been transitioning to an outcomes-based rather than a process-based accreditation process, the current and proposed duty hours appear to be based on process rather than outcomes. In practice, once the desired outcomes are defined, e.g., using the above three goals or some other model, it would be feasible to assess outcomes of a particular program's schedule by a multi-source evaluation of patients, residents, faculty, and other healthcare personnel, particularly nurses.

Second, ACP believes, through feedback it has received from residents, that the current and proposed requirements deprive residents of the ability to make any decisions that run contrary to duty hour regulations, even though such decisions might be in the best interests of patient care, professionalism, resident education, and their overall satisfaction with training. Although we have not systematically acquired data from a broad survey of residents, resident representatives on ACP's Council of Associates point out the fallacy of assuming that duty hour restrictions make their lifestyle more palatable, without other systematic changes in the training environment. Resident workloads have not decreased in proportion to the decrease in duty hours, so that the "work density" has often increased. The time pressure to finish work and leave the hospital strips residents of decompression or reflection time during the day, as well as formal and informal time for learning and for teaching other residents as well as medical students. Being forced out by the clock robs residents of their ability to leave the hospital with the sense of satisfaction that they have completed their responsibilities. If a resident wants to stay to take advantage of a "learning moment," that is not possible. Some residents have described the environment of duty hour regulations, as they are currently applied, as a "police state" that robs them of a sense of professionalism, independence, and self-determination.

Third, we do not believe there are adequate data supporting the benefit of all the current or the proposed duty hour regulations on patient safety or quality of care. As part of the process of developing and implementing any rigid requirements, it is important to have some evidence that outcomes on patient care and education are actually improved by specific regulations.

Fourth, despite the above reservations, however, we are fully supportive of the recommendations in the IOM report that focus on improving the quality of the resident experience through such measures as: 1) adjusting the resident workload by minimizing work that is of limited or no educational value and can be done well by others; and 2) providing adequate time for thorough evaluation of patients and for reflective learning. We also applaud the recommendations about providing safe transportation options for residents, improving the process and the effectiveness of resident handovers of patient care, and involving residents in systems to augment patient safety and quality of care.

ACP would also like to offer the following comments about specific duty hour recommendations in the IOM report:

1) *Maximum shift length:* The recommendation for a 5-hour protected sleep period is not feasible to implement, either in terms of "forcing" sleep or in terms of providing adequate staffing for patient care. The model of a five-hour interruption of care responsibilities for patients who were admitted before the 16 hour limit actually increases the number of hand-offs (i.e. a hand-off at the beginning of the 5-hour period and another hand-off at the end of the 5-hour period), with the attendant concern about patient safety. We also do not understand what type of practical coverage arrangements could be made to handle patient care during this five-hour period, and no specific models were suggested by the IOM. Although we agree that patients, when they are not acutely ill, report that they do not want sleep-deprived physicians, our informal feedback from patients is that, when they are acutely ill, they want their care to be as continuous as possible under the same physician.

   A model for patient care that many programs might find preferable to the one proposed by the IOM would have a 16 hour limitation to any shift, rather than a 30-hour shift interrupted by five hours of handing off patient care to another health care provider. This would essentially eliminate the traditional model of working during the day and having overnight call, in favor of a model that likely has two shifts. Although overlapping day and night shifts might be appropriate, optimal planning of two shifts would need to take into account the times at a particular institution during which the admitting loads are typically heaviest, as well as opportunities for teaching all residents during overlapping shifts, so that high quality education and supervision are provided to residents on night shifts as well as day shifts.

2) *Maximum frequency of in-hospital night shifts:* ACP has significant concerns with the recommendation that in-hospital night shifts be limited to four nights in a row, with a required 48 hour period off after three or four nights of consecutive duty. As noted under comment #1 above, the impracticality of implementing a five hour mandated sleep period essentially forces programs to adopt a "night float" or "night shift" system. This model is not necessarily bad, as it has been effectively instituted at many training programs around the country. However, imposing a four-night limit not only makes scheduling extremely difficult, but it prevents the night float resident from being able to acclimate to a reversed schedule before needing to flip back to a daytime schedule.

3) *Moonlighting:* Based on the assumption that sleep deprivation for any reason may prevent a resident from providing optimal patient care, we believe that external moonlighting hours

> should logically be included in overall duty hours. However, both residents and faculty feel that it is impractical to monitor external moonlighting and assure adherence to all duty hour regulations, taking into account the resident's internal work schedule plus both internal and external moonlighting. In addition, the burden of substantial educational debt can pose extreme financial hardships on individual residents that necessitate external moonlighting. Even if residency programs could fully control external moonlighting, they are unable to mandate a minimum amount of sleep for residents, just as they are unable to regulate other activities and responsibilities that may affect a resident's sleep patterns, such as responsibilities for children.
>
> Because the ultimate outcome of concern is patient safety and quality of care, we believe that individual training programs should have local autonomy in designing a system to assess and monitor fatigue and quality of care provided by those residents who are involved in moonlighting. A critical component of such a system would be the requirement that residents disclose external moonlighting commitments to the program director so that the resident's performance can be appropriately monitored. Although such monitoring is subjective, feedback obtained from peers, faculty, nursing staff, and patients can be useful input when identifying performance issues due to excessive fatigue.

An important consideration, as the IOM report appropriately notes, is that the proposed modifications in duty hour requirements would obligate increasing resources. Defining exactly what financial and personnel resources are needed is difficult and dependent upon the particular model used to meet the requirements at a given institution. Nevertheless, there is the risk of resource-requiring regulations presenting an "unfunded mandate" that will be impossible to follow. As recommended by the IOM, it is important to include all financial stakeholders in developing methodologies to generate the necessary resources for supporting resident education.

The ACP also feels strongly that policy development and monitoring of duty hour requirements should remain fully under the purview of the ACGME. As the profession's governing body for training, the ACGME is best equipped to work with the members of the profession, with training institutions, and with trainees themselves, to assure that the regulations best balance the interests of patient care and the education and well-being of trainees. We believe that mandated oversight of the ACGME by CMS might compromise the ability of ACGME to balance the needs and interests of all involved parties.

The American College of Physicians is most interested in being involved with further discussions about duty hour regulations. We believe that optimizing both patient care and training of the next generation of internal medicine specialists is critically important for the organization as well as the various constituencies we represent. Consequently, we would be pleased to participate in the Congress on Resident Duty Hours and the Learning Environment that is planned for June, 2009 in Chicago.

ACP
American College of Physicians
internal medicine | *Doctors for Adults*

Thank you again for giving us the opportunity to comment on the IOM report. We look forward to continuing to participate in further discussions about this most important topic.

Sincerely,

Steven Weinberger

Steven Weinberger, MD, FACP
Senior Vice President for Medical Education and Publishing
American College of Physicians

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April 15, 2009

Thomas Nasca, MD, MACP
Chief Executive Officer
Accreditation Council for Graduate Medical Education
515 North State Street, Suite 2000
Chicago, IL 60611

Dear Dr. Nasca:

The Association of Pulmonary and Critical Care Medicine Program Directors (APCCMPD) appreciates the opportunity to respond to the Accreditation Council for Graduate Medical Education's (ACGME) call for thoughts regarding the duty hour standards for medical trainees. Our society represents the nearly two hundred program directors of pulmonary and pulmonary/critical care medicine training programs in the United States. These program directors are responsible for training over 1800 fellows in the fields of pulmonary and pulmonary/critical care medicine. We urge the ACGME to not implement the Institute of Medicine's (IOM) recommendations to apply further duty hour restrictions.

We believe that additional restrictions on duty hours will have broad and unintended consequences for pulmonary/critical care medicine training programs. The skills required of a pulmonary/critical care physician are best attained through continuity of care in the patient care setting. Further restrictions may impact negatively on the provision of such continuity of care. Shortened shift durations result in more frequent handoffs of care and lost time for didactic instruction. They also increase the number of times a trainee must leave a critically ill patient. In addition, further restrictions will place more direct care responsibility on the attending faculty physicians and likely reduce time available for supervision and teaching of fellows. The current shortage of critical care medicine physicians will only be exacerbated.

A major concern of all program directors is the sense by the trainee that they are merely a "shift worker". This sense detracts from the professionalism that physicians develop for their patients and their work. In addition, faculty physicians are increasingly becoming the person responsible for caring for patients and families. This diminishes the senior fellow's roles and responsibilities for the overall care and management of the individual.

Developing the ability to evaluate, manage, and follow a patient over the course of the illness is an important learning experience for all fellows. Having the autonomy to provide this level of care is necessary for all to learn. Applying the same duty hour restrictions to all trainees regardless of the level of their training would not allow for the ongoing development of the trainee and likely have detrimental effects on the ability to train highly specialized physicians (e.g. a critical care physician). Providing flexibility in this regard is essential to allow the appropriate level of learning to occur. Limitation of duty hours detracts from this autonomy.

Finally, further restrictions on duty hours will likely impact the level of scholarly activity that is conducted by the fellow. Essential to the development and improvement of our healthcare system is the ongoing development of research. With further restrictions, there will be an increase in emphasis to maintain adequate levels of clinical instruction and experience and thus reduce the amount of time a fellow spends conducting research. The knowledge and skills regarding research and quality improvement that a fellow would otherwise gain during training will decrease leaving significant gaps in these areas.

Further research into the effects of duty hour limitations must be conducted. Prospective evaluation of new approaches to fellow duty hours would be helpful. This research should reflect the fellow's overall development of competence to practice in a real world environment. It should also reflect improvements to patient safety and quality of healthcare. Partnership with many organizations and societies regarding the development of such research, and avenues for funding, will be required to accomplish these outcomes. Such research should help to answer many of these questions in a scientific fashion and at the same time provide and promote safe and effective patient care.

We again thank the ACGME for the opportunity to respond to this question and urge the ACGME to not implement the IOM's recommendations to apply further duty hour restrictions without consideration of these other issues. Study of duty hour restrictions on the effects on fellow competence, the effects on patient safely and care quality, and the effects on attending faculty should be conducted prior to the widespread implementation of the IOM's recommendations. As further discussions ensure, the APCCMPD would be eager to assist in those discussions. We will be happy to participate in the meeting of "key stakeholders" being held later this spring. Please feel free to contact me with questions or comments.

Sincerely,

Brian W. Carlin, MD
President
Association of Pulmonary and Critical Care Medicine Program Directors

American College of Surgeons

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May 11, 2009

Thomas J. Nasca, MD, MACP
Chief Executive Officer
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Dear Tom,

Enclosed please find the American College of Surgeons (ACS) response to the IOM report, "Resident Duty Hours: Enhancing Sleep, Supervision, and Safety." The ACS response entitled "Resident Duty Hours in Surgery for Ensuring Patient Safety, Providing Optimum Resident Education and Training, and Promoting Resident Well-being" was prepared with involvement of a special ACS Task Force that included representation from across the House of Surgery. Task Force members included leaders of the ACS, chairs of all surgery residency review committees, leaders from various surgical specialty boards, and leaders of the Association of Program Directors in Surgery and the ACS Resident and Associate Society. As you are aware from the letter submitted by the Chair, Board of Trustees, of The Society for Surgery of the Alimentary Tract (SSAT), the SSAT unanimously supports the ACS response.

The ACS response includes the following sections: Background; Introduction to Related Activities of the American College of Surgeons; Underpinnings of the Education and Training Model for Surgery Residents; Summary of Analysis of Impact of Current ACGME Duty Hour Regulations; Recommendations from the ACS Position Statement Presented to the IOM Consensus Committee in March 2008; ACS Response to the Recommendations of the December 2008 IOM Report; Closing Comments; Members of the ACS Task Force; and References.

The ACS would be delighted to testify before the ACGME committee charged with the responsibility of reviewing responses from various organizations and to participate in the ACGME Resident Duty Hours and Learning Environment Congress in June 2009.

If you have any questions regarding the ACS Response, please do not hesitate to contact me.

With best wishes,

Sincerely,

Ajit K. Sachdeva, MD, FRCSC, FACS
Director, Division of Education
American College of Surgeons

cc: Timothy Brigham, PhD, MDiv, ACGME
Debra L. Dooley, ACGME ✓
L. D. Britt, MD, MPH, FACS
Gerald B. Healy, MD, FACS. FRCSI (Hon), FRCSE (Hon)
Thomas V. Whalen, MD, MMM, FACS
Thomas R. Russell, MD, FACS
Patrice Gabler Blair, MPH

Resident Duty Hours in Surgery for Ensuring Patient Safety, Providing Optimum Resident Education and Training, and Promoting Resident Well-being

A Response from the American College of Surgeons to the Report of the Institute of Medicine, "Resident Duty Hours: Enhancing Sleep, Supervision, and Safety"

L. D. Britt, MD, MPH, FACS; Ajit K. Sachdeva, MD, FRCSC, FACS; Gerald B. Healy, MD, FACS, FRCSI (Hon), FRCSE (Hon); Thomas V. Whalen, MD, MMM, FACS; Patrice Gabler Blair, MPH; and Members of the ACS Task Force on Resident Duty Hours

Address for Correspondence:

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American College of Surgeons - Division of Education

BACKGROUND

In 2007 at the request of Congress, the Institute of Medicine (IOM) convened the Committee on Optimizing Graduate Medical Trainee (Resident) Hours and Work Schedules to Improve Patient Safety in order to:

> 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, ... [and] Consider also evidence on the safety of the residents, the education and training experience of the residents, the quality of the interactions from both the resident and patient perspective, and other aspects of safety and quality of care such as care hand-offs and transitions.[1]

The IOM Committee conducted a review of research studies on the impact of duty hour requirements mandated by the Accreditation Council for Graduate Medical Education (ACGME) in 2003; examined scientific data relating to sleep, fatigue, work, and performance; and convened a series of public and private hearings involving individuals and organizations who were invited to testify before the Committee.

As the umbrella organization for all surgical specialties, the American College of Surgeons (ACS) was invited to appear before the IOM Committee. ACS President Gerald B. Healy, MD, FACS, FRCSI (Hon), FRCSE (Hon), appointed a special Task Force to conduct a thorough analysis of the impact of resident duty hour restrictions on patient safety, and the education and training of surgery residents. The ACS Task Force was chaired by L. D. Britt, MD, MPH, FACS; included leaders from a variety of surgical specialties; and was provided guidance and support by the ACS Division of Education. Following a thorough review, the Task Force developed a position paper addressing restrictions on resident duty hours that was forwarded to the IOM Committee, and the ACS leadership testified before the IOM Committee on March 4, 2008. The ACS Position Statement was formally approved by the ACS Board of Regents as a Statement of the ACS in October 2008.

In December 2008, the IOM released the report "Resident Duty Hours: Enhancing Sleep, Supervision, and Safety." The ACS continued to participate in discussions relating to the IOM Report with leaders of various surgical specialty organizations and with the ACGME in a number of national forums. Another broad-based, special Task Force representing all the surgical specialties was appointed by the ACS to prepare a response to the IOM Report for submission to the ACGME. The ACS Task Force has developed this Response, which includes the following sections:

I. Introduction to Related Activities of the American College of Surgeons
II. Underpinnings of the Education and Training Model for Surgery Residents
III. Summary of Analysis of the Impact of the Current ACGME Duty Hour Regulations

I. INTRODUCTION TO RELATED ACTIVITIES OF THE AMERICAN COLLEGE OF SURGEONS

The American College of Surgeons (ACS) was founded in 1913 and is the umbrella organization for the House of Surgery, including the specialties of general surgery, cardiothoracic surgery, colon and rectal surgery, gynecology and obstetrics, neurological surgery, ophthalmic surgery, orthopaedic surgery, otolaryngology—head and neck surgery, pediatric surgery, plastic and maxillofacial surgery, urology, and vascular surgery. The mission of the ACS is to support the delivery of optimum patient care and promote patient safety through its 74,000 members. The ACS has pursued this mission through a broad spectrum of seminal programs that have established new benchmarks for the profession of surgery. These programs have been developed to measure and improve the quality of surgical care, and have focused on surgeons, members of the surgical team, and systems of care.

The educational activities of the ACS are based on principles of contemporary surgical education and address surgical knowledge and skills and the other core competencies in an integrated fashion. Educational programs have been especially designed to positively impact the care of patients through a continuous process of practice-based learning and improvement.[2] Support for safe introduction of new procedures and technologies into surgical practice have been a major area of focus of the ACS.[3] Effective teamwork has been addressed through the application of teamwork principles from aviation to the operating room.[4] Also, special programs have been designed to teach exemplary professionalism and effective communication in a variety of surgical settings.[5,6] The ACS is currently developing educational programs focusing on communication skills to improve the transfer of patient care from one provider or team to the next. This is critical to the delivery of safe patient care because of the ever increasing complexity of surgical systems, and the more frequent need to transfer the care of patients in order to comply with the ACGME restrictions on resident duty hours. In addition, simulation-based surgical education has formed the basis of a number of innovative educational programs developed and launched by the ACS.[7] Many educational programs of the ACS are aimed at addressing the evolving needs of practicing surgeons, surgery residents, and members of the surgical team in this changing milieu of healthcare and education. The ACS has been, and continues to be, especially interested in residency education because of the need to educate and train a skilled workforce for the future and to provide safe patient care.[8] The ACS strongly supports optimum education and training of residents to provide patient care of the highest quality, and to inculcate in residents a profound sense of professionalism and responsibility towards patients.

II. UNDERPINNINGS OF THE EDUCATION AND TRAINING MODEL FOR SURGERY RESIDENTS

The combined priorities of quality medical and surgical care, excellence in education and training, and patient safety have been the cornerstone of this nation's healthcare system, and this trio of priorities has been embraced by learners at every level, from undergraduate and graduate medical education to continuing medical education. The current emphasis by the ACGME on the six core competencies and the establishment of the Maintenance of Certification (MOC) process by member boards of the American Board of Medical Specialties (ABMS) are a testament to the continuous improvement undertaken to ensure sustained quality healthcare, which is the underpinning of any patient safety initiative. In addition, the ACS has specifically focused on technical skills as a seventh core competency in designing and implementing new educational programs, because of its relevance to surgery.

Optimum training of surgery residents requires a longitudinal, comprehensive curriculum that focuses on the cognitive elements, technical skills, and judgment that are essential to providing safe patient care. The educational process involves progressive transfer of responsibility from faculty to residents over a period of time, and the close professional relationship between faculty and residents helps to ensure optimum outcomes. Achievement of expertise requires sustained deliberate practice,[9] and retention of skills requires periodic reinforcement. Structured experiences in simulated environments are important in achieving the requisite knowledge and skills and must be integrated with clinical experiences for the best outcomes.[3] The longitudinal educational and training model in surgery promotes a sense of personal responsibility for the care and welfare of patients and fosters professionalism.

The surgical boards, academies, and residency review committees have worked together to develop standards and state-of-the-art curricula that are especially designed to address the aforementioned elements and promote patient safety. The educational goals are difficult, if not impossible, to achieve during limited experiences that do not permit appropriate coverage of the content and adequate interaction between the faculty and residents. In particular, education and training relating to diagnosis and management of emergencies and critical conditions may be severely compromised with additional restrictions on duty hours. These key elements of the educational and training model in surgery must be considered and addressed in order to provide optimum patient care and offer residents the requisite experiences for them to function as safe and effective members of the current and future work force.

Surgeons and educators agree that the base of knowledge and skills required to be proficient practitioners has expanded rather than contracted in recent years. Many residents concerned about their readiness to enter practice are selecting subspecialty fellowship training in order to feel more prepared. Further restrictions in the hours available for training would result in patients being cared for by less qualified surgeons.[10-12] Alternatively, the length of training programs could be expanded; however, this would be an additional deterrent to medical students considering surgery as a career, many of whom are already daunted by the prospect of the length of surgical training and its impact on repayment of educational debt.[13,14] The country is experiencing a major shortage of surgeons. If medical students are deterred from entering surgery, the workforce shortage will be exacerbated and patients will encounter increasing difficulty in finding well trained surgeons and accessing quality surgical care. This workforce shortage will most likely be accentuated further with the current national moves to provide universal healthcare.

III. SUMMARY OF ANALYSIS OF THE IMPACT OF THE CURRENT ACGME DUTY HOUR REGULATIONS

The current restrictions on resident duty hours were implemented by the ACGME in 2003, in an attempt to improve patient safety and promote the well-being of residents. The efforts of many investigators to study the impact of the ACGME-mandated duty hours on patient care and safety, resident education and training, and individual residents and others, have yielded mixed findings. These have been summarized in a recent comprehensive review.[15]

Impact on Patient Care and Safety

The most important question in studying the impact of the current ACGME duty hour regulations is whether they have improved patient care. The results reported have not demonstrated such improvement in surgery; rather, the results in surgery appear to support no change in patient safety or suggest a decline in patient safety.[15] Several studies have demonstrated no differences in mortality.[10,16] Some studies have even found increased rates of preventable complications and errors.[17,18] Of special concern are studies from internal medicine that have reported increases in preventable adverse events and excessive use of laboratory tests secondary to cross-coverage by other residents.[19-21] One study reported improvement in mortality rates in medical patients but no differences in surgical patients.[22] These results highlight the differences among the various medical specialties, each of which has developed mechanisms to best care for patients with various medical and surgical conditions. Thus, specialty-specific differences must be considered as the impact of restricted resident duty hours is considered.

The adverse effects of reduced duty hours have been described in the medical literature from the United Kingdom (UK) and throughout Europe,[23,24] where severe restrictions on duty hours have been implemented. The European Working Time Directive (EWTD) was initiated for the "protection of the clinical personnel against overwork for the benefit of patients." With over a decade of experience with the EWTD, it has been considered by the greater medical community as a failure that has resulted in inadequately trained physicians. A position paper of the National Professional Organisations of Surgical Specialties describes the EWTD as an initiative that ". . . . destroys developed structures of training medical specialists and is in strict and severe conflict with the training of competent surgical specialists . . . ."[23] This paper also notes that published studies have demonstrated that no matter how efficient handover systems become, the loss in continuity of care has a detrimental effect on safe patient care.

The Association of Surgeons in Training (ASIT) at the Royal College of Surgeons of England highlighted that the EWTD has been "severely detrimental" to surgical training. Observed reductions in index operative cases performed in a large study of surgical trainee logbooks were cited. ASIT also reported that EWTD resulted in suboptimal patient care within the current National Health Service through poorly structured work patterns leading to cumulative fatigue, increased incidence of medical errors, and decreased continuity of care.[24] For these reasons, efforts are underway in the UK to underscore the differences in the training requirements of surgery as compared to many other medical disciplines, and attempts are being made to prevent further erosion in surgical training that will result from the new European directives regarding work hours.[25]

Impact on Resident Education and Training

Surgical residency programs must ensure sufficient training and experience with progressively increasing responsibilities for residents at higher levels of training. Appropriate educational opportunities need to be provided to residents to acquire the requisite knowledge and skills to graduate as proficient surgeons. Studies on the impact of the current duty hour restrictions on the training and education of residents have shown mixed results. In regard to operative volume, approximately equal numbers of studies have reported improvement, no change, or negative impact.[15,26-30] Of special concern is the finding that the experience of residents in a first assistant role in the operating room has been negatively impacted.[31] Experience as the first assistant is extremely important to prepare residents to assume responsibilities as operating surgeons later in their training, and the full impact of this reduced experience may not yet be realized. Also, experience as the primary surgeon during early years of residency has been found to decrease.[32] A decrease in clinic attendance and conference attendance also has been reported.[33,34] Another area of concern relates to the negative impact of restricted duty hours on the professional development of residents.[10] In contrast, a number of studies have revealed improvement in the American Board of Surgery In-Training Examination (ABSITE) scores, especially for junior residents.[34,35]

Impact on Individual Residents

The perceptions of surgery residents are important to consider in the evaluation of the impact of restricted resident duty hours. A survey of members of the ACS Resident and Associate Society (ACS-RAS) revealed that 41% of respondents (n = 246) stated that the current duty hour restrictions were a considerable or moderate barrier to their education. The responses were highly correlated with year of training, and across all subsets (program size, specialty, etc.). Senior residents were more likely than junior residents to perceive duty hour restrictions as an important barrier to their education and training.[36] Many residents expressed frustration regarding the lack of flexibility in the duty hour regulations and expressed a need to spend more time in the operating room and in continuity of patient care activities, particularly when unique learning opportunities arise. The concern of senior residents regarding their readiness for practice is underscored by the increasing number of general surgery chiefs planning to seek fellowships, which reached a new high of 77% in 2005.[37]

The aforementioned findings underscore the need for greater flexibility in resident duty hours, even if the total number of hours remains at the current 80 hours per week. This is especially true during the senior years of training to prepare residents for future practice. The lack of flexibility in duty hour requirements places residents in ethical dilemmas resulting from their desire to provide the best care for patients, address their educational and training needs, and meet reporting requirements while not placing their training programs in violation of duty hour requirements.[38,39]

The impact of the current duty hour restrictions on the quality of life of surgery residents has also received considerable attention. Findings from reported studies reveal that the quality of life of surgical residents appears to have generally improved, although a number of studies have revealed no difference.[10,40] Thus, the reported improvements in resident quality of life may be offset by concerns regarding readiness for independent practice.

Impact on Others

The impact of resident duty hour restrictions on the surgical faculty must also be considered to ensure recruitment and retention of faculty members to provide education, training, and mentorship to residents. Surveys of faculty have revealed their concerns regarding transfer of work from residents to faculty, decreased time for teaching and research, and negative impact on their quality of life inside and outside the hospital.[10,41,42] A survey of surgery faculty at one institution revealed concerns about academic productivity; however, no changes were noted in faculty work hours or clinical productivity.[43]

The impact of restricted duty hours on medical students needs to be considered, as well. One study found that students completing their surgery clerkship the same year as implementation of the work hour restrictions reported a negative impact on their ability to manage patient problems, lower levels in the clarity of expectations, and a lower quality of feedback, as compared with students who had completed their surgery clerkship prior to duty hours restrictions.[44] A decrease in the involvement of residents in medical student education is an unintended consequence of duty hours restrictions. The reduced interaction negatively impacts the education of medical students and also diminishes the residents' teaching opportunities, which are important for their learning and professional development.

A variety of strategies have been used to offset the reduction in duty hours, including the use of physician extenders. An area of concern expressed by residents is the involvement in the operating room of physician extenders initially hired to ease the residents' workload, while residents are relegated to performing routine work on the surgical floors.[36] Also, the need for an increase in the number of personnel requires additional resources that are not readily available in the current economic environment. Substantial increases in resources needed to support residency programs may compromise the financial well-being of institutions and lead to some teaching hospitals divesting themselves of graduate medical education activities. A reduction in the number of surgery residency programs at a time when more and not fewer programs are needed will compound the projected workforce shortage.

IV. RECOMMENDATIONS FROM THE ACS POSITION STATEMENT PRESENTED TO THE IOM CONSENSUS COMMITTEE IN MARCH 2008

The conclusions and recommendations of the first ACS Task Force presented to the IOM Consensus Committee in March 2008 are as follows.[45] The Task Force stated that the ACS supports all efforts to enhance patient safety that include thoughtful, evidence-based evaluation of the important contributing factors and the potential outcomes of such efforts. The Task Force emphasized that the impact of resident duty hours should not be addressed in isolation and without appropriate evidence; rather, it must be considered in the broader context of systems of patient care and surgical education, including continuity of care and handovers, a comprehensive curriculum to produce skilled surgeons, team training to enhance safety, costs to the healthcare system, and implications for access to high quality care for patients.

Five specific recommendations were made by the Task Force in its 2008 Statement. The first stated that a fully funded, multi-institutional study should be recommended by the Institute of Medicine to evaluate not only the impact of further reductions in duty hours but myriad other issues, including optimal duty hours to achieve curriculum objectives, to maintain continuity of care, and to address team training efforts. Discipline-specific outcome measures are needed in the areas of surgical patient safety and surgery resident education. This first recommendation is still important, because most of the studies completed to date are based on experiences at single institutions and are limited by small sample sizes and problems with generalizability. The second recommendation addressed the need for effective team training initiatives to be established with emphasis on patient safety. The third recommendation called for the integration of advanced information technology and simulation in all aspects of surgical residency training and healthcare delivery in order to enhance educational experiences and ensure patient safety. The fourth recommendation addressed the unique role and educational needs of the chief surgical resident, and the importance of exempting chief residents from duty hour restrictions that preclude acquisition of the requisite knowledge and skills for future practice, including full and independent patient responsibility. The fifth recommendation stated that the restrictive "cap" on graduate medical education (GME) positions funded by the Centers for Medicare and Medicaid Services (CMS) should be removed. The inability to increase residency training positions would be counterproductive to the current efforts to expand the undergraduate medical student pool in order to meet the future workforce needs.

V. ACS RESPONSE TO THE RECOMMENDATIONS OF THE DECEMBER 2008 IOM REPORT

The ACS appointed a second broad-based Task Force to review the recommendations of the 2008 IOM Report and develop a response to these recommendations. The second ACS Task Force was also chaired by L. D. Britt, MD, MPH, FACS, Chair of the ACS Board of Regents, and included leaders of the ACS, chairs of the all the surgery residency review committees, leaders from various surgical specialty boards, and leadership of the Association of Program Directors in Surgery and the American College of Surgeons Resident and Associate Society. The ACS Division of Education again provided guidance and support for this Task Force. Conclusions of the Task Force are presented below in two sections: General Principles and Specific Responses.

A. General Principles

Key Priorities and Goals

Consideration of restrictions on resident duty hours must take into account three priorities: safe patient care of the highest quality, appropriate education and training of surgery residents, and the well-being of surgery residents. The goal of providing safe patient care must be coupled with the goal of educating and training a skilled workforce for the future. Also, strategies to promote the well-being of surgery residents must be adopted. Balancing these priorities is a delicate matter requiring very careful consideration, as overemphasis on one will detract from the others. Limited short-term gains must not be permitted to compromise the long-term goal of ensuring access of the public to well trained surgeons.

Unique Aspects of Surgery

The profession of surgery is unique because of the often invasive and acute nature of surgical treatment. Patients place their trust in the hands of surgeons and surgical teams and in return, expect total commitment to their care and welfare. Surgeons must exhibit the deepest sense of responsibility and unwavering commitment to their patients. The culture of surgery mandates that the surgeon who performs the operation is ultimately responsible for the patient. A team effort is essential, but in the end, the surgeon who performed the operation is responsible, regardless of the clock. Because it is highly unlikely that the number of surgeons per 1,000 population will increase in the foreseeable future, surgeons must be prepared to extend themselves as necessary for the good of their patients. Part of this intense commitment to patients is innate in those who select surgery as a career. The other part is a result of training. Young surgeons cannot be deprived of the opportunity to prepare themselves adequately so that they are able to care for future surgical patients in their hour of need.

The surgical education and training model involves acquisition of knowledge, technical skills, and judgment through a longitudinal and structured experience. Residents need to be involved in all facets of patient care and participate in operations and procedures, assuming greater responsibility as they progress through the residency program. Acquisition of technical skills and judgment takes time and experience. Expertise is attained through deliberate practice using simulation and subsequent transfer of the newly acquired skills to real environments. This intense, immersive model is necessary for residents to acquire the requisite knowledge and skills to function as independent surgeons. Changes in duty hours that negatively impact this structured surgical education and training model will adversely affect patient safety.

The unique features of the surgical model for supervision of residents must be preserved and strengthened where necessary, because these features are essential to provide optimum patient care and appropriate mentorship and training to residents. Surgical education and patient care rely on a well developed team infrastructure whereby junior residents are supervised by midlevel residents, who have immediate access to the chief resident and attending surgeons. All major decisions are made by senior level residents. Critical patient management decisions regarding both operative and nonoperative care, are made at the attending surgeon level. This highly structured hierarchy provides the cross-checks and draws upon the expertise the senior members of the team to provide safe and optimum patient care. It also ensures that residents are assigned increasing responsibility as they gain experience and demonstrate proficiency. Thus, this surgical team concept provides a unique framework of safety for patients and of graded, progressive responsibility for residents.

Any changes in the resident duty hour regulations must ensure that the critical features of the surgical residency education and training model necessary to appropriately prepare the workforce of the future are preserved. Competency-based education and simulation are important in helping to ensure that residents achieve and demonstrate requisite knowledge and skills at various levels of training. However, these approaches cannot replace longitudinal, immersive experiences of adequate length in real environments to prepare residents for practice. Compromising the essential elements of this educational model will not serve the population well, either in the short-run or the long-term. The needs of various professions warrant different intensities of education, training experiences, and time commitments, in order to perform in a skilled fashion. For example, the rigorous training of the U.S. Navy SEALs was recently highlighted following a stellar performance in very difficult circumstances. Had they not been subjected to rigorous training in immersive environments, it is unlikely that they would have performed so well. Similarly, the special training needs of surgeons must be considered when contemplating changes in duty hours.

Flexibility to Meet Unique Needs

Surgery residents must be provided opportunities to engage in care of patients throughout the critical stages of a patient's illness. Such continuity of care is vital to providing care of the highest quality and ensuring that those professionals most familiar with the intricacies of the case are available and involved. Continuity is also essential from the educational and training perspective, as it promotes learning and understanding of the constantly evolving events that typically surround patients undergoing operations. Residents cannot be expected to leave patients as they are going into the operating room, or in the middle of an operation, or just after an operation when the patient may be unstable. Untimely departures are detrimental to optimum patient care, do not provide residents the requisite education and training experiences, and do not inculcate professionalism and a sense of responsibility towards the patients. Experience with the continuum of care including pre-, intra- and post-operative settings is essential for learning, and this critical experience should not be fragmented by artificially imposed time periods. Also, exceptions must be made for especially valuable and uncommon clinical and operative learning experiences.

Because of differences across the various surgical specialties and differences across the years of residency training, appropriate flexibility within the 80 hour week is imperative. Surgical specialties that manage patients with critical and emergency conditions require residents to spend extended hours in the hospital to acquire that experience. These specialties are especially vulnerable to additional restrictions on resident duty hours. Flexibility is also needed for surgery residents in different years of training. Strict duty hour limits may be appropriate for junior level residents who have finite roles in the delivery of patient care. However, senior residents (those in their final two years of training, and especially chief residents) who have higher levels of global responsibility for patient care must be afforded greater latitude to function effectively in this role. These final years need to prepare residents for transition to independent practice. Residents must acquire and learn to apply the requisite knowledge and skills to patient care with increasing levels of responsibility, and manage the care of patients in a progressively more comprehensive manner. Flexibility during these years is essential to provide quality patient care through a highly trained workforce well into the future.

Findings regarding the impact of sleep deprivation on performance must be appropriately extrapolated to the clinical environment. The intensity of experiences in clinical settings, such as the operating room and emergency department, may mitigate many of the side effects of sleep deprivation and fatigue. This important difference in environments, as well as the nature of the tasks and individual capacities, must be considered in implementing duty hour restrictions.

Responsibilities of Self Regulation

Special educational and training programs should be designed and implemented to teach residents to manage fatigue through prevention and mitigation techniques. Because of the vast individual variations in the need for sleep, residents must be educated in recognizing signs of fatigue, using appropriate opportunities to sleep, and regulating their personal and professional activities.

The desire of residents to be involved in the continuum of patient care and to pursue special and rare educational opportunities must be respected. Residents should not be placed in dilemmas that involve making choices among providing appropriate patient care, pursuing important educational and learning opportunities, placing their residency programs in jeopardy, or leaving the hospital when they are not fatigued. Residents should not be forced to make undesirable choices because of inflexible duty hour regulations.

The ultimate responsibility for patient care and residency education must rest with the respective specialties and not be regulated by external parties such as the federal government. Self regulation is a hallmark of the professions. In order to preserve the best elements of patient care and the education and training model in the surgical specialties, those specialties most familiar with these activities must be held accountable and be given the latitude and responsibility for self regulation. Local monitoring of resident duty hours should be conducted at the program and institutional levels, and the results provided to the ACGME for purposes of overall monitoring. This will provide the optimum balance between local implementation based on specific institutional and specialty needs, and oversight by the ACGME.

Resource Constraints

The impact of restrictions on resident duty hours extends to the faculty and medical students, as well as to institutions. The academic productivity of faculty members and their satisfaction are likely to decrease. Further, access of medical students to teaching by residents is likely to be negatively impacted. Certain types of work performed by surgery residents cannot be performed by physician extenders, and teaching hospitals may be unable to afford or find the additional clinicians to cover the hours vacated by residents. Many safety net hospitals and smaller residency programs may be unable to meet additional duty hour restrictions and be forced to close their programs at a time when the increased numbers of medical students being graduated to meet the impending shortages, are seeking positions. Thus, not only will surgeons of the future be less well trained, there will be fewer of them to meet the increasing demand. These effects must be thoroughly evaluated before significant changes are made to the existing duty hours model.

B. Specific Reponses to the IOM Committee Recommendations

Preventing and Mitigating Fatigue

The maximum of 80 hours, averaged over four weeks, is appropriate for junior level residents. For senior residents (those in their final two years of training, and especially chief residents), appropriate flexibility in duty hours must be built into the requirements to provide residents the requisite educational and training experiences and prepare them for the transition to independent practice. Duty hours for senior residents should be based on patient care responsibilities and educational needs, and must include mechanisms to monitor and self regulate activities to mitigate the impact of fatigue. Exceptions must be made to permit residents to participate in especially valuable and uncommon clinical and operative experiences. Appropriate steps should be taken by the program directors and faculty to achieve optimum outcomes in regard to the delivery of safe patient care of the highest quality, to provide requisite educational and training experiences to residents, and promote resident well-being. Program directors and institutional officials at the local level should be responsible for ensuring compliance with various resident duty hour regulations.

The duty hour adjustments proposed by the IOM Committee would be severely detrimental to safe and high quality patient care, as well as to optimum resident education. The maximum shift length of 16 hours with a five-hour protected sleep period is entirely unworkable in the surgical environment, which involves crises and emergencies and rapid changes in the conditions of patients. Surgery residents will be placed in extremely difficult situations if they are asked to handover patients with acute conditions in order to sleep for five hours. The desire of and necessity for residents to provide continuity of care and benefit from the educational experience will make this separation of the residents from patients unrealistic and potentially unsafe. Thus, the protected sleep period will most likely not be implemented, and will result in 16 hour shifts. Also, when combined with minimum off-duty requirements of 10 hours, the shift lengths will need to be no longer than 14 hours, given the typical 24 hour time frames. Thus, the result would be a work week considerably shorter than 80 hours. Patient care will be negatively impacted because the surgical team hierarchy of junior, midlevel, and senior level residents and corresponding cross-checks will no longer be sustainable. The team will be smaller and fragmented across time, and the number of handovers will be increased, raising the likelihood of errors. Those most knowledgeable about the patient will be unavailable at critical points. For example, residents responsible for post-operative care who have not been involved in the operation may not be sensitive to the possible complications because of lack of firsthand knowledge of the nuances of the case and may take longer to identify unfolding adverse events. Finally, the surgeon-patient relationship will be eroded, and patient satisfaction is likely to decrease.

The new proposed restrictions will be detrimental to resident education and training as well. The disintegration of the hierarchical surgical team will impair the process of assuming graduated responsibility and compromise engagement in the continuity of care. Residents will have more gaps in their comprehension of disease progression and experience with the management of surgical conditions across the continuum of pre-, intra- and post-operative care. The shorter hours resulting from the proposed adjustments would also contribute to decreased attendance in educational activities outside the operating room, such as conferences and skills laboratory experiences. Many believe that operative experiences of residents have been compromised with the current regulations; shorter hours would exacerbate this problem. The proposed restrictions might also result in more time being spent in the hospital at night when the full range of learning opportunities is not available to the residents. The crucial mentoring processes among faculty, senior and junior residents would be diluted, and residents may not feel responsible for patients beyond a specified time of day. All of these factors would combine to produce residents who are not as well trained and prepared for independent practice as those who have graduated in the past.

Special educational and training programs should be designed and implemented to teach residents the appropriate use of sleep opportunities and recognition of signs of fatigue. Residents must learn to prevent and mitigate fatigue by carefully regulating their personal and professional activities. This is especially important because of vast individual variations in the need for sleep. Implementation of artificial time controls for residents will fall short of the goals; instead, residents must be provided the support to learn and apply self regulation principles for preventing, mitigating and managing fatigue that will place them in much better stead for the realities of surgical practice beyond residency. In short, inflexible regulations relating to the resident duty hours are not likely to result in optimum patient care, education and training, or resident well-being.

The counting of both internal and external moonlighting in the 80 hour weekly limit is appropriate, and should be monitored and enforced by program directors and institutional officials at the local level.

Improving Adherence to Current Duty Hours

The responsibility for implementation and local monitoring of adherence to duty hours should rest with program directors and institutional officials. Oversight should be provided by the ACGME through the creation of effective strategies, as well as organizational and administrative structures. The ACGME is the appropriate monitoring agency in view of its regulatory role within the graduate medical education enterprise. The ACGME should work with the various specialties and disciplines, residency review committees, program directors, and institutions to design and implement new mechanisms for enhanced adherence. External agencies and organizations that are not directly involved with graduate medical education and do not possess the knowledge of the intricacies and nuances of education in the various specialties and disciplines should not be involved in the regulation and monitoring of duty hours.

Improving the Safety of Residents and the Public

Appropriate measures should be taken by individual institutions to provide safe transportation for residents if they are too fatigued to drive safely. This is essential for the safety of the residents and the public. Faculty must be highly attuned to the signs of such fatigue among residents.

Optimizing Resident Education for Resident Learning and Patient Safety

Institutions must provide appropriate support to limit the noneducational activities of residents. Steps must be taken to ensure that residents participate in appropriate patient care activities to acquire and maintain their knowledge and skills; however, extraneous workload with no educational value should be assigned to other professionals.

A variety of factors must be taken into account for appropriate and effective assignment of cases and workload. Decisions regarding assignment of cases to residents must be made at the local level and take into consideration a variety of factors, such as the complexity of patient care needs, knowledge and skills of individual residents, educational and training needs of the residents, specialty-specific nuances, systems issues, and resident fatigue. Arbitrary numbers or general guidelines for such assignments will not serve patients or residents well.

The robust features of the highly structured supervision model in the surgical specialties have been articulated in the previous section entitled General Principles. This well defined hierarchy provides the cross-checks and draws upon the expertise the senior members of the team to provide safe and optimum patient care. It also ensures that residents are assigned increasing responsibility as they gain experience and demonstrate proficiency. These features must be supported and maintained. Clear definition of expectations should help in strengthening the supervision model, where necessary.

Deploying Learning Systems for Handovers and Error Detection, Correction, and Reporting

Residents must be offered appropriate training and educational experiences to perform safe handovers, and appropriate information technology should be provided to support their efforts. Training in safe and effective handovers must focus on individual and team responsibilities, effective verbal and written communication, exemplary professionalism, and appropriate use of technology. Such training must address the transfer of critical information to the next team and highlight the responsibility for obtaining all essential information from the departing team. The importance of in-person handovers must be emphasized. Residents should also be provided education and training in specific areas pertaining to patient safety, continuous quality improvement, systems analysis, near misses, error detection and reporting, root cause analysis, and systems of care. Specifically, residents should participate regularly in conferences focusing on quality improvement and education, such as Morbidity and Mortality Conferences, to learn the principles and practice of patient safety, systems of care, and continuous quality improvement.

Obtaining Additional Resources for Implementation

Inviting the spectrum of financial stakeholders to support graduate medical education is a worthy goal, but may be difficult to implement in the current healthcare and economic environment.

Monitoring and Evaluation

The data needed to monitor implementation, prepare for future adjustments, and identify priorities for evaluation projects should be gathered by individuals from the respective specialties and disciplines in conjunction with the ACGME. An appropriately designed and validated annual resident survey should be used by the ACGME to obtain anonymous resident feedback regarding compliance with duty hours. This would provide valuable information to the ACGME, residency review committees, institutions, and program directors. Aggregate discipline-specific data from the survey could be shared with the respective program directors groups in addition to the residency review committees, to facilitate the sharing of information, experiences, and solutions across the community of individuals involved with resident education in surgery.

VI. CLOSING COMMENTS

Every resident duty hour schema must take into account the needs to provide safe patient care of the highest quality, ensure optimum education and training for residents that result in a skilled workforce for the future, and promote the well-being of residents. Efforts to enhance the safety of patient care at present must be coupled with the education and training of surgery residents who will be responsible for providing patient care in the future. The unique nuances relating to patient care and education and training in various specialties and disciplines must be taken into account as further duty hour restrictions are considered. A one-size-fits-all approach will not serve patients or residents well, especially in the surgical specialties.

The goal of residency training in surgery is to ensure that residents acquire the requisite knowledge and skills to provide skilled and safe care to patients. Mastery in surgery requires extensive experiences that extend over a substantial period of time. Also, the hallmark of the surgeon professional is commitment to and responsibility for the continuum of pre-, intra-, and post-operative care for the surgical patient. This critical sense of responsibility is inculcated in residents through appropriate experiences that require sufficient duty hours. Commitment and mastery are respected symbols of this profession that will always be associated with hard work and dedication. The highest level of patient safety and quality care can only be achieved by providing a longitudinal immersive experience in surgical training. The key features of the supervision model, through which the senior residents and faculty are engaged in critical patient care decisions and in mentoring residents, must be maintained.

Patient safety in an environment with escalating challenges (including new treatment paradigms and technologies, along with a growing and aging population) cannot be achieved by arbitrarily changing resident duty hours without thoughtful consideration of all issues impacting the care of the surgical patient. Rather, efforts should be focused on optimal utilization of information technology, electronic health records, telemedicine, and simulation to better support the healthcare system and residency education in surgery. Such initiatives are needed to facilitate reliable and safe handovers, to streamline work, and to make training more efficient. Development of strategies to improve the system would do more to address quality and patient safety concerns than merely assuming that a reduction of duty hours will improve safety.

After five years of experience with the resident duty hour restrictions implemented by the ACGME and numerous studies, the available evidence does not support the notion that decreased resident duty hours have improved the safety of surgical patients. Some recommendations of the IOM Report, such as training in prevention of fatigue and safe handovers, and including moonlighting hours in the 80 hour maximum, are appropriate. In the majority of surgery residency programs, moonlighting is already prohibited. Other proposed recommendations, particularly relative to adjustments in duty hours, would clearly jeopardize patient care and the capacity of our system to produce highly qualified surgeons. These proposed recommendations would combine to create a less than 80 hour week, resulting in increased handovers, disruption in continuity of care, erosion of the surgeon-patient relationship, and a decrease in patient satisfaction. In addition to the negative impact on patient care, the education and training of future surgeons would be seriously compromised. With shortened hours, residents would be unable to experience the appropriate breadth and depth of surgical conditions, and would be unable to care for patients during in the pre-, intra- and post-operative stages of care. Many surgeons and senior residents alike believe that the current 80 hour week is a barrier to education and are concerned that graduating residents are not fully prepared for independent practice. Any further restrictions in resident duty hours also would create gaps in coverage, and the additional personnel needed to fill these gaps would be cost prohibitive and difficult to find. Some programs may be unable to continue to support surgery residency programs, thereby compounding challenges in access to surgical care in both the near- and long-term.

At the time the ACGME duty hours restrictions were implemented, the surgery profession overwhelmingly believed that additional flexibility in the 80 hour week would be necessary for senior level residents (those in their final two years of training, and especially chief residents) to make the successful transition to practice. This need for flexibility is even more evident now, following five years of experience with the current regulations. Such changes should be implemented immediately to mitigate the negative impact of the current duty hour restrictions. Monitoring and evaluation of compliance with duty hour restrictions should remain the purview of those directly involved in patient care and resident education and training. The ACGME should provide oversight and facilitate research efforts to evaluate the impact of duty hour restrictions. The long-term impact of the duty hour restrictions must be investigated through multi-institutional studies that focus on specific needs of the patients and surgery residents. Patient care, resident education and training, and resident well-being should be the focus of such studies. A thoughtful approach that takes into account the many nuances associated with residency education will ensure delivery of safe patient care of the highest quality, now and well into the future.

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May 8, 2009

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Dear Dr. Nasca:

We write to you on behalf of the Association of Program Directors in Surgery (APDS) to offer our perspective upon the December 2008 Institute of Medicine Committee report entitled "Resident Duty Hours: Enhancing Sleep, Supervision, and Safety". Our association represents the program directors, associate program directors, and residency coordinators of the 248 ACGME-accredited General Surgery residency programs in the United States of America. Founded in 1977, we are entrusted with and committed to preparing our nation's surgeons of tomorrow to deliver excellence in patient care. Our April 30-May 2, 2009 annual meeting in Salt Lake City, Utah, included scientific papers, panel presentations, and open discussion periods devoted to the IOM Committee report and to the findings of a survey of our membership concerning the educational impact of current and proposed duty hours standards. Based upon these recent, wide-ranging discussions we have prepared this consensus statement, paying particular attention to the impact of the IOM Committee recommendations upon the education of the surgical trainees for whom we are responsible.

The APDS supports <u>both</u> of the stated goals of the IOM Committee's work: "to recommend ways to improve conditions for safety during training while maintaining the necessary educational experience to ensure long-term patient safety after trainees are on their own". We concur with several of the IOM Committee's recommendations for potential improvements to the safety of residents during their training and to the safety of patients in whose care residents participate. However, we disagree strongly with several well-intended recommendations that will undermine short and long-term patient safety by substantially degrading the educational experience of surgical trainees. We describe our areas of agreement and disagreement in detail below.

I. The APDS endorses the IOM Committee's goal "to recommend ways to improve conditions for safety during training"

Our wholehearted support for resident and patient safety initiatives at teaching hospitals stems from several perspectives. As individuals, APDS members seek care at teaching hospitals, where we want competent and safe medical care for ourselves and our families. As practicing surgeons at teaching hospitals, program directors share the desire of all healthcare professionals to provide competent and safe care to our patients. As faculty role models to our residents, we are keenly aware of our professional obligation to teach by example our commitment to practicing safely. As program directors, we share accountability with our sponsoring institutions for providing an optimal and safe learning environment for our residents.

A. **The APDS endorses the IOM Committee's recommendation calling for the provision of safe transportation for fatigued residents.** In addition to providing transportation, sponsoring institutions should make appropriate space available for off-duty residents to rest prior to leaving the teaching hospital should they elect to drive themselves. This option recognizes that returning to the hospital to retrieve vehicles may create schedule conflicts or unintended hardships for residents and their families. Residents who choose to rest in the hospital should not be required to count those rest hours as duty hours. We also applaud the IOM Committee's recognition that the oversight of this important resident safety provision appropriately rests with our sponsoring institutions through their Graduate Medical Education Committees.

B. **The APDS endorses the IOM Committee's recommendation calling for the development of accurate and effective systems to ensure patient care handovers**. This topic has relevance to patient care regardless of the duration and configuration of resident duty hours and was recognized as one of great importance at our recent meeting, with six papers and a 90 minute panel focused on surgical patient handovers involving residents. The variety of approaches tested and the variable successes reported by our members provide evidence that safe surgical patient care transitions are still in evolution and are very sensitive to local factors (e.g., information technology, non-physician personnel work schedules). Each institution has a unique mix of resources so that effective handover strategies may appear different at specific hospitals; however, each facility should be expected to utilize available and identify needed assets to develop efficient and accurate patient care handovers. We recommend that institutions be allowed time and maximal flexibility in crafting and implementing handover solutions, with oversight resting at the individual institutional level and based upon outcomes rather than rigid process requirements. Pragmatic and effective strategies learned from us by our residents will presumably be carried by them into their post-residency practices, contributing to surgical patient safety over the long-term.

C. **The APDS endorses the IOM Committee's position that all moonlighting activities should be counted as duty hours.** The breadth, depth, and intensity of General Surgery training demands full engagement by the resident in his/her education. Moonlighting by clinically active residents should be strongly discouraged within our programs. Trainees conducting research during "protected" time should be allowed to moonlight with written permission from the program director and the concurrence of his/her research supervisor. Current duty hour standards should apply to research residents who undertake moonlighting. Such oversight will ensure that "research years" are indeed educationally productive for residents performing them and will foster the development of surgical scientists to meet future healthcare needs. Through its Institutional Review Committee, the ACGME should encourage sponsoring institutions to provide support such as subsidized child care and financial counseling to minimize pressures on residents that lead to moonlighting. In support of resident and patient safety, the IOM should exert its influence on relevant governmental policies such as loan deferment and debt forgiveness in exchange for service to underserved areas post-residency.

D. **The APDS endorses the IOM Committee's recommendations regarding enhancing resident supervision.** We believe that our specialty may in fact serve as a model in this regard. The ethical and professional obligations of faculty members to provide appropriate supervision of surgical residents are clearly recognized in the Residency Review Committee for Surgery's Program Requirements. Evidence of resident supervision is sought by field site surveyors during ACGME accreditation visits and by our institutional Graduate Medical Education Committees during their internal reviews of our surgical programs. Robust oversight of resident supervision is facilitated by meetings of ACGME and internal site reviewers limited to residents who are elected by their peers. Independent of the ACGME external and internal site review processes, appropriate supervision is inherent in the structure of surgical residencies. Patient care teams typically include residents from multiple postgraduate year levels, and reporting relationships up the chain of command to chief resident and attending surgeons are clearly defined. The redundancy and graded responsibility within our teams are key elements supporting the safety of surgical care by residents. Frequent discussions of patients during trainee-trainee and trainee-attending interactions provide a continuous quality of care review process that reduces preventable errors and enhances patient safety. Resident opportunities to function within their teams as both teacher and learner provide the immediate motivation for learning, prompt feedback, and guided reflection that are necessary to successful adult learning. Other external regulatory processes further guarantee appropriate supervision of surgical residents. Our residencies include experiences at "designated" and/or "verified" trauma centers which have passed inspections with strict standards for organization, resources, and capacity. Continuous on-site senior resident and attending surgeon presence are required to attain trauma center status, providing the "immediate access to an in-house supervisor" deemed essential by the IOM Committee for first postgraduate year residents. Finally, despite significant financial support at multiple governmental levels for graduate medical education, academic medical centers are dependent upon reimbursement for the professional services provided by attending faculty members. As noted by the IOM Committee, "teaching surgeons" are held to the most demanding of supervision standards by CMS in order to submit claims: the presence of a faculty member for the key or critical portions of <u>every</u> procedure. Faculty surgeons must also document their involvement in the preoperative and postoperative care of every patient billed.

E. **The APDS supports the call of the IOM Committee for a thoughtful review of graduate medical education financing.** The explosion of medical knowledge, evolution of healthcare information technology, graying of our nation's population, medical workforce concerns, and national focus on patient safety place steadily increasing demands for precious resources upon our graduate medical education system. All current and future patients, not just those in government-funded healthcare programs, benefit from our system of graduate medical education system, one that is eagerly sought after by physicians-in-training from around the world.

II. **The APDS endorses the IOM Committee's goal of "maintaining the necessary educational experience to ensure long-term patient safety after trainees are on their own"**

As acknowledged by the IOM Committee, "a fundamental requirement of resident education is in-depth, firsthand experience caring for patients" and residency is designed for the provision of "the rich and varied educational experiences necessary to become competent in the complexities of diagnosing and treating patients". As educators dedicated to preparing the surgeons of tomorrow, we recognize our connection to the patients for whom our trainees will provide care after leaving us. Long-term safety of those patients is most reliably assured through the provision of care by physicians who have reached competence sufficient for independent practice, while still our trainees.

A. **The APDS supports the IOM Committee's focus upon "ensuring a patient workload appropriate to learning and reducing the amount of non-educational work for residents". However, the APDS *<u>cannot support</u>* the IOM Committee's recommendation to restrict or regulate surgical resident workload based upon arbitrary metrics (e.g. "number of patients residents should be permitted to treat during a**

shift"). As professional graduate medical educators, we absolutely support the primacy of education over service for residents. Workload design is particularly complex, however, for our specialty. General Surgery is the most broad-based and wide-ranging of all surgical specialties. The types and range of educational needs of General Surgery residents are extraordinarily diverse and include ambulatory and inpatient settings, elective and emergent operations, provision of routine and complex/critical care, cognitive and technical elements, and simulated and live didactic venues. Workload design is further compounded by the unique profile of each institution's resources (e.g., simulation facilities, faculty subspecialty areas) and patient catchment (e.g., volume, acuity, breadth of diseases). Additional complexity is introduced by the inherent heterogeneity of our residents as adult learners. Not only do residents learn at different paces from each other, each resident acquires various types of knowledge and skills at variable rates (e.g., cognitive diagnostic, cognitive intraoperative decision-making, endoscopy, minimally invasive operative, open operative). The Residency Review Committee for Surgery Program Requirements and the certification eligibility requirements of the American Board of Surgery already define the cognitive and experiential needs of our residents and residencies. Strategic planning, tactics, and oversight for meshing the educational needs of our residents with their learning profiles is best accomplished at the individual and residency levels by professional surgeon educators familiar with their residents and their residency resources--program directors. Our organization interacts regularly and substantively with the RRC-Surgery and the ABS, and many members of the RRC-Surgery and the ABS are sitting or former program directors, leading to a shared focus on creating appropriate graduate General Surgery educational opportunities for each and every resident. Under the sponsorship of the ABS, the APDS, RRC-Surgery, the American College of Surgeons, the American Surgical Association, and the Association for Surgical Education work closely together with the ABS as the Surgical Council on Resident Education (SCORE). The IOM Committee's recommendation to mandate more detailed resident workload metrics in the absence of a data-driven evidence base for so doing would actually harm resident education in all specialties by reducing resident education to a "one size fits all" formula which would in reality fit few if any residents and residencies.

B. **The APDS shares the desire of the IOM Committee that evaluation and monitoring of resident workload, duty, hours, and educational outcomes be robust and credible. However, the APDS *<u>cannot support</u>* expansion of oversight to multiple other entities.** As program directors, we are fully familiar with the strengths and weaknesses of the current oversight processes, including the ACGME resident survey. We wholeheartedly share the concerns of our residents as described in the IOM Committee's report about the ethical dilemmas created for them by the competing demands of professionalism, educational needs, and duty hours standards. The APDS believes that monitoring and evaluation of residents workloads, duty hours, and educational outcomes are inextricably linked and are best achieved through a robust, credible, and collaborative process involving trainees, programs, sponsoring institutions, and the ACGME. Though we respect the expertise of the Center for Medicare and Medicaid Services and the Joint Commission in their respective fields, we oppose the expansion or transfer of resident oversight to them or to a newly created board. Adding layers of oversight by entities whose focus and expertise lie in other areas of healthcare appears to risk a less effective and more cumbersome process incapable of rapid response as well as introducing political uncertainties into an already complicated system. Potential opportunities for meaningful enhancement of oversight include reformulation of the ACGME resident survey process to include sound methodology, cross-validation, and pilot testing of delivery formats. Expanded public membership in the governance of existing active participants in graduate medical education could also be considered. Appropriate processes will hold residency programs and institutions accountable and will provide full protection for resident whistleblowers. Similarly, appropriate oversight of resident supervision must rest at the program, sponsoring institutional, and Residency Review Committee levels.

C. **While the APDS has adopted the current (2003) duty hour standards, we *cannot support* the package of revised standards recommended by the IOM Committee.** Our organization has serious reservations about trying to maintain the quality of our educational programs by further reducing learning opportunities. Adaptation to the 2003 standards has been challenging, and solutions have varied across residencies. Optimizing adaptation remains a work-in-progress as evidenced by the multiple papers, panels, and workshops devoted to duty hours topics at each of our annual meetings since 2002. June 2008 marked the first group of finishing chief residents in General Surgery who could have completed their entire residencies under the current standards, having begun their training in July 2003. Because a substantial number of our residents pursue one or more dedicated research years, it will likely be June 2010 before all of the 2003 entering residents finish their residencies. Hence we will not have any data that comes close to measuring the full impact of the 2003 duty hour standards until at least late 2010 on reliable measures such as Board examination pass rates. Early data suggested minimal decrements in overall experience. However, larger and more detailed studies of increasing scientific rigor continue to emerge and are not encouraging. Chief resident operative experiences are flat or decreasing, a worrisome trend given the IOM Committee's goal of "long-term patient safety after trainees are on their own". Operative experiences as first assistant and teaching assistant have fallen substantially. As a result, residents more often come to the Operating Room as primary resident surgeons having seldom previously participated at a lesser level in procedures. Simulation and other skills training can narrow but not close this experiential gap; data are mounting that simulation learning gains are greatest for junior/novice surgical learners Simulation provides no substitute for the cognitive aspects of operations including preoperative and postoperative care as well as intra-operative decision-making. The role of simulation may expand as educational technology advances, but we are definitely far from the reliability and validity of aviation simulation. The loss of the teaching assistant opportunity for senior residents may be even more harmful to patient safety. The opportunity for a senior resident to take charge of a patient's surgical episode of care including the operation itself while under the watchful eye of an experienced faculty surgeon, is far better than having a resident's first opportunity to truly take charge occur when s/he is no longer a resident. Clinical activities are being redistributed to more senior levels regardless of the resident level who can achieve maximal educational value from any given activity. Further reductions in patient contact time for General Surgery residents should be deferred at least until rigorous, longitudinal, comprehensive assessments of the educational results of the 2003 standards become available. The APDS believes that the public is clearly better served by credible, data-driven duty hours changes made later than by immediate changes based upon hypothetical linking of performance data for markedly dissimilar tasks to surgery and surgeons.

D. **The APDS believes that implementation of the revised work hours standards recommended by the IOM Committee are incongruous with the clinical educational experiences necessary for trainees to achieve competence in General Surgery.** Our residency graduates will be required ethically to respond competently and professionally at all hours to demands by patients and their families for the care of complex and urgent conditions. Development of the cognitive, technical, and personal attributes and behaviors that allow surgeons to perform well with little advance notice and over extended time periods is an intrinsic part of General Surgery residencies. Our residencies have sacrificed some formal and informal educational time to maintain irreplaceable patient contact time. Since 2003, we have struggled to reduce resident duty hours and still graduate residents in five years who can expertly and safely serve the public. Though the IOM Committee's proposal has not reduced the overall 80 hour limit, those 80 hours now include nearly 10 hours per week of protected nap time using the most common every fourth day residency call structure. Nap time therefore must be subtracted from functional time for residents, leaving at most 70 hours for educational and clinical activities. This change alone, a further 12% reduction from experiential learning time, is inimical to meeting the needs of the public for general surgeons without a compensatory increase in residency duration. Resident personal finances as well as current GME funding streams are insufficient to support longer residencies. A proposal in which all residents have less time for education and exposure to patient care is simply unacceptable if we are to continue to educate competent and safe general surgeons.

E. **The APDS is concerned about the impingement of the current (2003) and proposed (IOM Committee 2008) duty hours standards on the quality and quantity of teaching of residents.** Our survey data are also of great concern to us on this topic. Over one third of programs have reduced total teaching conference hours since implementing the 2003 duty hour standards. This reduction has not been mitigated by less formal didactic interactions. Nearly one-half of program directors report at least a 25% decrease in bedside/clinic teaching. Fewer residents at all levels are available due to duty hours limits or assignment to important patient care experiences (performing operations under supervision). It is illogical to expect that further hours reductions will reverse this ominous trend. When residents are not available, demands upon faculty time often increase (e.g., assisting each other with operations), reducing the number of faculty members available for focused teaching activities for residents. Residents and their future patients cannot afford the continued erosion of the quantity and quality of teaching encounters as are already occurring under 2003 duty hour standards.

III. System Issues

The APDS is committed to continuing improvement of our healthcare system from multiple perspectives as seen from our roles as surgical educators, program directors, practicing surgeons, patients, and family members of patients. As program directors, we are the effectors of incorporating a culture of safety into our residents' knowledge base and skills sets. We are proud of our linkage to future patients through our trainees and we deem ourselves privileged to prepare them to deliver surgical care that is competent, compassionate, ethical, professional, and safe. Like our patients and our residents, we find ourselves in an era in which our healthcare system is under intense scrutiny and for which "transformation" has been documented. We are concerned that approaches focused on residents/graduate medical education are being substituted under the guise of patient safety for more appropriate system-wide delivery system changes. We are also concerned about the unintended consequences of manipulating one element of a complex healthcare system without consideration of the system as a whole.

IV. Educational Relationship Transformation

Surgical graduate education continues to evolve and General Surgery residency program directors have held pivotal roles in stimulating, designing, and implementing change to a system that favors education over service, supervised practice over untutored floundering, and systematically guided learning of a defined curriculum over randomly chosen and undirected reading. APDS members, including our associate program directors and our residency coordinators, devote countless hours to our programs and residents. We hold ourselves to high standards as surgical educational professionals and we welcome external assessment of our outcomes. Simultaneously, the relationship of program director to his/her residents had changed from one of absentee landlord to one of valued coach/mentor. Implementation of the 2003 duty hour standards is eroding this hard-won progress to a better relationship. We are fast regressing to the role of timekeeper or even warden over our residents. Our time and energy, which we have happily devoted to betterment of our programs is increasingly consumed with duty hour documentation and desperate attempts at adaptations to preserve educational value. Residents and their future patients cannot afford further erosion of the program director-resident relationship.

V. Professionalism and Continuity of Care for Surgical Specialists

The APDS is committed to providing a graduate educational experience that recognizes and addresses the distinct needs of surgical residents. The unique features of professionalism and continuity of care for surgeons are eloquently outlined by Frank Lewis, MD, Executive Director of the American Board of Surgery in his commentary to the ACGME. We fully endorse the principles and concerns outlined by Dr. Lewis.

VI. Conclusion

The APDS welcomes the interest of the IOM in graduate medical education. We find much in the work of the IOM Committee report with which we can agree. However, for all of the reasons outlined above, we must wholeheartedly and firmly disagree with the proposed duty hours revisions as inimical to properly preparing the surgeons of tomorrow and to the long-term safety of surgical patients.

The APDS appreciates the opportunity to provide input into the ACGME's deliberations about the 2008 IOM Committee report "Resident Duty Hours: Enhancing Sleep, Supervision, and Safety". Our association is fully committed to working with the ACGME to ensure that current and future surgical residents are guaranteed to have the necessary educational experiences in a safe and nurturing environment that will prepare them to meet the needs of the patients they will serve as independent practitioners.

Karen R. Borman, MD, FACS
President, Association of Program Directors in Surgery

George M. Fuhrman, MD, FACS
Immediate Past President, Association of Program Directors in Surgery

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The American Board of Surgery, Inc.
Incorporated 1937

April 30, 2009

Thomas J. Nasca, M.D., M.A.C.P.
Chief Executive Officer
Accreditation Council for Graduate Medical Education
515 North State Street, Suite 2000
Chicago, IL 60610

Dear Tom:

The appended report has been generated by the staff and directors of the American Board of Surgery, and has been shared with other surgical boards, who have indicated their substantial agreement with the points made and the need to avoid further restrictions on resident work hours. The other nine surgical boards have therefore asked to endorse this document and have signed on to it, so it represents the combined opinion of all ten surgical boards.

The principal concern of the ABS is that the present work-hours restrictions are subjugating the primacy of patient care, the provision of optimal resident education, and the teaching of professional ethics to residents to arbitrary work-hours limits that bear little relevance to the day-to-day requirements of patient care for residents. It is our belief that global restrictions on resident work hours should continue, but that the specifics in regard to shift length should be made more flexible, should be secondary to patient care needs, and should be eliminated for senior and chief residents. Proposed additional restrictions beyond those already in place are incompatible with optimal patient care in multiple specialties. Professional responsibility for work-hours regulation within residency by program directors with appropriate monitoring by the ACGME, rather than arbitrary limitations, should be the standard maintained in the best interests of both patient care and resident training.

We look forward to an opportunity to attend the ACGME meetings scheduled on June 11-12, and to further oral testimony at that time.

Sincerely,

Frank R. Lewis Jr MD

Frank R. Lewis, M.D.
Executive Director

FRL/dd

COMMENT OF

THE AMERICAN BOARD OF SURGERY

ON

THE RECOMMENDATIONS OF THE

INSTITUTE OF MEDICINE REPORT:

RESIDENT DUTY HOURS: ENHANCING SLEEP, SUPERVISION, AND SAFETY

April 25, 2009

INTRODUCTION

On December 2, 2008, the Institute of Medicine ("IOM") released a report, Resident Duty Hours: Enhancing Sleep, Supervision, and Safety, recommending new restrictions on resident hours ("Report"). (1) The report was written by the IOM's Committee on Optimizing Graduate Medical Trainee (Resident) Hours and Work Schedules to Improve Patient Safety ("Committee"). The Accreditation Council for Graduate Medical Education ("ACGME") the agency responsible for setting residency program accreditation standards, including restrictions on resident hours, has solicited input from other organizations concerned with resident education, and on June 11-12, 2009 will hold a symposium where participants may discuss their perspectives on the recommended restrictions and their potential effect on patient safety. This paper presents the American Board of Surgery's ("Board") response to these most important issues.

BACKGROUND

American Board of Surgery

The American Board of Surgery is a non-profit organization founded to define high standards of surgical care for the protection of the public, and to examine and certify residents who complete surgical training in the areas of general surgery, vascular surgery, pediatric surgery, surgical critical care, and surgery of the hand. Protection of the public and the values of professionalism, which place the primacy of patient welfare above the interests of physicians, have been the goals that inform all of the Board's purposes since its founding in 1937. Consistent with these overarching goals, Board applicants must meet stringent training criteria and then pass both a written and oral examination. Training must include the completion of a five-year residency and applicants must demonstrate that each year of residency consisted of 48 weeks of full-time surgical experience. Applicants "must have been the operating surgeon or teaching assistant for a minimum of 750 operative procedures in five years and a minimum of 150 operative procedures as a chief resident" to be eligible for Board certification. (2) Applicants must tabulate their operative experience and indicate their level of responsibility for procedures in which they participated. They can claim responsibility for operations they performed "only when they have actively participated in making or confirming the diagnoses, selecting the appropriate operative plan, and administering preoperative and postoperative care." (3)

These requirements reflect a fundamental principle of surgical training: that carefully monitored and supervised experience is tied directly to proficiency. This is particularly so in the surgical specialties where supervised resident experience treating patients pre-operatively, intra-operatively, and post-operatively is essential to learning the safe practice of surgery. When it comes to surgical skill, adequate experience in actual performance of surgical procedures is essential to competence. By requiring such experience, the Board's certification standards increase surgical skills across the spectrum of care and protect the public by helping establish an educational environment that produces competent surgeons who can safely treat patients under real life pressures. The Board adheres to the values most recently stated in "Medical Professionalism in the New Millennium: A Physician Charter," a current statement on medical ethics created by the American Board of Internal Medicine Foundation, American College of Physicians Foundation, and the European Federation of Internal Medicine (4), and seeks to maintain training standards where surgeons will refuse to compromise their commitment to the primacy of patient welfare in the face of bureaucratic and corporate assaults.

IOM Report

The impetus for the Committee's Report, whose recommendations seek to advance the safe treatment of patients, came from Representative John D. Dingell (D-Michigan) of the United States House of Representatives. In 2007, Representative Dingell charged the Committee with formulating recommendations on how to optimize resident hours to improve patient safety. The feeling in the medical community was, as one official told the Committee - "If we don't give members of Congress some workable solutions, they'll come up with their own." (5) This added greater urgency to the Committee's work and increased pressure to recommend immediate changes to resident hours.

The Committee's analysis in the Report includes an exploration of current 80-hour work week limitation on resident duty hours implemented by the ACGME in 2003. The Report also examines the methods of monitoring adherence to these ACGME policies and the ways in which various residency programs have adapted to the current restrictions. The Report analyzes the possibility that (further) resident hour restrictions may improve the resident learning environment and it considers the impact of duty hours on resident well-being. It also examines the numerous factors that may contribute to medical errors in the resident environment and strategies to reduce fatigue in resident work schedules. Finally, the Report addresses various approaches that may be used to improve patient safety, with an emphasis on possible improvements that may be made to patient handover techniques.

Changes Recommended in the Report

The principal recommendation in the Report is that accrediting agencies further restrict resident duty hours. The Report recommends that residents be limited to working shifts no longer than 16 hours unless provided with a continuous five-hour sleep break, in which case they can work up to 30-hour shifts. (6) The Report leaves intact the 2003 ACGME 80-hour maximum resident hours per week limitation, but recommends that external moonlighting now be included in calculating the 80 hours. (7) Moonlighting hours are also to be included in calculating all other duty hour limits. (8)

Under the recommendations, maximum resident in-hospital on-call frequency, formerly every third night on average, is now limited to every third night with no averaging. (9) The recommendations would also require that residents take a minimum of 10 hours off after a day shift, 12 hours off after a night shift, and 14 hours off after any 30-hour shift (which is allowed only if a continuous five hour sleep break is provided) with the added restriction that the resident may not return until 6 a.m. of the next day after such a 30-hour shift. (10)

What the Report Lacks

Unfortunately, with all of its analysis and detailed recommendations, the Report lacks a prudent consideration of the effect of resident hour restrictions on surgical practice and surgical resident education. Though the report repeatedly acknowledges differences in the effect of previous resident hour restrictions on general medical practice versus surgical practice, it gives this no consideration in formulating its recommendations, which are broad recommendations of general applicability and do not consider specialty-specific patient needs. This failure, which undermines the credibility of the report, was perhaps a result of the composition of the Committee. Of seventeen members, only one was a surgeon, and none were present from the disciplines most affected by work hours restrictions – general surgery, orthopedics, and neurosurgery. None of the members were actively practicing surgeons. Six members were clinicians, from non-surgical disciplines, but only two were in active practice that would put them in daily contact with residents; most were in senior administrative positions. The remaining members were principally non-physician experts in medical quality and safety, and had no involvement with resident training. Thus the membership of the committee had limited current experience with resident training (2/17) and no experience with the surgical disciplines where emergency care is an integral part of practice. The group was therefore not representative of the constituency to which its recommendations were directed, and it is not surprising that those recommendations would be incompatible with the realities of surgical resident training. It is unclear why the IOM constituted a committee to address such important regulations which excluded the disciplines most affected.

General History and Significance of Professionalism Training in Surgical Residency

The "primacy of patient welfare" is a fundamental principle of medical practice (11) that has survived through millennia. Protecting this principle requires "placing the interests of patients above those of the physician." (12) As aptly stated in the Physician Charter: "Market forces, societal pressures, and administrative exigencies must not compromise this principle." (13) Medical ethics have always put patient welfare above that of the doctor, who often finds that working long hours and sometimes sacrificing portions of one's personal life are necessary in order to care for patients. Such considerations are particularly important to surgical specialties which have primary responsibility for treating a large fraction of medical emergencies and trauma.

Such altruism is important to all medical practice but is indispensable to surgical practice and training. Unlike general medicine, which mostly involves care of patients with chronic illness over an extended period of time, surgical practice frequently involves the provision of acute care to critically ill patients, and the subsequent in-hospital care that follows. The extended hours incident to such treatment are intrinsic to the provision of surgical care - they are the real world necessities of residency training and post-residency surgical practice. Residents who are not trained in and do not develop an understanding of the realities of surgical care during training are ill-prepared to meet patient's needs in practice.

A surgeon caring for a critically ill patient must be available to that patient as long as circumstances require. The subtleties of a surgeon's examination and tracking of a critically ill patient and the nuances of his/her observations cannot simply be handed off to the next shift without harmful effects on patient care and on the surgeon's own professionalism. Arbitrary limits on surgeons' time and "shift-work" mentalities simply have no place in quality surgical care. The perception that transfers of responsibility ("hand-offs") simply need an improved system for data transfer fundamentally misses the fact that dozens of clinical observations are qualitative and subjective and that there is no known way such perceptions can be accurately or reliably transferred from one physician to another. For example, a surgeon's evaluation of an acute abdomen often involves considerable nuance in the physical findings, and the specific description of the location and degree of tenderness and/or guarding cannot be accurately conveyed to another surgeon by verbal or written description, except in the grossest way, no matter what system is used. These subtleties, and their significance in the subsequent evolution of the disease process, are certain to be lost when surgeon care becomes discontinuous. These issues are not significant with elective clinical problems, nor with chronic disease with little day to day change; however, with emergencies and acutely ill patients, changes occur rapidly, and continuity is essential.

The same is true for surgical residents, who must comply with the same demands of surgical practice if they are to provide competent surgical care as residents and to become capable surgeons by the end of their residency programs. Surgical residency programs have demonstrated over time that emphasis on personal responsibility and rigorous experience produce surgeons with the skill necessary to practice independently and competently on their own. Surgical residents need adequate opportunities and experience for the development of mature surgical judgement - that quality that separates excellent from marginal surgeons in and out of the operating room.

Lastly, more than a quarter of practicing general surgeons in the country today are in solo practice, typically in rural areas. Often they are the only surgeons in their communities. Such surgeons do not have the luxury of "signing out" to someone else, and when confronted with a surgical emergency must attend to the patient for whatever time is necessary to provide needed treatment. Residents who are taught that all care is administered in 16 hour shifts with five hours of sleep, or 30 hour maximum time frames, will be ill-prepared for such realities, and unwilling to take on practice in such locales. The consequences of such a policy therefore extend far beyond immediate circumstances in residency training to future care in all parts of the country.

Any reasonable analysis of the present surgical residency system must recognize that it works very well, and that any proposal for significant changes to it must not create greater problems than the proposed changes seek to remedy. The United States system of residency training is the model for most of the world, and the fact that 8,000 international medical graduates come to the United States yearly to obtain such training provides ongoing validation of this.

ABS PERSPECTIVE

Summary

The Board welcomes all recommendations to improve surgical patient outcomes that are based on sound rationales and grounded in objective measurable evidence. The Board must consider any such recommendations, particularly generalized recommendations proposed to be applied to the surgical field, through its unique perspective and awareness of the specific attributes and requirements of surgical practice.

With regard to the impetus for the Report, the Board appreciates the concern of elected officials and their reaction to public perceptions of the impact of fatigue on medical professionals. The Board also recognizes, however, that before we change an ethic that has developed over centuries and a residency structure that has evolved for several decades, which works well to produce competent surgeons, we need rigorous evidence that the changes will improve the structure and will not do more harm than good. The Board encourages elected officials and entities contemplating any changes to surgical residency to demand such evidence and to resist the temptation to allow special interests to compromise the primacy of patient welfare.

With regard to the Report's findings, the Board agrees with the Committee that there are insufficient data on the precise link between resident hours and patient safety. The Board also agrees with the Committee that studies of the effects of the ACGME's previous resident hour restrictions have shown no positive impact on surgical patient outcomes. Reduced hours have not, as some presumed, improved patient safety. The implicit assumption that reduced hours would logically translate into greater patient safety has not been proven. The possibility that there might be overriding negative effects from decreased continuity of care, increased handoffs, increased "surrogate" care, and decreased resident training opportunities seems not to have been seriously considered and has not been the subject of study. Given the known relationship between handoffs and medical error, the potential negative impact of reduced continuity of care is real. Absent evidence of improved patient safety with the present limits in work hours, there is no reason to believe that further limits will achieve that aim either.

It is important to note that surgical residency training, including post-residency fellowships, is 5-7 years in length in most surgical specialties. As a result, the group of residents who entered residency in 2003, the first year of mandated ACGME 80-hour restrictions, is only now beginning to complete training. There has not yet been an opportunity to evaluate the effect of reduced hours on the performance of these individuals in practice, and the effect this may have on their choice of practice venue. One may note that residents more than 10 years ago averaged 90-100 hours per week, so over a five-year residency they spent 3000-5000 additional hours in-hospital compared to present-day residents. The impact of this massive reduction in time on breadth of experience and overall competence can only be assessed going forward.

It is logical to assume that the experience of 80-hour workweeks in residency will make lifestyle an important consideration for these individuals in practice, and one may assume that they will be less inclined to make themselves available for emergency call in hospitals and less likely to choose rural or solo practice. Hospital administrators have already noted that emergency department trauma coverage for general surgery, orthopedics, and neurosurgery is their #1 problem in physician staffing today. The negative effects on emergency care for the public are obvious.

In light of these concerns, the Board strongly cautions against adopting the Report's recommendations as applied to surgical residents at this time. The risk to the quality of surgical training, the quality of subsequent surgical care, and patient safety is simply too great.

Impetus for the Report

The apparent impetus for the Report - public perception - does not provide a compelling reason to adopt the Report's recommendations. To the contrary, it provides a compelling reason to question them, particularly as applied to surgical residents. There are two places where we find an explanation as to why the ACGME should consider further resident hour restrictions - the charge from Congress that initiated the Report and the Report itself. The charge from Congress is very clear that the Committee is to review the evidence on "optimal resident work schedules" and recommend changes to the schedules to increase patient safety. (14) Rather than asking for objective evidence of the effect of resident duty hours on patient care, the charge assumes that a change in resident work schedules will increase patient safety and essentially requires a recommendation to that effect.

The Report also fails to provide an adequate explanation as to why the Committee recommended increasing resident work restrictions. Evidently, a high number of patients indicated in a survey that if they knew a doctor "about to perform their surgery had been on duty for 24 consecutive hours," they would feel anxious about their safety and probably ask for another doctor. (15) The Report cites this and similar evidence - based on public perception - as a "patient safety" concern behind these recommendations.

The survey suggests that large numbers of individuals outside of the medical profession feel that long working hours for doctors threaten patient safety. The Committee then applies this concern, about doctors in general, to residents. The Report uses this as a basis to make general recommendations to restrict resident hours.

Patients' subjective perception that they would not want to be treated by a doctor who has been on duty for twenty-four hours, without objective evidence or consideration of the potential risks of the alternatives, should not mandate a change in resident work hour restrictions. From a surgical perspective, one is left wondering how surgical patients would answer the survey question if posed in a more realistic context: "Would you prefer a well-rested doctor who is not familiar with your condition, to a tired doctor who is knowledgable about your problems and can provide the care you need?" "Would you prefer your doctors to leave in the middle of your surgical procedure so that fresh doctors completely unfamiliar with the first half of your surgery and your unique surgical needs can take over?" Intuitive responses to hypothetical questions regarding doctor and resident hours should not be the basis for profound changes to surgical residency programs. Instead, we should be guided by demonstrable evidence of how such changes affect patient care.

Lack of Causal Evidence

The Report openly acknowledges that the most basic, yet essential, evidence needed to support a change in resident hours - evidence of how residents and resident hours affect patient safety - is missing. According to the Report, "the impact of residents on patient safety is unknown." (16) Considering the lack of evidence demonstrating that long resident hours negatively affect patient safety, it is not surprising that the Report correctly observes that there is insufficient data to determine the "extent to which errors in performance by fatigued residents affect patients and cause them harm." (17)

The Report acknowledges that this lack of data constrained its ability to fully respond to the Congressional charge and that it used limited information to paint only a "partial picture of the relationship between residents, errors in hospitals, and patient safety." (18) Thus, according to the Report, there is insufficient data to show how resident hours impact patient safety. Without knowing how resident hours affect patient safety, we cannot determine, with any degree of confidence, whether any changes in resident hours, including the proposed recommendations, will actually improve patient safety.

In reality surgical residents operate within a strict hierarchial care system in which a fully qualified attending surgeon is in charge of all care administered within the hospital. Resident autonomy is limited, and all critical decision making regarding diagnosis and therapy as well as all performance of operations is directly overseen by on-site attending surgeons. The capacity for critical errors by residents, even if their working hours predisposed them to make such errors, would be obviated because of the oversight provided by attendings. For junior residents, such oversight is multi-layered, as they are immediately overseen by intermediate or more senior residents, and ultimately by attending surgeons. This feature of surgical residencies renders them substantially different from non-surgical residencies, where the level of on-site supervision may be less. The Committee showed no awareness of this difference, and its relevance to patient safety.

Continuity of Care - A Special Requirement of Surgical Practice

Several unique attributes of surgical practice mean that further constraints on resident hours and work patterns threaten surgical patient safety in ways they may not in non-surgical specialties. With surgical patients, it is essential that the same surgeon be involved to the maximal extent possible in the examination, diagnosis, intra-operative treatment, and post-operative care of each patient. Some level of shared responsibility is inevitable in the 24-7 ongoing care of critically ill patients, but crucial decisions and overall determination of care priorities should generally be vested in a single surgeon who has responsibility for the patient. While the concept of a "surgical team" is well established, it is equally important that the team have a leader so that care can be consistent and integrated; that leader is the patient's surgeon, who is expected to have the most comprehensive knowledge of the patient and to bear responsibility for the patient's outcome. This concept is ingrained in the ethos of American surgery and in the expectations of patients, yet it is this very ethos which is being undermined by the recommendations of the IOM report.

Concerns exist regarding the continuity of care in critically ill patients because they require not only the assessment of objective data such as laboratory values and radiologic images but additional dozens of subjective and qualitative clinical observations on a frequent basis. The patient's appearance and mental status, the respiratory and cardiac parameters, the assessment of physical signs in the abdomen and extremities – all of these involve qualitative observations by the responsible surgeon, and the evaluation of changes as indicators of patient improvement or decline. Most of these clinical observations are subjective, and a surgeon will remember his/her own findings from a previous period, but would have difficulty describing them with sufficient precision through a "handoff" to allow a surrogate who had not seen the patient before to know whether the patient had changed or not. Follow-up of a critically ill patient by multiple surgeons will therefore be inferior in regard to the quality and accuracy of daily observations, and the care which results will suffer from imprecise observations and delayed diagnoses. This principle underpins surgical care, with the recognition that detailed knowledge and careful daily tracking of the patient by a responsible surgeon who ensures continuity of care is vital to optimal surgical practice.

It is essential in training residents that they learn these processes of care, and the responsibility they undertake as the patient's surgeon, even though during residency they are operating under supervision of an attending and are not themselves responsible for overall direction of care. This training encompasses not only the intellectual appreciation of "how and why" such management is done, but also an appreciation of the moral obligation that the surgeon bears personal responsibility for conscientious oversight of the patient's care on a continuing basis and that the patient's outcome is crucially dependent on this. This type of experience and learning is essential to the training of competent and conscientious surgeons, and eliminating this leads to surgical training in which the resident learns that multiple hand-offs are acceptable, and that adverse outcomes resulting from lack of continuity are permissible. Arbitrary hour limitations, inevitably, threaten patient safety by reducing the quality of care received by patients treated by residents and by preventing residents from learning how to provide this essential aspect of surgical care. Data evaluating the effects of the 2003 work hours restrictions show that such adverse effects are already being observed. (19)

Disruption in Continuity of Care Provided by Residents

As already noted, there is no reliable data indicating that restricting resident hours improves surgical patient safety. (20) The Report acknowledges that previous resident hour restrictions have not resulted in even a modest improvement in surgical patient outcomes. (21) There are, however, significant data indicating that such restrictions have no benefit (22) and it has been posited that the lack of improvement in surgical patient outcomes may be due to the reduction in continuity of care and its unique importance in surgical practice. (23) Even more concerning, it has been suggested that hour restrictions may have harmful effects on surgical patient safety. (24)

The Report acknowledges that as resident hours are further restricted, patient handoffs will increase in frequency. Such handoffs are a proven source of patient errors. By decreasing continuity of care provided by residents and, concomitantly, increasing the frequency of patient handoffs, these proposed restrictions may therefore worsen patient care quality.

The Report recommends several ways to improve handoff procedures, but fails to recognize the insurmountable difficulties of accurately transmitting the qualitative and subjective data essential to continuous treatment of a critically ill patient. Both resident and non-resident surgeons are aware of this problem and sacrifice their personal time for their patient's safety by caring for their patients until it is safe for them to stop, not until an arbitrary shift ends. The Report recommends that handoffs be improved, but does not consider that they may not be amenable to improvement. The need for improved handoffs has been recognized in surgical care for more than two decades, and major efforts have been made to "improve" the process through computerization, check sheets, and a variety of other mechanisms, all with no discernable effect. This suggests that future improvement in handoffs cannot be assumed.

Resident input to the ACGME also shows that residents acknowledge that they may misrepresent their working hours if they feel a moral obligation to stay and provide continuity in patient management rather than leave at an arbitrary time. Our present system is therefore forcing residents to be dishonest in order to meet what they consider to be their moral obligation to patients – <u>how much more of an indictment is needed of the misguided and inappropriate nature of the hours regulations than a realization that residents who want to provide conscientious care for their patients are being forced to lie in order to do so!</u> Our educational systems should aim to strengthen and reinforce residents' moral and ethical behavior, not undermine it.

<u>Reduced Resident Experience in Operative and Postoperative Care</u>
Surgical care broadly subdivides into elective and emergency problems. Elective problems are those which do not pose urgent issues, and the diagnostic and treatment process can generally be carried out on a scheduled basis; elective care can be accommodated in a Monday to Friday 8 to 5 type of schedule. Emergency problems are entirely different. By definition they present in an unscheduled way, typically in a hospital emergency department or delivery suite, and they occur randomly at any hour. Since the normal workweek only consists of 40 hours, this means that there is better than a 3:1 likelihood of emergency conditions presenting outside of normal working hours during the other 128 hours of the week. Surgeons must therefore be on call and available to see such patients whenever they present, and must be prepared to manage and treat them promptly.

Resident training must necessarily involve the evaluation and treatment of such emergency patients, in order to become familiar with the multiple conditions involved, and the appropriate diagnosis and management of each. While there is a spectrum of disease which presents emergently, many such conditions are immediately life-threatening, and delays in diagnosis or treatment are directly correlated with increased mortality. The differential diagnosis of emergency conditions is medically complex and requires extensive direct experience with such patients for proficiency. No method of simulation or alternative training has yet been developed to replace this. Since the presentation of emergency patients occurs randomly, a resident's likelihood of seeing and treating such patients is proportional to the time spent in the hospital, and is one of the reasons resident training is an inefficient process that takes so long. If residents had only to be trained to treat elective problems, it could be done on a Monday to Friday daytime basis in less than five years, and the time spent could be scheduled efficiently.

Surgical specialties have unique challenges in learning to manage emergency conditions. The diseases normally seen as surgical emergencies, with few exceptions, represent a different spectrum of disease from those that present electively. Perforated bowel, acute diverticulitis, acute GI bleeding, and all the varieties of trauma, both blunt and penetrating, have unique presentations for which there is no elective analogue. As a result, surgical residents cannot obtain the needed experience in treating these conditions by treating only elective patients; they must obtain specific experience with emergency patients. The development of competence in the management of these emergency diseases requires considerable time to be spent taking emergency call, as a specific problem may occur infrequently, and the resident may have to be in the hospital for extended periods before encountering examples of the wide variety of conditions for which competence is necessary. This is obviously inefficient, but a resident's training is necessarily subject to the vagaries of patient presentation.

Work hours restrictions have lesser effects on resident experience with elective procedures because, as already noted, these can be scheduled and occur generally during a Monday to Friday daytime period. Experience with emergency procedures, however, decreases markedly with reduced resident hours. The ACGME does not separately tabulate emergency procedures in resident logs; hence there is presently no way to objectively assess the negative impact of current restrictions. However, trauma cases, which by definition are all emergencies, have decreased dramatically in surgery residents' recorded experience during the last few years, such that the RRC for Surgery has had to reduce its minimum requirements by 50%, to 10 operative cases from 20, even though the latter already represented marginally adequate experience.

Still other examples can be cited of negative effects of present work hours restrictions on resident operative experience. Surgical residents themselves have reported "doing fewer operations and missing out on learning opportunities." (25) Data also indicates the restrictions have decreased surgical residents' experiences in complex cases, in technically advanced procedures, and as first assistants. (26)

Data on the ACGME 2003 restrictions also suggest that reduced resident hours have decreased resident participation in reoperation on the same patient. (27) The ability to reoperate on the same patient is essential to residents' ability to learn the natural history and pathophysiology of disease processes and the elements of postoperative care. Failure to follow up and perform reoperations on patients when complications occur represents an abrogation of the most fundamental obligation to provide continuity of care to patients, as well as to appreciate the continuum of disease processes, but is often physically impossible for residents with present restrictions on work hours and allowed shifts. Thus the work hours restrictions are requiring residents to consciously abandon what is a basic obligation to patients.

Proposed restrictions on resident hours requiring that residents be given 10 hours off after a day shift, 12 hours off after a night shift, and 14 hours off after any 30-hour shift will unquestionably reduce residents' involvement in post-operative care. If diagnosis and active treatment of a patient took 16 hours, the restrictions would prohibit the resident from participating in the post-operative care of the patient that followed. A practicing surgeon who adhered to these same standards would be guilty of negligence and abandonment and could successfully be sued for malpractice. Such rules force the resident to lose out on the opportunity to learn the proper course of post-operative treatment for his patient and teach that patient abandonment is okay. Data showing that previous restrictions on resident hours have already decreased residents' participation in the continuous care of surgical patients is alarming given the extreme importance of continuity of care to patient outcomes and residents' need to be trained to provide this.

Data also indicates that resident hour restrictions have resulted in an increased shift mentality. Residents are effectively being trained to feel less personal commitment to their surgical patients and those patients' outcomes because of the arbitrary way in which they are required to manage their hours. The hours served are the essential mandate governing resident presence in the hospital – patient welfare and quality of care, and unique resident learning opportunities are both made irrelevant by these arbitrary rules. No element of common sense or logic is allowed to intrude on the rules – it does not matter that a resident on duty last night may have gotten a full 8 hours of sleep in the hospital, and therefore have no reason or need to leave early.

Exacerbating this effect is the probable need to use other medical professionals to fill the void left by absent residents. These professionals (nurse practitioners, advanced practice nurses, and physician's-assistants), more so than residents, work on defined shifts, usually of 8-12 hours length and their involvement only increases the disruption in the continuity of care provided to surgical patients, in addition to their having far less training and experience than residents. These professionals themselves acknowledge severe apprehension about being used to fill the personnel gap created by resident hour restrictions and their desire for more - not less - supervision if they were to play such a role.

As noted earlier, residents who became subject to the work hour restrictions in 2003 are only now beginning to graduate from residency. There has therefore been no opportunity to date to thoroughly evaluate the impact of the restrictions on their level of operative experience and competency. However, it seems clear that it will be less than prior generations of residents – the only uncertainty is the degree of reduction.

Data on How Previous Resident Hour Restrictions Affect Surgical Residency

Though data on the impact of the 2003 ACGME restrictions on surgical residents is limited, and comprehensive studies are in order, the Board is concerned by present indications that these restrictions have negatively impacted surgical patient care. Accordingly, we will discuss the results of one such study.

Before the ACGME's 2003 resident hour restrictions went into effect, several surgeons designed a study to "assess the impact of the 80-hour resident workweek restrictions on surgical residents and attending surgeons" by measuring and evaluating data collected from residents and attendings in a single academic surgical department. (28) The study measured changes in the components of residents' and attendings' daily activities and used quantitative data to measure the "quality of patient care, resident operative experiences, and resident knowledge before, and 1 year after the work-hour changes." (29) The study also used a survey, based primarily on the Maslach Burnout Inventory Human Services Survey ("MBI"), a well-tested and validated survey instrument, to measure perceptions of quality of care and quality of life. (30)

The study found that work-hours averaged 99.5 hours per week before the restrictions and 78.9 hours per week after. (31) The study's analysis of National Surgical Quality Improvement Program (NSQIP) results from cases before and after the restrictions showed no statistically significant differences in complication or mortality rates after the restrictions went into effect. (32) First-year and second-year residents saw a decrease in the number of surgical procedures they performed, but when aggregated with more senior residents, there was no aggregated difference in case volume after the restrictions. (33)

Study results suggest that the restrictions did not achieve their purpose of increasing resident sleep. "There was no measurable difference in the amount of sleep the residents got or the number of pages they received." (34) The restrictions seemed to have a positive effect on residents' leisure time - after the restrictions they were more likely to spend time eating lunch and reading. They were more likely "to spend time in teaching conferences." (35) Residents spent "less time rounding in the afternoon", "fewer days in the outpatient office setting.", and were less likely to be present in the OR before the patient went to sleep." (36)

Attending physicians felt residents were less prepared for their cases and teaching conferences after the restrictions. They also felt "the covering resident at night knew the patient less well" after the restrictions. (37) One year after the restrictions, attending surgeons perceived their interns to have "less technical skill, less clinical judgment, less sense of responsibility for the patient, less preparedness for cases, and less efficiency compared with the interns before the work-hour changes." (38)

The study also identified a troubling phenomenon. Educationally valuable clinical care opportunities for more junior residents were being lost because those residents are not available due to work hours restrictions. This resulted in an upward shift of clinical care to more senior residents and attendings for whom the educational value is far less and potentially diminishes their ability to focus on supervision of less experienced trainees. Participating attendings and residents felt that patient care had not suffered because, essentially, "the ball gets rolled up the hill." (39) Senior residents "pick up the slack" for junior residents and attendings pick up the slack for senior residents. (40) This was consistent with the study's finding that fifth year residents performed significantly more surgical procedures after implementation of the duty hour restrictions. A similar finding was made in another study that found no difference in trauma and emergency surgery patient volumes for senior residents after work hour restrictions, but found a shift in the median number of emergency surgery patients to more senior residents. (41)

The study findings suggest that resident hour restrictions have not achieved their goals as applied to surgical residents. The 2003 ACGME resident hour restrictions were designed to increase resident sleep in order to increase patient safety. According to this study, neither happened. It also identified another potentially negative effect of the resident hour restrictions – clinical care previously performed by residents working lengthy hours may get pushed to more senior residents or attendings. This could, in turn, affect attendings' ability to engage in the training of residents. The long term effects of this reallocation of clinical care are unknown and must be determined in order to understand what effect it may have on the quality of resident clinical training. (42)

Effects on Other Specialty Residencies

All physician care is overseen by professional standards defined by 24 specialty boards, of which the American Board of Surgery is one. These operate under the aegis of the American Board of Medical Specialties, which ensures a degree of standardization and uniformity among these boards in their requirements for the certification of physicians. Of these specialties, approximately two-thirds are minimally affected by work hour restrictions, because training of physicians in those areas can take place in a mostly elective way and does not require training in emergency care. Even some specialties which require training in emergency care, such as emergency medicine, radiology, or anesthesia, can adjust because the care they provide is acutely focused and episodic, and does not involve ongoing continuity of care in the hospital. They can therefore employ shift scheduling that will not affect the quality of patient care and can meet work hour limitations.

The remaining specialties which are significantly affected by hours restrictions therefore represent only about a third of the boards, and consist almost entirely of surgical specialties, plus selected subspecialties of internal medicine and pediatrics. Of this group, general surgery, orthopedics, neurosurgery, cardiac surgery, vascular surgery, transplantation, and obstetrics have the most intensive need for emergency training and therefore for extended hours in the hospital. These are the specialties which have been most negatively affected by present work hour restrictions, and would find it nearly impossible to maintain present standards of patient care and resident training under the proposed additional restrictions.

It seems anomalous that the present work hour restrictions developed by the ACGME do not recognize or reflect the differences in specialty training needs; the establishment of uniform work hour restrictions across all 24 specialties is illogical, given their marked differences in patient care requirements. It would be far more appropriate for the ACGME to allow each specialty RRC and board to define the most appropriate professional requirements and work hour standards for the highest quality patient care and most effective resident training, within broad universal standards. The surgeons of each RRC and board are those who are most knowledgable about the appropriate standards and needs for resident training in that specialty.

The second reality is that the number of residents who are negatively affected by work hours restrictions is small relative to the whole. There are approximately 25,000 residents in each yearly class in all medical specialties. Of this number, there are fewer than 1800 (7.2%) in the three specialty areas most affected – general surgery, orthopedics, and neurosurgery – and fewer than 4400 (17.6%) in all 10 surgical specialties. These are the principal areas where greater flexibility in work hours rules are needed.

In addition to the above, there are two real-life models that confirm the Board's view that additional restrictions on surgical resident hours should not be adopted at this time.

The New York Model

The Board is persuaded by data on the effect of New York State's resident hour restrictions on surgical patient safety. In 1989, New York State legislatively enacted resident work hour limits. Under the law, resident hours were limited to 80 hours per week averaged over four weeks. A resident's work period could not exceed 24 hours, and residents were required to have at least one 24-hour period off each week. Additionally, "physicians in training were also to be supervised 24 hours a day by in-house attending staff or senior resident physicians." (43) Virtually no hospitals complied with these restrictions until New York State began "inspecting teaching hospitals for work hour limit compliance" in 1998. (44)

One study measured the effect of the enforcement of these restrictions "on standardized surgical Patient Safety Indicators (PSIs) including the rates of accidental puncture or laceration (APL), postoperative pulmonary embolus or deep venous thrombosis (PEDVT), foreign body left during procedure (FB), iatrogenic pneumothorax (PTX), and postoperative wound dehiscence (WD). (45) It compared PSI trends from before and after enforcement of the restrictions in New York teaching hospitals and in two control groups (New York non-teaching hospitals and California teaching hospitals).

The study found that enforcement of the restrictions had no immediate impact in any group. It also found that, over time, New York teaching hospitals experienced increased rates in APL and PEDVT. There were no changes over time in the control groups for these same PSIs, and there were no changes in New York teaching hospitals for FB, PTX, or WD. The study provided evidence "that resident work hour limits enforced in New York State were not associated with surgical patient safety measure improvement in teaching hospitals." (46) The study ultimately concluded that "resident work hour limits in New York teaching hospitals were not associated with improvements in surgical patient safety measures, with worsening trends observed in APL and PEDVT corresponding with enforcement." (47)

These results are important because they suggest that the true impact of resident hour restrictions on surgical patient outcomes may not be evident immediately, and that they may worsen over time. They also provide measurable evidence over a sufficiently long period of time of such effects, which were ultimately non-existent or negative. This is consistent with the Board's assessment of the current data on resident hour restrictions as applied to surgical residents. As described above, the Board finds and the data shows that duty hour restrictions produce either no change or a negative change on surgical patient safety and that initial data may be inflated, reflecting more positive patient outcome rates than will be the case in later years.

The European Model

There is an even larger study that has shown how resident hour restrictions can adversely affect surgical practice - the European Working Time Directive ("EWTD"). This model admittedly contains tighter restrictions than those considered in the Report, but it nonetheless provides real world insights on how limited duty hours can affect surgical training, including what can result when individuals succumb to the temptation to allow elected officials to dictate medical residency requirements based on social perception rather than medical evidence.

The creation of the EWTD bears similarities to the proposed recommendations. Though enacted as legislation, the EWTD, at its inception, was termed "Protection of the clinical personnel against overwork for the benefit of Patients." (48) It was guised as providing protection to medical professionals in order to help patients and was based on the unproven assumption that long duty hours and lack of sleep causes medical errors and decreases patient safety. (49)

The EWTD limits working hours, including those of "trainees" (European equivalent of residents) to 58 per week. (50) This limit must be reduced to 48 per week by August 2009, the deadline for compliance with the EWTD. (51) Current EWTD requirements also mandate a minimum rest period of 11 hours in every 24 hour period. Work performed in hospitals can reach 60 hours per week, but after night duty, a trainee must leave the hospital and rest for at least 11 hours. (52) The EWTD shows how far restrictions can go when they are based on assumptions rather than evidence and are public opinion-oriented rather than patient-oriented.

The EWTD's effect on surgical practice has been remarkably negative. Detrimental effects include decreased patient interaction, decreased ability to learn from more senior professionals, decreased ability to follow full patient clinical history, and decreased participation in structured training. (53) Many of these same effects have been documented among American surgical residents since the 2003 ACGME resident hour restrictions, several of which are mentioned above. (54)

Studies of the European system have proven that no matter how efficient patient handover procedures become, "the loss of continuity of care has a detrimental effect on patient safety." (55) European surgical specialists conclude that the EWTD "has completely destroyed a training system that has been developed and continuously improved over 4 decades. "Training a competent surgical specialist with sufficient experience within 6 years is no longer possible" in Europe. (56)

The EWTD has negatively affected the general practice of medicine in Europe as well. Workforce shortages have been worsened, and a workable solution has not been found. The experience in Europe also fails to show benefits for patients. This evidence on the European experience is vitally important to any consideration of the effects of restricting resident hours. It is objective evidence of the damage these restrictions can cause, particularly in the surgical field.

Public Perception

The overriding problem with resident work hours regulations from the beginning until the present has been that the public does not understand why residents should have to work twice as many hours as the national average, and believes that residents are being exploited by senior physicians for financial gain, which is completely untrue. The controversy began with the Libby Zion case in New York, in which the tragic and preventable death of a young woman occurred in large part because her care was being overseen at night by a junior resident with inadequate experience, who had no on-site supervision or effective backup. Ms. Zion's father, Sidney Zion, no doubt because of his justified grief and rage at the system, and utilizing his power as a journalist, made this a cause celebre, and somehow the real errors morphed into an indictment of resident work hours and potential sleep deprivation, when in fact these had no causal role. To the public, however, it "makes sense" that long work hours are causative of errors in patient care, even though, as we have seen, no such connection is present when the question is actually examined, and the surgeons who are most heavily involved in providing such care have consistently rejected such a connection.

Public perception has been so strong that none of the involved agencies, including the IOM, has seriously considered that work hours limitations might have negative and adverse effects which are overriding, and might actually worsen care and training.

The public's perception of the issue, and fear of its possible effect on their own care, created a political groundswell for the external regulation of resident work hours. This was reflected in Congressional discussion in the 2001-2002 period that external regulation, either by Congress or OSHA, would be necessary. To retain professional control of the training environment, the ACGME asked to retain jurisdiction in setting hours standards, and in 2003 promulgated the current regulations . The ACGME no doubt felt constrained to establish regulations similar to those which had been approved in New York, in order to satisfy external political organizations and protect their own autonomy in overseeing residency training. The IOM Committee and Report which is the subject of this paper, were commissioned to evaluate the effect of these regulations after five years implementation and to recommend any needed change going forward.

The unfortunate aspect of this scenario is that the management of resident work hours has become a highly politicized issue in which objectivity and rationality have been submerged to hype, biased investigation, and third-party goals other than improvement in patient care. As we have tried to demonstrate, this has gotten us to a situation in which arbitrary hours regulations have assumed operational primacy over medical ethics and quality of resident training. Paradoxically, the very regulations which were promulgated to promote patient safety have had the opposite effect on continuity of patient care, have resulted in mandated resident behaviors which constitute definable malpractice, and have degraded the training of residents in specialties which are heavily dependent on experience with emergency care. The recommended modifications of the IOM Report in regard to shift limitations of 16 hours, mandated sleep of 5 hours, and other specific hours restrictions, are basically unworkable in the context of real patient care and resident training for these specialties, and in some cases would actually worsen sleep cycles of residents. The constitution of the IOM Committee was such that only two of seventeen members had any present involvement with resident training, and none of seventeen had any experience with the surgical specialties which are most affected by the regulations; it is not surprising that they would lack the experiential base to understand the effects of their recommendations on real-world resident training.

RECOMMENDATIONS

Restoration of Ethical Priorities

It is essential for the long term quality of patient care and resident teaching that future ACGME mandates return the primacy of patient welfare to the position it has enjoyed over centuries. It is unacceptable that residents today are being forced into behaviors in which clock-watching and adherence to arbitrary standards guide behavior, and the quality of patient care is secondary. Such training not only teaches the wrong ethics to trainees, but gives rise to expectations of later practice which are unrealistic and which lead to avoidance of responsibility for emergency call. This latter problem is already being seen and represents a major problem in the future provision of care to the public.

The second priority, after patient care, is the quality of resident education and training, and the need for the development of resident competence in practice, so that they are prepared for all contingencies after completion of residency. In selected specialties training in the care of emergency conditions is essential, and emergencies constitute a large part of the clinical experience which residents in those areas must obtain. Present restrictions are degrading the quality of training in multiple ways that will ultimately result in reduced willingness and ability of the affected surgeons to provide needed emergency care to the public.

Global work hours restrictions have been shown to be needed to limit the extremes of resident hours, and the IOM Committee has determined that a continuation of the 80-hour limit is appropriate. In addition, restriction of on-call in-house duty to an average of one night in three, the requirement for one day off in seven, and the stipulation that a resident should not undertake care of a new patient after a 24-hour period of service are all consistent with good patient care and should not negatively impact resident education. The Committee's recommendation that moonlighting be included in total work hours is also appropriate. However, the specifics of implementation in regard to shift length, and time off should be made more flexible, should be individualized to each specialty, and should always be made secondary to the provision of the highest quality patient care and the preservation of optimal resident education, which are optimally determined by educators in that specialty area. In particular, residents should never be required to leave an operation they have begun because an arbitrary time has passed, nor prohibited from providing needed monitoring and care for patients on whom they have operated.

The variability in medical requirements, intensity of work, and opportunities for sleep are highly variable across specialties, hospitals, and individual days of duty. It is unrealistic to expect that uniform shift lengths can be adapted to these continuously variable patient responsibilities on any given day. The imposition of such rigidity creates problems that are impossible to integrate into the usual processes of patient care. The additional shift length restrictions proposed by the IOM Committee would worsen this situation to the point of complete impractibility.

For millennia, professional ethics and personal responsibility have guided physician care, and will no doubt continue to do so in the practice setting. The same standards should be restored to resident training, and should take priority over arbitrarily established hours requirements. Imposition of rigid hours restrictions has no place in the clinical work environment, and is inimical to the teaching of autonomy and personal responsibility needed for optimal resident functioning. The establishment of global limits in defining an 80-hour week is all that is needed to ensure the central purpose of the resident work hour restrictions.

Individualizing work hours restrictions by resident level

The second suggestion we offer is that the markedly different nature of resident responsibilities during the five years of general surgical residency require different commitments of residents to patients. Residents at the fourth and fifth year level in particular have advanced to the point where they are asked to independently assess patients, make clinical decisions, and provide operative care, all under the supervision of attendings. It is crucial for them to perfect these skills before entering independent practice. An essential feature of senior and chief level resident training is putting them in situations where they can exercise independent judgment, as they will have to do in practice, but to do so in a supervised environment where patients are protected.

Continuity of care for a given patient is especially vital for senior residents at these levels, and without it they are unable to develop an appreciation for the progression and resolution of various disease states, and the consequence of operations. Arbitrary work restrictions that force residents who have direct patient care responsibilities to leave the hospital during operations, or to miss specific portions of a patient's postoperative care is a form of mandated negligence. Such requirements are unacceptable in regard to patient care quality and medical ethics and they are teaching residents exactly the wrong behavior.

For these reasons, it is essential that, at a minimum, the work hour restrictions be relaxed for senior and chief residents in the circumstances where emergency experience and continuity of care are most important in the development of competence. These residents should either be exempt from hours regulations, or expected to comply with them only as guidelines, secondary to the exigencies of patient care. Residents themselves have shown by their behavior that they already feel an obligation to behave appropriately, and we must stop requiring that they abandon professional obligations for arbitrary standards.

CONCLUSION

The residency system prior to the change in work hours worked well to produce competent surgeons. The competency of the residents completing the current system remains to be assessed. Any changes to the system must be based on demonstrated and identifiable deficiencies and should not create greater harm than they propose to solve. The assumption that resident hours relate directly to patient safety and the public perception that long resident hours are threats to care are not empirically supported.

There is insufficient evidence linking length of resident hours to patient safety generally. There is ample evidence that such restrictions have no or negative effects on surgical patient safety. The unique requirement of continuity of care in surgical practice indicates that further restricting resident hours will negatively affect surgical patient safety by decreasing the quality of care residents provide surgical patients and by decreasing the ability of residency programs to produce competent surgeons. There is evidence suggesting we have not seen the full negative impact of previous restrictions on surgical patient outcomes and that they may be worse than the data currently shows. This suggestion is supported by the New York state study. Finally, there is documented and very persuasive experiential evidence from Europe that resident hour reductions increase risks to patient safety, particularly in the surgical field.

The problem with currently mandated work hour restrictions is not per se with the 80-hour limit, but with the rigidity with which shifts are defined. Flexibility needs to be introduced into the work hours requirements such that unique needs of different specialties can be accommodated, and the work hours can be made secondary to the primacy of patient care and the opportunities for resident learning. Medicine for centuries has been self-regulating as a profession, and the arbitrary external enforcement of work hour restrictions attacks the very professionalism that has served the best interests of patients and residents alike. The present restrictions therefore need to be modified to allow flexibility in application, especially for residents at a senior and chief level who are at a point in their training where they are developing independent judgment and decision making capabilities. It is inherently unacceptable at present that a system has been constructed which forces dishonesty among residents in order to allow them to meet their moral obligations to care for patients or to pursue unique learning opportunities.

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The following surgical boards wish to endorse the preceding position paper and indicate their substantial agreement that similar concerns and problems are seen in their specialty area.

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36. Id.

37. Id. at 866-67.

38. Id. at 867.

39. Id. at 868.

40. Id.

41. Curet, Resident Work Hour Restrictions, 207 J. Am. C. of Surgeons at 770.
42. Meltzer, More Work to Do, 298 JAMA at 1056.

43. Benjamin K. Poulose, MD, et al, Resident Work Hour Limits and Patient Safety, 241 Annals of Surgery 847, 848 (June 2005).

44. Id.

45. Id. at 847.

46. Id. at. 852-53.

47. Id. at 847.

48. Surgical Disciplines of the Countries of the European Union, The European Working Time Directive and the Effects on Training of Surgical Specialists (Doctors in Training): A Position Paper , 148 Acta Neurochir 1227, 1227-28 (2006).

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50. About WTD, Healthcare Workforce Portal, http://www.healthcareworkforce.nhs.uk/wtdaboutus.html.

51. Id.

52. Id.

53. The European Working Time Directive, 148 Acta Neurochir at 1229.

54. Hutter, The Impact of the 80-Hour Resident Workweek, 243 Annals of Surgery at 868.

55. The European Working Time Directive, 148 Acta Neurochir at 1229.

56. Id.

THE SOCIETY OF THORACIC SURGEONS

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April 28, 2009

COPY SENT VIA E-MAIL

Thomas J. Nasca, MD, MACP
Chief Executive Officer
Accreditation Council for Graduate Medical Education
515 N. State Street
Suite 2000
Chicago, IL 60654

Dear Dr. Nasca:

Thank you for your February 19 correspondence to our Executive Director, Rob Wynbrandt, soliciting input on various issues related to ACGME's review of its standards for Resident Duty Hours and key dimensions of the Learning Environment. We appreciate this opportunity to respond on behalf of The Society of Thoracic Surgeons ("STS").

STS is committed to the education of all cardiothoracic surgery residents and the practice of post-graduate surgeons. We approve any initiative which improves the quality of our residents' education, expedites safer medical/surgical care, and improves the safety of the general public.

We have received and reviewed the suggested changes in resident duty hours as proposed by the Institute of Medicine in its December 2008 Report, "Resident Duty Hours: Enhancing Sleep, Supervision, and Safety." The Society acknowledges the initiative of the Institute of Medicine ("IOM") to further regulate resident duty hours to enhance sleep, supervision and safety, thereby anticipating a reduction in preventable adverse events ("PAEs") and improvement in patient outcomes.

We note that the well-written article, "Cost Analysis for the Institute of Medicine Project, 'Optimizing Graduate Medical Trainee (Resident) Hours and Work Schedules to Improve Patient Safety," authored by Teryl Nuckols, MD, MSHS and Jose J. Escarce, MD, PhD, acknowledges the following:

A. There is no current evidence that further decreasing the resident work hours will decrease PAEs; in fact, the three studies referenced demonstrate no change in surgical PAEs since implementation of the 2003 standards.

B. There is no current evidence that reducing resident hours further will affect resident or public safety.

C. Reducing resident hours further would necessitate increasing the number of hand-offs per shift, further disrupting the continuity of patient care and thereby potentially *increasing* the incidence of PAEs. Furthermore, the concept of protected nap time after 16 hours would necessitate another layer of providers who are expensive to provide (no financial plan is in place currently), difficult or impossible to find, and a further obstacle to the concept of patient care and continuity. The current proposal dictates further additions to week-end time off, requiring 5 weekend days off per month, as well as the day off following the night on call, totaling 13 days off per month. Because patient responsibility is a cornerstone for professionalism in cardiothoracic surgical residency programs, these interruptions in continuity of care increase risks of multiple hand-offs, degrade the concept of professionalism, and produce shift-work mentality rather than surgeons with an inbred commitment to the doctor-patient relationship.

D. There is no mechanism in place to provide personnel (either physicians or physician extenders) to off-load the proposed administrative burden resulting from further duty hour restrictions.

E. Funding this initiative is theoretical at best:

    i. The cost analysis of this initiative is between $500M - 1.6B (in 2006 dollars) and would likely be much higher.

    ii. Financing must be achieved through third-party payers (CMS, VA and others) as they, not the hospital, profit most from decreasing PAEs.

    iii. There is no reliable monitoring system available, nor is it financially feasible to adopt one.

    iv. The current attending cardiothoracic surgeons have borne the burden of resident hour reduction by being the only common element of continuity for patient care, providing the necessary increased coverage for out-patient clinics, intensive care units, and operating room time. (Because health care reimbursement is a zero sum game, financing the cost of this initiative by further reducing cardiothoracic surgeon reimbursement would be disastrous.)

Most importantly, there is no evidence that the IOM plan improves resident education. In fact, based on American Board of Thoracic Surgery examination results since 2003, the opposite would be true.

The Society of Thoracic Surgeons supports:

A. Limited or no moonlighting;

B. Continued initiatives to improve resident education through simulation, e-learning and new curricula;

C. Initiatives to improve resident safety within the teaching institutions; and

D. Continued need for institutional systems changes to reduce PAEs.

Furthermore, because there is little or no evidence that the proposed changes (enhancing sleep, supervision and safety) will produce the proposed results (decreasing preventable adverse events), the Institute of Medicine has not proven to The Society of Thoracic Surgeons that the plan is effective, educationally advantageous, or fundable. In fact, results of the 2007 ACGME Resident Survey, administered four years after the common duty hours standards took effect, indicated that the number of hours residents slept per week was *not* different than the number of hours slept per week prior to implementation of the 80-hour work week. Although the rule decreased the number of hours per week that residents could spend in the hospital and was based on the premise that residents were sleep deprived, the residents did not sleep any more. Such data imply that even if the number of hours residents spend in the hospital is reduced further, there is no evidence to suggest that such restrictions would lead to more sleep. It will, however, further compromise their education.

It also should be noted that for the past five years, cardiothoracic surgery has not filled its available residency program positions. As a result, the country will be facing a critical shortage of cardiothoracic surgeons within the next 5-8 years. Reducing resident exposure to patients and surgery could possibly lengthen the training process (already one of the longest), undoubtedly contributing to further declines in the numbers of cardiothoracic surgery residency program applicants and accelerating the severity of this pending shortage.

The Society of Thoracic Surgeons feels strongly that the current duty hours limitations have hurt the education of cardiothoracic surgery residents by diminishing continuity of care, minimizing professionalism with regard to doctor-patient relationships and adversely impacting patient safety because of inadequate system improvements to limit PAEs. Any further restraint in work hours would only magnify these current deficiencies. The 80-hour work week standards have been in effect only 5 years, and it is premature to consider overhauling a revised system that has not been tested.

The Society is willing and eager to participate in the Resident Duty Hours and the Learning Environment Congress proposed by ACGME for June 2009. A broad spectrum of specialties must be represented in such an important meeting. Not all medical and surgical specialties are the same. A "one-size-fits-all" approach to resident duty hours is impractical and ultimately unworkable for surgical specialties. Surgery is different; and cardiothoracic surgery, a subspecialty that trains two to three years beyond general surgery training, is unique. We would welcome the opportunity to bring this added experience and perspective to the table.

Thank you again for inviting these comments. We look forward to hearing from you.

Sincerely,

Gordon F Murray

Gordon F. Murray, MD
President

George L. Hicks, Jr., MD
Chair, Workforce on Graduate Medical Education and Thoracic Surgery Resident Issues

cc: STS Board of Directors
STS Workforce on Graduate Medical Education and Thoracic Surgery Resident Issues
Mr. Robert A. Wynbrandt
Ms. Nancy Gray Puckett

ASSOCIATION OF PEDIATRIC SURGERY
TRAINING PROGRAM DIRECTORS

George W. Holcomb, MD, MBA, President
Keith T. Oldham, M.D., Secretary/Treasurer

April 10, 2009

Thomas J. Nasca, MD, MACP
Chief Executive Officer
Accreditation Council for Graduate Medical Education

Dear Dr. Nasca:

We write to represent the views of the Association of Pediatric Surgery Training Program Directors (APSTPD) as revisions to the ACGME Resident Duty Hour Standards and the related December 2008 recommendations of the Institute of Medicine are considered. To be clear, this letter summarizes strongly held consensus views among our group, developed after extensive discussion among all program directors, relevant additional faculty and our trainees.

We are in agreement with those groups and individuals representing the public interest and with other various stakeholders with regard to the general goals of the current standards and the recent IOM recommendations: 1) to improve patient safety, 2) to alleviate fatigue among trainees, 3) to improve supervision by senior physicians, 4) to improve communication at times of transferred responsibilities ("hand overs") and 5) to transparently and honestly comply with appropriate work hour standards. To these, we wish to add emphatically the two most consistent concerns articulated by our trainees: to maintain the quality of surgical education and to do so without lengthening the obligatory period of training for future surgeons.

The quality of the educational experience must <u>not</u> be diminished. Indeed, a key responsibility of a Program Director is to certify at the conclusion of training that each of our graduates is competent to practice the specialty independently. In a discipline such as pediatric surgery, the clinical experience required for competence demands exposure to episodic bedside and operating room events which are routinely complex, infrequent and sometimes fleeting. For example, the types of newborn surgical emergencies which led to the development of this discipline (eg. congenital diaphragmatic hernia, esophageal atresia/tracheoesophageal fistula, gastroschisis/omphalocele, sacrococcygeal teratoma, conjoined twins and others) occur with frequencies from approximately 1 per 2000 live births to as few as 1 per 50,000 to 100,000 live births. Even today in a high volume center, a trainee may complete training with exposure to only a few individual patients with a given anomaly. Sufficient flexibility to allow trainees maximal access to these relatively infrequent but critical educational events <u>must</u> be retained in the work hour standards. Didactic and Socratic educational activities as well as simulations and other formats support, but cannot replace, this clinical exposure.

At present, trainees are required to have a minimum of 7 years of postgraduate education for eligibility for certification in Pediatric Surgery by the American Board of Surgery (ABS). Many of our residents have participated in research training and most have 9 to10 years of graduate medical education. This means that most trainees are into their mid 30's or beyond when they enter clinical practice. Issues such as a high personal debt burden, very modest salaries during training, worries about advancing maternal age for women, and other family issues are already perceived as real disincentives to those considering a career in pediatric surgery. Efforts to shorten, not lengthen training for physicians are receiving serious consideration in a number of forums. If standards are adopted which sufficiently restrict work hours and therefore clinical experience, the competence standard will not be met without extending training further. We do not believe that a well rested but insufficiently practiced graduate properly serves the public or any other interest.

With increasing regulation and requirements for maintenance of competence, retirement ages in surgery have declined. The shortage of manpower in general surgery and related specialties has been the subject of considerable public attention in recent months and years. Simultaneously, work hour limits and other factors have decreased the exposure of general surgery residents to children, so that fewer recently trained general surgeons in the US treat children, leaving many communities with no appropriate surgical providers for the 25% of their population made up of children. Thus, there is real tension generated by the competing needs to provide sufficient clinical exposure for surgical competence, to meet manpower demands, and to achieve the goals enunciated by the IOM. It is our considered opinion that lengthening the educational period for pediatric surgery would be detrimental to the specialty and our patients and families.

Since entry level trainees in pediatric surgery have a minimum of 5 years of postgraduate medical education and are eligible to sit for, or have already obtained certification by, the American Board of Surgery they have substantial clinical perspective and personal maturity at the outset of this training. As the ACGME considers work hour standards, we submit that because our trainees already possess or are eligible for a primary ABMS certificate (from the ABS), and are making a transition to practice, they are best served with standards that allow the type of professional self assessment and monitoring that will soon follow. We believe that a combination of general and specialty specific standards should be developed with regard to work hours, just as they are currently for the other program requirements.

We do concur that adequate supervision of trainees by faculty is an essential component of all training programs. Our pediatric surgery programs rigorously provide senior surgeon supervision for all aspects of care of children. Our goal is always to maximize children's safety.

The APSTPD shares a number of highly relevant but more generic concerns articulated by other organizations as well:

1) Although data linking human fatigue to diminished performance in a variety of experimental and real life circumstances are clear, there are no data which demonstrate improved patient safety or better clinical care in a surgical training environment through the specific policies recommended in the IOM report. At a time of considerable public emphasis on evidence-based decision making in medicine, it is particularly ironic that policies of such import be recommended without specific supporting data. We believe it is incumbent upon the various decision making bodies in this process to develop directly applicable data including patient safety endpoints and assessments of educational impact to inform this process, both now and going forward.

2) On the other hand, there is a consensus view among our program directors and some data to indicate that every "hand over" of responsibilities, no matter how well designed or executed, includes some potential for loss of information and perspective about an individual patient. While transitions are necessary events, we believe a goal of the Common Resident Duty Hour Standards should be to create a

system which minimizes, rather than maximizes, the number of these transitions. We do support the recommendation that structured hand overs be developed and taught in all training programs in an effort to minimize this potential risk to patient care.

3) With regard to enforcement, we suggest that appropriate, flexible duty hour standards that best meet the training needs of the various surgical disciplines will result in improved compliance, more accurate reporting of work hours, and better data from which to develop meaningful enforcement policies.

4) Concerns have been raised at the March 2009 ACGME meeting and elsewhere that both fiscal and additional manpower projections by the IOM ($1.7 billion annually; and an additional 5984 mid level providers and 5001 attending physicians nationally) are substantial underestimations of the actual needs in order to successfully implement the IOM recommendations. Individual members of the IOM task force have stated that without adequate funding and manpower, their December 2008 recommendations cannot succeed. New standards must be supported with appropriate resources from relevant institutions and governments. To require adherence to additional "unfunded mandates" by the graduate medical education community and related physician practice groups will not be a successful strategy.

5. In your February 20, 2009 open letter to the ACGME community, you suggest that a cultural shift in the relationship between physicians/surgeons and their patients may be accelerated by the IOM recommended changes. We share that concern. The tradition of dedicated individual care and accessibility to expert health care for children is an essential feature of pediatric surgical practice. We believe a culture of personal surgeon responsibility and engagement improves patient care and we know it is expected by the families of our patients. We strive to develop this in our trainees, we demand it of one another after training, and we believe strongly that our young patients benefit as a result.

To conclude, we agree with you that "one size does not fit all", and agree with the concept that specialty specific duty hour regulations are needed to adequately train the next generation of pediatric surgeons. The uniqueness of our specialty and the small number of training programs (34 in the U.S.) differentiate it from other specialties and require solutions that may be different from larger programs with many junior trainees.

We appreciate your attention to this very important issue and our concerns. We look forward to working further with you in this effort.

W Holcomb

George W. Holcomb, III, MD, MBA
President
Association of Pediatric Surgery Training Program Directors

Keith T.

Keith T. Oldham, MD
Secretary/Treasurer
Association of Pediatric Surgery Training Program Directors

CC: Tom Russell, MD, Executive Director, American College of Surgeons
Michael Harrison, MD, President, American Pediatric Surgical Association

Comments

of the

American Board of Neurological Surgery
Society of Neurological Surgeons
Residency Review Committee for Neurosurgery
American Association of Neurological Surgeons
Congress of Neurological Surgeons

to the

Accreditation Council for Graduate Medical Education

on the subject of

Resident Duty Hours

April 30, 2009

Staff Contact:
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American
Association of
Neurological
Surgeons
Harvey Cushing

The American Board of Neurological Surgery
Inc 1940

The Society of Neurological Surgeons
19 20

Congress of Neurological Surgeons
1951
Eruditio Observantia Societas

EXECUTIVE SUMMARY

1) *Your organization's formal position on the recommendations contained in the Institute of Medicine Report, including impact analysis, from your organization's perspective, on costs and impact of implementation*

Conclusions:

- It would be virtually impossible for a typical neurosurgical program to be in compliance with the proposed IOM duty hour rules, while at the same time maintaining appropriate patient care and resident education activities. Under one model, a hypothetical neurosurgery program would be in violation under the new IOM proposed regulation and would have to sacrifice 80 hours of program activity ***each week***.
- The negative effects of the proposed IOM regulation far outweigh any possible benefits. These include:
  - Lack of patient continuity of care, increase the number of risky patient hand-offs
  - Reduced clinical experience and educational opportunities
  - Flattening of the hierarchical nature of neurosurgical training, which inhibits a resident's growth into a more capable and mature surgeon, leaving him or her ill-equipped for independent practice
  - Eroding the trust between the attending physician and resident, impairing the resident's experience in the operating room

Recommendations:

- The ACGME should follow its present plan of analyzing the impact of the current work hour restrictions and carry out the proposed pilot projects emphasizing flexibility and recognition of the differences between medical and surgical specialties.
- The ACGME is the appropriate institution to monitor and oversee resident training and education, including setting and enforcing resident duty hour rules. We oppose the IOM's proposal for a "complementary oversight role for both the Centers for Medicare and Medicare Services (CMS) and the Joint Commission."

2) *Your organization's formal position on the current ACGME Resident Duty Hours Standards including impact analysis, from your organization's perspective, on costs and impact of implementation*

Conclusions:

- Mastery of the knowledge and skills required to expertly manage the extensive and wide-ranging list of neurosurgical disorders clearly requires several years of continuous commitment and intensive experience.
- The results of several studies and surveys demonstrate a number of deleterious effects from the current duty hours standards, including:
  - A drop in overall scores on the written examinations
  - A reduction in the overall hours of surgical experience
  - A need to employ midlevel practitioners to assume some of the activities that residents previously performed (reducing resident experience),
  - Reduction of time in elective operations
  - Compromises in the continuity of care
  - Altered conference schedules
- These studies also demonstrate that more medical errors in neurosurgery derive from transfers of clinical responsibility ("handoffs") than from fatigue.
- Current duty hours rules are leading to the development of a "shift mentality" and loss of professional responsibility to the patient.
- Neurosurgical practice is unlike virtually any other physician specialty. Neurosurgical procedures are long, lasting an average of 4 hours, but often more than 8-10 hours. Residents must develop the capacity to see long operative cases through from beginning to end.

Recommendations:

- Allowing a more flexible schedule within the 80-hour week would help residents internalize the importance of the continuity of care and of taking personal responsibility for their patients

3) *Your organization's formal recommendations regarding dimensions of Resident Duty Hours standards, and justification (wherever possible) for this position with evidence*

Conclusions:

- Duty hour standards must vary according to the level of training; junior residents spend more time "in house" and can fit into a "shift" approach better than senior residents who are assuming a greater degree of responsibility for patient care.

Recommendations:

- A paradigm for graduated responsibility and work hours for neurosurgical training:

  PGY 1-3: Residents taking in-house call are the "first contact" for patient care.
  - 88 hours/week, averaged over 4 weeks
  - 1 day in 7 off duty, averaged over 4 weeks
  - 10 hours off between duty shifts
  - In house call (24 hour shift) may be followed by up to 10 hours to permit resident to attend in the operating room, participate in didactic activities and maintain continuity of care.

  PGY 4-5: Residents in a supervisory role or not taking call in-house. By definition, these individuals are not the "first contact" for patient care.
  - 88 hours/week, averaged over 4 weeks
  - 1 day in 7 off duty, averaged over 4 weeks

  PGY 6 (or last year of training): chief resident
  - 1 day in 7 off duty, averaged over 4 weeks

4) ***Your organization's formal recommendations regarding standards governing key aspects of the Learning Environment, and justification (wherever possible) for this position with evidence***

Conclusions:

- The production of well-trained neurosurgeons requires:
  - Technical mastery, which requires many hours to achieve and effective duty hours standards should not limit necessary operative experience
  - Professionalism and surgical ownership; patients expect their surgeon will be present to see the patient throughout their surgical encounter and duty hours should not interfere with this, especially in the senior or chief residency year
  - Graduated and supervised responsibility throughout the evolution of the residency training period
  - Fatigue management

- Neurosurgical training takes up to 7 years, and if further duty hours standards require extending clinical training, residents are unwilling to train for longer periods of time and the recruitment of high quality, talented medical students to the field would be compromised.

Recommendations:

- Neurosurgical practice is unique and duty hours standards must reflect this fact.
  - The scope and breadth of neurosurgical disease requires a diverse set of surgical skills without substantial overlap by other specialties
  - Neurosurgeons lack meaningful counterparts in other specialties to provide similar care in their absence.
  - Operations are long and technically demanding; the average operating time of four hours doubles other fields
  - The diversity of operations demands that each resident gain exposure to the range of normal post-operative recovery and the recognition of untoward, immediate post-operative complications
  - Neurosurgeons face a substantial outpatient load and a unique workforce demand to staff trauma centers and take care of emergency neurosurgical cases

5) ***Your organization's willingness to participate, if invited, in a Resident Duty Hours and the Learning Environment Congress, to be held in June 2009 in Chicago Illinois. This Congress will be configured to provide the ACGME leadership will the breadth of perspectives of the medical community as they embark on review and revision of the Resident Duty Hours and Learning Environment Standards***

- Neurosurgical organizations will enthusiastically participate in the Resident Duty Hours and the Learning Environment Congress in Chicago in June. Representatives from ***each*** of the neurosurgical organizations would like to participate:
  - American Board of Neurological Surgery
  - Society of Neurological Surgeons
  - Residency Review Committee for Neurosurgery
  - American Association of Neurological Surgeons
  - Congress of Neurological Surgeons
- Invitations and details about the Congress meeting (registration, hotel, etc.) may be sent directly to Ms. Orrico, whose contact information is provided on the cover sheet and at the end of this letter.

American
Association of
Neurological
Surgeons

April 30, 2009

Thomas J. Nasca, M.D., MACP
Chief Executive Officer
Accreditation Council for Graduate Medical Education
515 North State Street
Suite 2000
Chicago, IL 60610-3422

Dear Dr. Nasca,

On behalf of the American Board of Neurological Surgery, the Society of Neurological Surgeons, the Residency Review Committee for Neurological Surgery, the American Association of Neurological Surgeons and the Congress of Neurological Surgeons, we thank you for the opportunity to comment on the Institute of Medicine report, "*Resident Duty Hours: Enhancing Sleep, Supervision, and Safety*," the current ACGME resident duty hour standards and provide you with our views on resident duty hours standards for neurological surgery. In response to your recent letter, this document represents Organized Neurosurgery's position paper. Our specialty looks forward to participating in the ACGME process to evaluate this important issue. Our responses to your inquiries are indicated below:

1) ***Your organization's formal position on the recommendations contained in the Institute of Medicine Report, including impact analysis, from your organization's perspective, on costs and impact of implementation***

Introduction and Background

Though unregulated for the better part of a century, the individual apprenticeship model of graduate medical education has been eroded in stepwise fashion and replaced by a team-based approach over the last two decades. The now famous 1984 Libby Zion case provided anecdotal impetus for reducing resident work hours.[1, 2] Political pressure funded and led to the publication of the Institute of Medicine (IOM) report "*To Err is Human,*" which culminated in the establishment of the 80 hour work week by the Accreditation Council for Graduate Medical Education (ACGME).[3] The concepts that fatigue in house officers places patients' safety at risk and inhibits education of residents has been the driving force behind the Institute of Medicine's recent recommendation to further restrict and regulate the distribution of resident work hours.[4] Many previous authors have noted it ironic, that in a field where data driven decision making is held as the gold standard, trends in graduate medical education instead appear to change with political palatability.[5, 6]

The 2003 work hours regulations designed by the ACGME and those proposed by the 2008 IOM report have thus far been assumed to benefit patients' safety and residents' education alike regardless of specialty.[7] This paper seeks to analyze the impact of the proposed regulations on small surgical subspecialties, using neurosurgery as the model. Our hypothesis is that for smaller and more deeply specialized programs the effect of imposing evenly distributed work hours not only imposes a disproportionate burden on these smaller programs but also significantly inhibits education of residents, placing future generations of patients at risk.

Table 1: Summary of IOM recommendations

Proposed IOM duty hours regulations	
Maximum hours	80 hours per week averaged over 4 weeks
Maximum shift length	30 hour shifts only allowed if 5 hours of protected sleep time are identified, otherwise 16 hour shift maximum
Maximum in hospital call frequency	Call may not occur more frequently than every third night, no averaging
Minimum time off between scheduled shifts	10 hours off after day shift 12 hours off after night shift 14 hours off after extended 30 hour
Maximum frequency of in hospital night shifts	48 hours off after 3 or 4 consecutive night shifts
Mandatory time off duty	5 days off per month, 1 day off per week (no averaging); 2 days off must be consecutive
Moonlighting	Moonlighting included in duty hours

Table 1 summarizes the IOM committee's recommendations. The committee suggested that new regulations to provide patient coverage could follow one of two paths. First, a resident could work 30 hours, but after 16 hours into that shift should be required to nap for five hours and then use the remaining time for education or patient hand offs. The alternative plan calls for straight 16-hour shifts. Residents must also have 5 days off per month, 2 of which must be consecutive.[4] The effect of these regulations are not to change the overall hours worked by residents, but instead to more closely regulate their distribution, and to eliminate the common practice of averaging work hours over a 4 week period such that each resident would work a more regulated and specific daily or nightly shift.

Without a large number of residents with multiple people in house each night, neurosurgery – and other surgical specialty programs – would be forced to adopt the 16-hour model taking into account the 10 hours off after every day shift and 12 hours off after night shifts with 48 hours off mandated after 3 or 4 night shifts in a row. We intend to discuss here the direct and indirect effects of these regulations on providing safe patient care and an adequate educational experience for residents. We will emphasize that it is not the 80 hour workweek but the inflexibility of how these hours are distributed that make this system untenable.

Methods

With these restrictions in mind, we have used a typical neurosurgical residency educational structure and patient care volume to construct a scenario, which models the impact of these rules on training. This hypothetical neurosurgery program performs 1500 cases per year at two hospitals (one major academic center and a smaller community hospital or VA), has a seven-year training program (1 year of internship and 6 years residency), has two residents per year (total of 12 neurosurgery residents), 3 physician assistants, and dedicates 2 training years to research. The program provides residents with 3 weeks of vacation per year and 1 week to attend conferences or courses. The program dedicates one morning per week (Wednesday) as an academic morning during which few or no cases are scheduled, in order to provide additional lectures and education for the residents as a group. The object of this exercise will be to look at the impact of these regulations on patient safety and the educational variables that make up an excellent training program and produce competent clinical and academic neurosurgeons.

When drawing conclusions regarding impact there are certain assumptions, we make. First, we understand that no two programs are alike in educational resources and patient volume. Secondly, we will assume that the major philosophy driving neurosurgery training for many years still holds - that a minimal volume of cases are necessary for technical competence, that exposure to evolving neurological disease requires the continuity of following a single patient's change over time in order to assimilate clinical judgment, that senior residents must learn to attend to their patients at any required moment in order to simulate the responsibility expected of them after training, and finally that only research exposure during residency will continue to provide the next generations of academic neurosurgeons to move our field forward and to provide valuable analytic techniques for all neurosurgeons regardless of the career path they choose. As the new restrictions force residency programs to alter the manner in which residents function, we prioritize resident activities in the following order:

1. As continuous as possible patient care coverage
2. Adequate surgical volume for the training of safe and competent neurosurgical residents
3. Hierarchical shifting of responsibility from more junior to more senior residents
4. Educational conferences
5. Research activity

Results

In Tables 2 and 3, we quantify and graphically depict the number of clinical man-hours required each day and by category to cover the activities of the program each week. This is approximately 1077 hours covered by twelve residents and supplemented by three PA's working forty hours per week each. The residency is divided into thirds: 4 junior residents, 4 mid-level residents, and 4 senior residents. We assume that a well-trained physician assistant can function between the level of an intern and junior resident by providing floor or ICU care so long as a physician is immediately available to them; they are not trained or expected to take independent in-house call.

Table 2: Total hours for all residents by day of week

	Monday	Tuesday	Wednesday	Thursday	Friday	Saturday	Sunday	Total
Total actual work day	177	165	209	165	202	80	80	1077
PA coverage	24	24	24	24	24			120
Resident work hours	153	141	185	141	178	80	80	957
Average length of resident weekday	13.9	12.8	16.8	12.8	16.1			
Evenly distributed 80 hour week	137	137	137	137	137	137	137	960

Table 2 accounts for the hours spent by residents and physician assistants on all service activity for an average week, including ICU and floor coverage, consults, emergency room coverage, rounding, operating, clinics, conferences, and research activity; the total number of resident work hours rest within current ACGME limits for an 80 hour work week. In the second row, the hours spent by the physician assistants are subtracted from this total, leaving the man-hours worked each day by the residents (row 3). This total is divided amongst the available residents to arrive at the average workday per resident (row 4). When compared with the hours available in an evenly distributed 80-hour workweek such as the IOM suggests, one sees that every weekday would exceed the evenly distributed available man-hours for the service, highlighted in yellow, in some cases significantly. Both weekend days fall well under the required hours, highlighted in red. It is interesting to note that the total hours worked by residents in the week (957 hours) does not violate the 80-hour rule for the week (960 hours).

In order to be in compliance with the 10 hour off rule and return to work on time the following day, no resident may work more than 14 hours per day. Thus, the practical work day for a small surgical service is 14 hours under the IOM proposal, not 16 hours, and total work hours on Wednesday and Friday exceed this limit. Our hypothetical neurosurgery service would violate this shift limit on Wednesday and Friday under the IOM proposal, indicating that some activities of the service would need to be sacrificed – no amount of shuffling or shifting residents would prevent this sacrifice. Additionally, the service would be unable to schedule its residents to work 14 hours per day consistently, as this would quickly violate the total hours per week, leaving the service without call or weekend coverage. The solution is to decrease the daily work hours to an even distribution of shift work, as indicated by the red line. In addition, the table does not take into account the hierarchical nature of a neurosurgical service. All residents are shown with an even distribution of the work. However, the senior and chief residents work in a supervisory capacity. They are often engaged in the longest of the operations and have irregular hours; thus most frequently violating the 10-hour rule.

This table highlights another aspect of the strict regulation of shift distribution. Though the IOM has not explicitly recommended a decrease in the total hours worked per resident, they have forbidden averaging resident work hours over a four-week period. As a result, though there are 12 residents in the program, because each resident is provided 3 weeks vacation and 1 week for conferences a courses, there are only 11 residents available each week. This would effectively decrease the total hours available each week from 960 hours to 880 hours. These extra hours were previously available since work hours could be averaged over a 4-week period. Again, the hypothetical neurosurgery program would be in violation under the new IOM proposed regulation and would have to sacrifice 80 hours of program activity *each week*.

Table 3: Distribution of total work hours by category

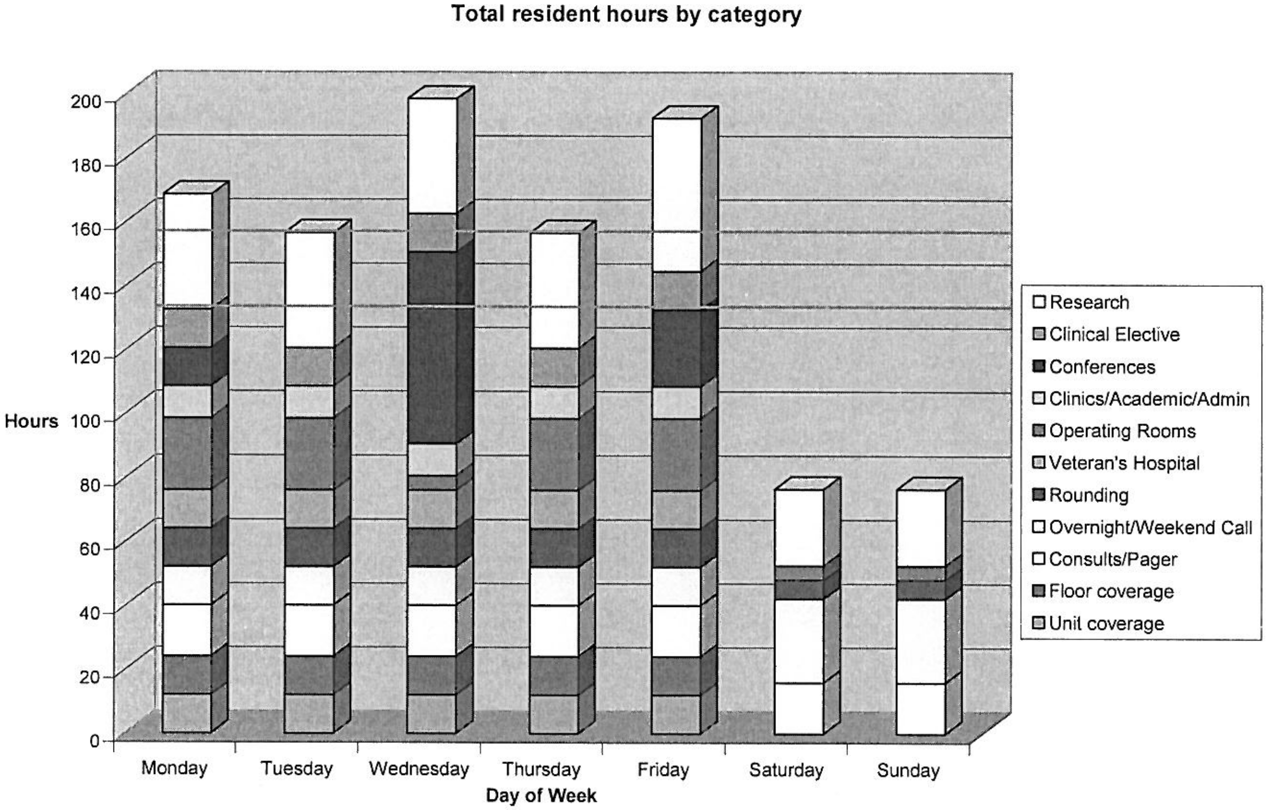

Table 3 graphically depicts the distribution of resident activity and specifies the category in which activity occurs. Categories are ordered bottom to top from most critical to least critical (as specified in the priorities identified above). The red line indicates 126 hours, or the evenly distributed 80-hour workweek amongst 11 residents. Though any individual shift could last up to 14 hours for a day shift (green line) and still be in compliance with the 10 hour off rule for rounds the next morning, the whole service cannot behave this way and still remain within the 80-hour rule and 5 days off per month rule. Hence, the reasonable expectation for a small surgical subspecialty service is to evenly distribute the hours over the course of the week. Of note, there is considerable variation in the number of hours required each day based on conferences, educational activities, and operative volume; in particular, the "academic morning" requires considerably more man-hours, since the clinical needs of the service remain constant for that day. When comparing the actual hours needed for service activities each week with what would be available based on the new IOM regulations, it is apparent that all five weekdays would be in violation, most strikingly on Wednesday and Friday when most educational conferences occur and the workday extends to 16 hours on average.

It is important to note that this analysis does not account for unscheduled operations or unanticipated long cases. It is not unusual, for example, for a case to be postponed due to another emergency and to start later in the afternoon than expected. A resident who finishes operating late in the evening may not return to work for 10-12 hours depending on the length of his or her shift. That resident must then search for an available resident to cover for his patients for rounds the following morning, and thereby creates a domino effect, which ultimately results in a dilution of quality care. For smaller programs, finding available coverage becomes increasingly more difficult, and may lead to gaps in coverage, which would need to be filled by attendings who are not currently subject to regulation and which would leave residents out of the patient care loop, simultaneously impairing their ability to learn how to care for these challenging patients.

Discussion

There are many ways to approach the issue of how one may most efficiently and safely provide patient care concomitant with quality medical education. The current IOM recommendations have focused on the effects of sleep deprivation, using available sleep literature to support proposed regulations that would more strictly disperse periods of rest. We believe that this proposal is short sighted, and fails to consider the educational and patient safety tradeoffs inherent in this equation; while a more rested resident is good, a 33% reduction in educational conferences and an 80% reduction in research is not.

Below we highlight four areas where we believe the negative direct and indirect impacts of the IOM proposal would outweigh any benefit. Fundamentally, it seems counter-intuitive to attempt to regulate the even distribution of work in a field where natural variation in clinical volume inherently exists both in planned and unpredictable fashion. In order to provide safe care, allow for educational activities, and facilitate research projects, residency programs must be allowed flexibility to distribute work hours in an optimal fashion.

- ***Providing continuity of care and clinical judgment:*** Although the committee offers a 16 hour shift, no resident can work that shift during the day starting at the usual 5:30 AM rounds and be able to attend morning rounds the following day, nor would they be able to scrub on a 7:30 AM case the following day because of the overlap of the 16 hour shift and the ten hour at home rule. Thus, a resident who has worked up and followed a patient who requires surgery that may go beyond 7:30 PM will not be able to scrub that case. Each day shift must be no longer than 14 hours; each night shift must be no longer than 12 hours.

- ***Daily variation of clinical volume and educational opportunities:*** No two clinical days are alike. The above tables and charts demonstrate the necessary planned variation in any typical week; unplanned variation would only amplify the above findings. The average workday on Wednesday becomes 15 hours long for the entire service, and for some residents it is likely longer. These residents must return the following morning to care for their patients and go to the operating room. The disadvantages to shortening their workday are similarly unpalatable – one simply cannot replace the educational advantage in bringing together the residents for conferences; replacing weekday conferences with weekend conferences is similarly unacceptable since this would violate already existing work hours regulations. Distributing them throughout the workweek would mean limiting resident participation in the operating room, or reduce the number of residents attending the conference. Flexibility to accommodate variation in volume – be it medical or surgical emergencies, or planned educational conferences – is critical both to the educational and clinical mission of the department.

- ***Flattening of the organization:*** To some degree, the hierarchical nature of medicine and neurosurgery has already changed with the 80-hour rule. This has shifted a great deal of service work to PA's and CNP's. Indeed, flattening an organization is an effective tool used in many organizations to improve efficiency and allow young creative minds additional autonomy. However, the hierarchical nature of training is important both educationally and for patient care. For example, when the junior resident can formulate a decision and then present to the senior/chief resident they both learn from that interaction. This critical component of data analysis and decision-making would be eliminated should the senior or chief resident replace the junior resident in the call schedule. Likewise, major decisions are never made without attending input, which adds to the education of both junior and senior residents and solidifies patient safety by providing redundancy in a system designed to solve complex problems. The degree to which this redistribution and flattening of the hierarchy should occur remains a debate and we believe the new regulations take this too far. This not only inhibits a resident's growth into a more mature surgeon who may help craft decisions but also creates an artificial training environment which will leave him or her ill-equipped to care for patients in the faculty or private neurosurgical role.

- ***Eroding of the trust between attending and resident:*** Neurosurgery faculty allow their residents progressive degrees of independence based upon their trust in the resident's technical ability and dedication to the patient. To some degree, this trust is built over many hours, days, weeks, months, and years of observing their clinical work. Let us be clear: the stakes are high when an attending permits a resident to dissect an acoustic neuroma from the brainstem. Mistakes which result in neurologic injury here cannot be undone. Should that patient later develop a complication which the resident is unable to help with because of the 10-hour rule, the attending neurosurgeon would be left alone to manage the postoperative hematoma or hydrocephalus. How, the next time, would this surgeon feel when deciding whether to turn the operative chair over to the resident? We believe that erosion of this trust

> which is an indirect result of the new IOM regulations may impair all residents' experience in the operating room.

Training exposure to multiple nervous system problems includes acute immediate surgical interventions for trauma and vascular diseases, urgent intervention in most forms of brain tumors, and more elective approaches to disorders such as epilepsy, movement disorders, and pain. What each of these disorders has in common, however, is that surgical intervention is most often dependent on detecting a change in neurological condition over time. That change may be dramatic and sudden such as a stroke or hemorrhage or may be slow with subtle neurological changes as pressure build up in the brain or a nerve malfunctions from compression. Regardless, during early years of training, residents are taught to recognize neurological change, understand the implications of that change and develop clinical judgment regarding when intervention is necessary and what form that intervention should take. The senior and chief years of training are most often devoted to combining this experience with close mentorship in successive subspecialties, where a special bond emerges between resident and faculty. The common ground here is, of course, the individual patient, and learning proper continuity of care begins with a decision to intervene, the operation and the follow up. It would be professionally destructive for a chief resident to engage in a long complicated procedure where he or she assumes a major role in surgery, guided and observed continually by the attending and then not to complete a surgery or attend to that patient's potential complication because it falls at a time after a 16 hour shift. That behavior will not only fail to teach the resident about how to handle a postoperative problem but will break the bond of trust between mentor and student and resident and patient. The lack of patient follow-up would be even more absurd in patients evaluated in the many "resident" clinics throughout our medical centers where the residents are clearly identified by the patient as *their* doctor. Would these patients find it acceptable that their doctor could not care for them at night because work hour regulations forbid it?

It is clear that there were several advantages to the first work hour restriction rules. Hospitals responded by providing support staff in the form of PAs and nurse practitioners, better ancillary services and continual progress in electronic streamlining systems such as an EMR and digital imaging systems. Neurosurgery has been working with the ACGME to pilot trials that may have made certain restrictions, such as the 10 hour at home rule, more flexible for our senior residents. Organized Neurosurgery has also been working on major curricula changes in order to improve competency-based training, enfold fellowships in the residency programs and work to shorten and improve the quality of our present system. We believe that none of the suggested rule changes should be forced on our specialty and that we should continue to work within the present system, collecting data on our training product and outcomes on our patient care.

We recommend that the ACGME follow its present plan of analyzing the impact of the current work hour restrictions and carry out the proposed pilot projects emphasizing flexibility and recognition of the differences between medical and surgical specialties.

Though there will always be resistance to change, we feel that our analysis describes a training model which is anathema to what we – and the American public - expect of future neurosurgeons. Those who choose the field do so with knowledge and understanding of the challenges which lay before them. Altering our training system to create a surgeon who may lack the tools necessary to care for the thousands of patients who will come before them puts generations of patients at risk. Until we better understand the tradeoffs at stake, we are obliged to adhere to the long-tested principles of neurosurgical training – responsibility, professionalism, and dedication. These may only be taught through experiential learning and mentorship, which can no more easily be scheduled into a 16-hour shift than an aneurysmal rupture.

Duty Hour Regulation

Organized Neurosurgery wholeheartedly believes that the ACGME is *the* appropriate institution to monitor and oversee resident training and education, including setting and enforcing resident duty hour rules. We therefore strongly oppose the IOM's proposal for a "complementary oversight role for both the Centers for Medicare and Medicare Services (CMS) and the Joint Commission." Neither of these organizations has the requisite knowledge, infrastructure or experience to take on such a role, and from our perspective it is outside their missions to be involved in resident training and education.

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2) *Your organization's formal position on the current ACGME Resident Duty Hours Standards including impact analysis, from your organization's perspective, on costs and impact of implementation*

Neurosurgery's position on the current ACGME Resident Duty Hours Standards and the impact of their implementation

When a patient presents to a neurosurgeon for assessment and treatment the neurosurgeon has to have had training sufficient to expertly manage and execute a series of decisions and interpretations. These begin with taking a detailed history, interpreting the salient points, as well as performing a neurological examination, to reach a preliminary diagnosis. To reach a reasonable preliminary diagnosis the resident must have knowledge of a myriad of neurological disorders, surgical and non-surgical, affecting the brain, spinal cord, and peripheral nerves. S/he must then decide on what diagnostic tests to order, and must be able to correctly interpret them. These include MRI, CT, electrodiagnostic studies (EEG, EMG, NCV), lumbar puncture and CSF analysis, pituitary hormones, and others. The resident must then consider a range of diagnostic possibilities, reach a differential diagnosis, and provide the patient with a recommendation. This requires that s/he be knowledgeable of the medical and surgical options for treatment, and their expected benefits, limitations, and associated complications. The resident must have experience with the natural history of a wide range of disorders, so that s/he can decide if and when to intervene with treatment. If a surgical treatment is needed, s/he must be able to select the optimal operation, plan the procedure, and expertly perform the surgery. This requires not only fine motor skills, precise knowledge of neuroanatomy and neurophysiology, and experience and practice in precisely executing many different surgical procedures, but also experience and knowledge to make the correct decisions for a range of contingencies that can occur during surgery. The resident must also have the stamina to maintain concentration and peak performance for operations that often take many hours. After the surgery, s/he must be able to provide expert postoperative care, including the capacity to diagnose and manage a range of potential complications for each disorder that s/he treats. This list of essential skills and knowledge are required for a wide range of disorders within each of a long list of categories of disease including, but not limited to, brain trauma; spinal trauma; degenerative disease of the spine; brain tumors; spinal cord tumors; metastatic tumors; pituitary tumors; CNS infections; cerebrovascular disease from ischemic stroke, or hemorrhagic stroke caused by aneurysms or arteriovenous malformations or hypertension; pediatric disorders such as hydrocephalous; scoliosis; epilepsy, Parkinson's disease and other abnormal movement disorders; pain syndromes from trigeminal neuralgia to chronic pain disorders; etc. The list is extensive.

Concerns related to the 80 hour work week since its introduction in 2003

Mastery of the knowledge and skills required to expertly manage this extensive and wide-ranging list of disorders clearly requires several years of continuous commitment and intensive experience by even the most capable individual. When the 80 hour/week limitation was introduced there was considerable concern that the reduced experience that it would produce would compromise the clinical and academic experience of neurosurgical residents and that it would lead to a "shift" mentality, which would have substantial repercussions on the adequacy of the performance of neurosurgical care when the resident was finished and engaged in the independent practice of neurosurgery. Whether the 80-hour workweek has resulted in these expected changes in training is, to a certain extent, unknown, as a detailed prospective study of its effects has not been performed.

However, the effects of the 80-hour week have been studied by examining the cumulative number of hours in surgery during neurosurgical residency, indicators of cognitive knowledge, such as the scores on the written neurosurgical examination of the ABNS, and by surveys of neurosurgical residents and neurosurgical program directors. The results of these studies and surveys indicate that there has been a drop in the overall scores on the written examinations since 2003, a reduction in the overall hours of surgical experience, the requirement to employ midlevel practitioners to assume some of the activities in the operating room and the clinic that residents previously performed (reducing resident experience), reduction of time in elective operations, compromises in the continuity of care, and altered conference schedules. The studies/surveys also suggest that more medical errors in neurosurgery derive from transfers of clinical responsibility ("handoffs") than from fatigue.

However, because it is difficult to quantify, there is limited information on the most concerning aspect of the effects of the 80 hour work week, that of the development of a "shift mentality" and a loss of the development of a sense of professional responsibility to the patient by the resident as part of his training. This concern derives not entirely from the 80-hour workweek limitation, but is, to a great extent, a product of the inflexibility of the current restrictions.

Distinguishing features of the practice of neurosurgery and of neurosurgical training

Several features of neurosurgical practice are different from many other medical disciplines. For example, neurosurgical emergencies are common, they often develop at night, and they often require systematic evaluation of changes in language, level of consciousness, or motor performance, serially over time to judge the optimal care of the patient, evaluation that must detect subtle changes. These serial evaluations are best performed by the same individual, not only for optimal patient care, but also as part of a valuable resident experience.

Neurosurgical cases last an average of four hours. Many take considerably longer, often more than 8-10 hours. The self-discipline to maintain intense concentration steadily over many hours and the stamina needed to retain peak motor and intellectual performance over several hours are learned by practice and experience, and are critically important features of neurosurgical training.

If residents do not have the capacity to see a long operative case through to the end, if they must leave a patient in the midst of a critically important interval of their patient's care in the intensive care unit, operating room, or on the ward, not only do they lose the training necessary for optimal patient care, in and out of the operating room, but, just as importantly, we risk that they will not develop an essential and core component of neurosurgical training, that of taking personal responsibility for their patients' care. It is this "shift mentality," a trend toward not internally assuming responsibility for individual patients that is among neurosurgical leaders' greatest concern of the effects of the 80-hour workweek.

Flexibility in the guidelines for distribution of the schedule within the 80-hour week would help the resident to internalize the importance of the continuity of care for their patients and of taking personal responsibility for their patients.

Residents perspective of the 80 hour work week

This was the first year that neurosurgery participated in the national Resident Matching Program (NRMP). All 191 available positions were filled, 90% with US Seniors. Among all disciplines, only 3 with at least 100 positions offered had at least 90% of the positions filled by US seniors, all of which were surgical subspecialties -- neurosurgery, orthopedics, and otolaryngology (Data from NRMP 2009). This suggests that graduating medical students consider the current 80-hour workweek acceptable.

Despite that a recent survey of active neurosurgical residents indicated that the 80-hour week had provided more leisure time and more time for reading, written ABNS examination scores have not increased. In fact, they have dropped in the years since implementation of the 80-hour week. Written examination scores for neurosurgical residents taking the exam for self assessment dropped from 310 in 2002 to 259 in 2006 (a 16% decrease; $p<0.05$). Further, although there was an increase in the number of resident registrations to the annual meeting of the American Association of Neurological Surgeons, the number of abstracts presented by residents decreased from 345 in 2002 to 318 in 2007 (a 7% decrease; $p<0.05$).

Summary

It is the position of organized neurosurgery, in general, that the implementation of the current 80-hour resident duty hour limitation has had adverse effects on resident training, but that those adverse effects can be mitigated by greater flexibility in the requirements, flexibility that will enhance the preparation of neurosurgical residents for the independent practice of neurosurgery.

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3. Khalessi AA. Neurosurgical Resident Survey of Duty Hour Policy 2009. In preparation.

3) *Your organization's formal recommendations regarding dimensions of Resident Duty Hours standards, and justification (wherever possible) for this position with evidence*

Recommendations for Dimensions of Resident Duty Hour Standards

Our organizations are deeply concerned about achieving a successful balance between patient safety/resident physician health and ensuring that the US public has access to well trained and responsible neurosurgeons. Neurosurgery training programs have incorporated the 80 hour work week as a viable standard, though a substantial minority of programs (43%) have requested and been granted an 8 hour/week education exception. We believe that duty hour standards must vary according to the level of training; junior residents spend more time "in house" performing a wide range of activities and can fit into a "shift" approach better than senior residents who are assuming a greater degree of responsibility for patient care, both in the operating room and afterwards. The following recommendations acknowledge several factors in place today: (1) almost 50% of program directors believe that 8 additional hours are needed to satisfactorily meet educational goals; (2) the 10 hour rule is a major impediment for senior resident training; (3) there is a major difference between surgical training and medical training -- junior surgical residents are very closely supervised both in the operating room and in post-operative care by more senior residents and attending physician staff; and (4) small surgical programs such as neurosurgery have substantially less flexibility in staffing -- the majority of programs have between 1 to 2 residents at each post graduate year. Accordingly, we strongly recommend the following dimensions for resident training in neurological surgery:

PGY 1-3: Residents taking in-house call and/or are the "first contact" for patient care.

- 88 hours/week, averaged over 4 weeks
- 1 day in 7 off duty, averaged over 4 weeks
- 10 hours off between duty shifts
- In house call (24 hour shift) may be followed by up to 10 hours to permit resident to attend in the operating room, participate in didactic activities and maintain continuity of care.

The nature of these dimensions increases the flexibility for house staff and program directors to modify a daily schedule to maximize the educational experience. By restricting the total hours to 88/week, requiring 10 hours rest between duty cycles, and insuring 1 day in 7 free of duty, residents have sufficient opportunity to rest and engage in personal activities. We recognize this is a demanding schedule- neurosurgery is a demanding profession with the highest of stakes. Since these junior physicians are highly supervised, the chance for patient harm due to a tired physician is minimized.

PGY 4-5: Residents in a supervisory role or not taking call in-house. By definition, these individuals are not the "first contact" for patient care.

- 88 hours/week, averaged over 4 weeks
- 1 day in 7 off duty, averaged over 4 weeks

Specifically, the 10 hours off between duty shifts is eliminated for these individuals since their schedule requires much less moment to moment patient contact (outside of the operating room). Residents at this level are supervising, assigning tasks, and checking on results reported by the junior residents as well as participating to a much higher extent in lengthy operations.

PGY 6 (or last year of training): chief resident

- 1 day in 7 off duty, averaged over 4 weeks

The chief resident is making a transition to practice where s/he will be entirely responsible for a patient's well being, before, during and after neurosurgical intervention. These individuals need to assimilate the professionalism and clinical skills to perform in practice which most commonly consists of 2-4 neurosurgeons in a community hospital setting, covering 1-3 hospitals.

4) *Your organization's formal recommendations regarding standards governing key aspects of the Learning Environment, and justification (wherever possible) for this position with evidence*

Standards Governing the Learning Environment

In commissioning the Institute of Medicine to review resident duty hours, Chairman Dingell's letter to the AHRQ cited "a skilled and knowledgeable workforce" as a necessary prerequisite to any regulations geared towards patient safety.[1] Resident duty hours are no exception. Standards governing the learning environment thus represent an important starting point in guaranteeing the continued production of well-trained physicians. For surgical disciplines, performance outcome measures include: (1) technical procedural skills, (2) medical fund of knowledge and patient care, and (3) professional ethics and conduct.

Technical Mastery

Neurological surgery routinely involves unforgiving disease processes and manipulation of the most vulnerable organ system. Technical competence is not sufficient; effective neurosurgical intervention demands technical mastery. Well-established literature studies the concept of mastery in fine motor tasks. Concert musicians, for example, require 20,000 practice hours to achieve elite performance levels. Patients demand no less from their neurosurgeon. Effective duty hour regulation must not limit such operative experiences.

Professionalism and Surgical Ownership

Medical fund of knowledge and professional ethic concerns in neurosurgical training coincide with the interests of other medical specialties. Surgery involves a certain audacity; surgeons perform invasive procedures on their patients in hopes of making them better. The surgeon-patient agreement carries an implicit understanding that the surgeon will be present to see the patient throughout their singular, and at times harrowing, experience. The culture of ownership and doing what a patient's care demands are central pillars of the neurosurgical training experience.

Moreover, the Carpenter dilemma raises the insidious threat to professionalism posed by existing duty hour standards.[2] When duty hour restrictions interfere with an important but ill-timed patient care task, physicians-in-training face a conflict between regulatory compliance and patient advocacy. The maintenance of the physician-patient relationship cannot come at the expense of personal integrity.

One hundred years of neurosurgical education rests on the culture of graduated and supervised responsibility. Coupled with appropriate systems management of fatigue, modern training methods assure adequate resident preparation for the unique elements of independent neurosurgical practice. Subsequent discussion explores the neurosurgical learning environment, and greatly informs contemplated changes in resident duty hour standards. The senior and chief neurosurgical residency fosters technical maturation, facilitates junior resident instruction, and reinforces the committed professionalism required for effective neurosurgical practice. Duty hour standards should not interfere with this senior experience.

Graduated and Supervised Responsibility

Neurosurgical residency training fundamentally differs from the culture of some other specialties. For example, the hierarchical approach of surgical training inverts the pattern wherein tremendous responsibility is borne by junior individuals in the medical and pediatric paradigms. In contrast, senior and chief level neurosurgical residents dictate all aspects of patient care with supervised junior involvement in a manner commensurate with their individual level of ability. Review of the junior and chief neurosurgical resident responsibilities will elaborate this critical difference, and emphasize the importance of treating senior and chief level residents differently with new duty hour restrictions.

These important differences may explain the differing impact of existing duty hour standards on medical and surgical resident well-being. While Gopal et al. found decreased emotional exhaustion and trends towards decreased depersonalization and depression among medical residents with duty hour restrictions, Gelfand et al. found no difference in these parameters among surgical residents.[3,4] Neither group reported greater job satisfaction with duty hour standards.[4] Duty hour standards may provide a floor for the most vulnerable residents in medical specialties, and a ceiling that obstructs the progress of the otherwise well-compensated, senior surgical resident. The different patterns of responsibility for patient care between medical and surgical specialties may further explain the data tying fatigue to patient safety in medical patients, and the paucity of such studies in the surgical literature.[2]

Junior Neurosurgical Residency

In terms of technical skills development and medical fund of knowledge, the junior residency provides a "book end" approach to neurosurgical training. Perioperative management, ranging from surgical indications to ICU and wound care, represents foundational medical knowledge. Ancillary neurosciences including pathology, radiology, and neurology augment this early patient care experience. Procedural skills center on patient positioning and stepwise mastery of operative opening and closing. Safe approach, meticulous hemostasis, and efficient wound closure are essential prerequisites for any successful surgical procedure, and therefore the early emphasis of junior resident training. Finally, outpatient and emergency department consultations allow the junior resident to recognize neurosurgical emergencies in a timely fashion and take the appropriate initial steps in care.

Professionally, the junior resident's responsibilities are even more straightforward. First, reliable reporting of information to senior residents demands honesty at all times. Second, when given a set of clinical duties, the junior resident must provide an accurate accounting of completed tasks to allow resolution of outstanding patient care by the senior resident. Finally, junior residents must know their limitations and exercise a low threshold in requesting senior help. Adherence to these three principles will assure a successful junior resident. It falls to the senior resident to be supportive and available. In the neurosurgical culture of delegated responsibility, the chief sets the professional tone.

Senior and Chief Neurosurgical Residency

The senior and chief residency in neurosurgery cements the culture of ownership fundamental to successful neurosurgical care. Chief neurosurgical residents participate throughout a patient's surgical encounter, and develop technical proficiency in the key aspects of the patient's surgical case. Investment in the surgery itself breeds concern and engagement of the chief resident in the perioperative course. This involvement prepares the chief resident for the rigors of independent practice at a time when the maximal support of senior attending staff remains available, and sets an important example for the junior residents. Duty hour regulations must not abridge this critical process.

Beyond technical skills development and issues of professionalism, chief level continuity mitigates against the transfer-of-care errors that impact patient safety. The hierarchy of surgical culture renders the military analogy appropriate. Rotation of infantry can rejuvenate a war effort; switching generals may bring disaster. Given that further duty hour restrictions rely on a greater number of care transfers, later discussion revisits the magnitude of transfer and fatigue-related errors on patient safety.

Finally, fundamental changes in the structure of senior neurosurgical residency threaten the cornerstone of medical education, the attending academic neurosurgeon. Grady, Batjer and Dacey rightly emphasize the reluctance of an attending to trust a chief with the critical technical elements of a case when duty hour restrictions would preclude resident management of the complication resulting from a technical failure. Without a basic principle of ownership, the technical development of senior neurosurgery residents would be stunted by this unease.[5] Of greater concern, the ACS cites increasing faculty dissatisfaction and the prospect of faculty attrition from academics in the face of greater duty hour restrictions.[2] Despite professional commitments to the contrary, diminished accountability for their mistakes denies surgical residents a fundamental element of their technical education, and taxes the altruism of the most dedicated medical educator.

Fatigue Management

Fatigue management at the individual resident level follows from a culture of graduated, supervised responsibility. Senior residents and attending staff closely monitor the efficacy of junior residents and make adjustments to provide for effective patient care. Senior residents participate throughout a patient's course at a time in their training when conditioning, patient care skills, and insight are sufficiently honed to minimize the deleterious effects of fatigue on patient safety.

At a systems level, redundant checks from pharmacy and nursing may decouple resident fatigue from errors reaching the patient. Duty hour reductions serve as the crudest policy instrument to manage fatigue, and are premature when a single cohort of neurosurgical residents has yet to train completely under the existing duty hour standards. The absence of data tying surgical patient safety to fatigue-related errors reinforces this concern. Indeed, patient safety meta-analyses clearly demonstrate the outperformance of private institutions by academic medical centers.

Barger et al. case-crossover analysis of 2,737 interns self-reporting of fatigue related errors provides one of the principal empiric supports for fatigue related errors impacting patient safety. Aside from the questionable ability of an intern to judge a medical error at this early stage of training, the data places the magnitude of fatigue-related errors in an important context. Though the fatigue related error rate was 0.038 in person months, only one-tenth (0.003) impacted patient safety in terms of an adverse event (0.002) or fatality (0.001). Moreover, 0.064 of respondents, or roughly double, reported making significant errors due to issues other than fatigue; one-fifth of non-fatigue related errors led to an adverse outcome (0.010) or fatality (0.003).[6]

Thus, patients were five times more likely to suffer an adverse event and three times more likely to suffer a fatality due to a non-fatigue related error. The trend persisted for 1-4 extended duty hour shifts and only reached non-significant equal footing with greater than 5 extended hour shifts. The data reinforces the current system's success in shielding patients from fatigue-related errors, the dominance of other error sources such as transfer of care, and the importance of insulating junior level practitioners from fatigue. Only at a limitless number of extended hour shifts did fatigue-related errors begin to balance the patient safety impact from other sources of medical errors.[6]

Duty hour regulation must further account for the dramatic variety in day-to-day tasks across medical specialties. Work environment matters. Emergency physicians, for example, independently adopted a shift approach to manage a relentless emergency department census and acknowledge the lesser importance of continuity in short, acute clinical interactions. Radiologists, with a dark ambient environment and attention to detailed pertinent negatives, must manage fatigue in a manner different from surgical specialties. Neurosurgeons engage in active, physical tasks requiring extreme and trained focus. Prolonged attention and the stakes involved prompt a sustained sympathetic discharge familiar to any neurosurgeon, and rarely duplicated in scenarios outside of the operating room. These unique practice environments, while anecdotal, are well-described and merit consideration in any discussion of fatigue management.

Unique Elements of Neurosurgical Practice

The scope and breadth of neurosurgical disease requires a diverse set of surgical skills without substantial overlap. Neurosurgical residents must enjoy significant exposure to each area to function in independent practice. Unlike other fields, neurosurgeons lack meaningful counterparts in other specialties to provide similar care in their absence. Operations remain long and technically demanding; the average operating time of four hours doubles other fields. The diversity of operations further demands each resident gains an exposure to the range of normal post-operative recovery and the recognition of untoward, immediate post-operative complications.

Aside from these practical issues surrounding neurosurgical procedures, neurosurgeons face a tremendous outpatient load and a unique workforce demand to staff Level I trauma centers. These aspects of neurosurgical epidemiology and health service delivery emphasize the vigorous practice awaiting neurosurgical trainees. A successful neurosurgical workforce must necessarily manage these diverse clinical responsibilities.

Continuity of care is central to neurosurgical practice. With the highest critical care census per capita, the opportunity for the senior or chief resident to navigate a patient through a complete clinical encounter is fundamental to future practice. The art and gestalt of serial neurological exams, a skill, and experience not readily transferred or duplicated, is essential to clinical neurosurgical success. The erosion of patient care continuity by further duty hour reductions therefore threatens the fabric of modern neurosurgical practice.

From a macroeconomic standpoint, should duty hour reductions prompt extension of clinical training, active neurosurgical residents are overwhelmingly unwilling to train longer than the current seven-year standard, and talent recruitment to the field would be compromised.[7] Coupled with attrition of faculty and decreased elective time within residency necessitated by further duty hour reductions, long-term scientific progress in the field would diminish.

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7. Khalessi AA, *Survey of Active Neurosurgical Residents Regarding Duty Hour Regulation and Proposed IOM Recommendations.* Unpublished data.

5) ***Your organization's willingness to participate, if invited, in a Resident Duty Hours and the Learning Environment Congress, to be held in June 2009 in Chicago Illinois. This Congress will be configured to provide the ACGME leadership will the breadth of perspectives of the medical community as they embark on review and revision of the Resident Duty Hours and Learning Environment Standards***

Neurosurgical organizations will enthusiastically participate in the Resident Duty Hours and the Learning Environment Congress in Chicago in June. Ideally, neurosurgeons attending the Congress should include representatives from ***each*** of the following neurosurgical organizations: the American Board of Neurological Surgery, the Society of Neurological Surgeons, the Residency Review Committee for Neurosurgery, the American Association of Neurological Surgeons, and the Congress of Neurosurgeons. Invitations and details about the Congress meeting (registration, hotel, etc.) may be sent directly to Ms. Orrico, whose contact information is provided at the end of this letter.

Thank you for giving us the opportunity to comment on this important issue. We look forward to hearing more from you about the June Congress meeting. In the meantime, if you have any questions or need further information, please do not hesitate to contact us.

Respectfully submitted,

M. Sean Grady, M.D. Chairman, American Board of Neurological Surgery
H. Hunt Batjer, M.D., Immediate Past Chairman, American Board of Neurological Surgery
Daniel L. Barrow, M.D., Secretary, American Board of Neurological Surgery
Edward H. Oldfield, M.D., President, Society of Neurological Surgeons
Robert J. Dempsey, M.D., President-Elect, Society of Neurological Surgeons
Dennis Spencer, M.D., Immediate Past President, Society of Neurological Surgeons
A. John Popp, M.D., Past President, Society of Neurological Surgeons
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AOA
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Thomas J. Nasca, MD, MACP
Chief Executive Officer, ACGME
515 N. State St., Suite 2000
Chicago, IL 60654

Dear Dr. Nasca:

I am writing to thank you for the opportunity to respond to the Institute of Medicine Report on Resident Duty Hours. The Academic Leadership Committee of the American Orthopaedic Association is preparing a response based on the results of symposia, publications and surveys of program directors in orthopaedic surgery. As the home of the Council of Orthopaedic Residency Directors (CORD), this is an issue of the utmost importance to our membership. Our response will be sent prior to the May 1 deadline.

In addition, the American Orthopaedic Association would welcome the opportunity to participate in a Resident Duty Hours and Learning Environment Congress to be held in Chicago in June of 2009. Our Annual Meeting dates are June 9-13, but a representative could be made available.

Sincerely,

Terrance D. Peabody, MD
Chair, Academic Leadership Committee
The American Orthopaedic Association

AOA

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April 27, 2009

Thomas J. Nasca, MD, MACP
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Re: American Orthopaedic Association Response to the Institute of Medicine Report on Resident Duty Hours

Dear Dr. Nasca:

The American Orthopaedic Association (AOA) appreciates the opportunity to provide comments regarding the recent IOM recommendations regarding resident duty hours. The AOA is the home of academic leaders in orthopaedic surgery. It has performed research involving orthopaedic residency and fellowship directors (6, 7). This research has resulted in survey data (an attached Executive Summary of which was submitted to the IOM), national forum presentations and peer review publications that concern resident work hours and resident and faculty well-being. The subject of graduate medical education in orthopaedic surgery is core to the AOA mission and we welcome the chance to respond to the proposed changes in our residency and fellowship programs.

AOA comments will attempt to delineate the following: an impact analysis of current duty hour standards, an impact analysis of the proposed duty hour standards, a description of the dimensions of resident duty hour standards, recommendation for ACGME /Resident Review Committee oversight, funding and success of mandates, our recommendations for strategies regarding the key aspects of the learning environment, and the AOA's willingness to participate in the ongoing discussion regarding resident duty hours. We will attempt to focus the discussion on patient care and safety, resident education and financial health based on the available evidence.

A. Impact of Current Work Hour Restrictions:

The introduction of the work hour restrictions in 2003 have been accommodated by most orthopaedic programs. (7) The strategies have included:

1) Employing physician extenders in the form of physicians assistants, nurse practitioners, and non-accredited fellows
2) Night Float rotations
3) Moving in-house call to home call
4) Elimination of rotations

5) Eliminating traditional senior resident and junior resident call responsibilities, reducing overlap, and resident-resident teaching
6) Increasing faculty responsibilities.
7) Aggregating services for night call, thereby reducing the number of residents required for in-house coverage and expanding the scope of responsibility for those who are in house.

Survey data reveals that the benefits of the current restrictions include a perceived improvement in resident well-being. (4, 6, 1), Barrack, et al, reported improvement in the sense of personal accomplishment with trends towards less emotional exhaustion and lower measures of depersonalization (1). In addition, programs were forced to critically evaluate the educational value of rotations and focus on education over service. As a result many "non-educational" experiences were eliminated. (6)

Unfortunately, to date there is no evidence that the anticipated improvements in patient safety have been realized. It is apparent than any improvements that may have resulted from less fatigue have been offset by difficulties in communication and patient care handoffs, i.e., the lack of continuity of care. (6)

This is despite a hospital environment where there have been significant additional commitments and programs designed to improve patient safety. These include medical staff requirements and risk management programs that mandate increased resident supervision and faculty participation in care, sign your site, preoperative whiteboard and checklist, SCIP measures, and critical outcome measures programs.

In the current environment, it is apparent that those in training, and orthopaedic surgery residents in particular, rarely make critical decisions without attending physician oversight. This has challenged the assumption of progressively increasing responsibility expected of residents and required by the ACGME common program requirements.

In addition, the programs have borne a tremendous financial burden to comply with the work hours restrictions including the employment of physician extenders who only partially fulfill the service provided by orthopaedic residents. Precise expenses and lost revenues are not available but are estimated at $500,000-1,000,000 in cost for the average program.

Night float rotations are largely non-educational service activities, particularly for surgeons, and are associated with performance deficits over time. (3)

Hazards associated with resident travel from frequent home call are well documented and recognized.

Residents do not appear to be sleeping more and are no better rested or attentive than prior to the hour restrictions imposed in 2003.(6)

Improved performance as measured by test scores, clinical performance and research accomplishments has not been noted in this time period. (6)

Operative case volume does not appear to have been affected. (2) Unfortunately, this means that residents' non-operative ambulatory experience is decreased. Likewise, continuity of care, believed to be essential in the education of a future physician, is further challenged.

More importantly, in the AOA's research, orthopaedic program directors noted a more insidious and difficult to measure negative effect of hour restrictions and resulting handoffs in patient care: that of a lack of ownership and personal responsibility among residents for the patient, which strikes at the heart of our profession and results in a less safe environment. A definite shift-worker mentality has been noted. The word "shift" is used in the recommendations of the Institute of Medicine Report multiple times. The ethos of professionalism that is integral to the practice of medicine has become increasingly difficult to teach and is no longer practical to model for residents who have been taught to punch a clock. They are simply not present enough to learn the altruism and commitment that are essential in the care of patients. While we understand that the basis for the IOM recommendations is ***safety*** in patient care, we believe that high quality care is an important component of safe patient care and a compromise in the professionalism of our physician work force will only further erode the public trust and detract from the quality and safety of patient care in our teaching hospitals.

Programs need to balance the negative effects of fatigue with the reality that, in practice, orthopaedic surgeons are required to work long hours and expected by the public to take continuous responsibility for their patients. Our "profession" cannot endure if we adopt a strategy that allows for our trainees to work shifts in preparation for the independent practice of orthopaedic surgery. Our programs must continue to assure that our graduates are competent and safe.

The vast majority of orthopaedic residency programs have preserved the residents' education and patient care through internal funding (clinical revenue) and increased commitment and dedication of their faculty. The residents have been good partners in this effort. In consideration of the five year residency, one year fellowship, and a two year practice period prior to board certification, the effects of the 2003 duty hour limitations upon orthopaedic surgeon competency and patient safety are not yet available. It remains to be seen if the reported reduction in Board scores noted in Neurosurgery and possibly in other fields will be noted in orthopaedic surgery. (Lister, J. and Friedman, W., ACGME Bulletin, January 2009, pages 4-6)

B. Impact of Proposed Changes:

For orthopaedic surgery residency programs, the most concerning and problematic recommendations from the IOM report are:

1) 5 hour mandated sleep period during "shifts" of over 16 hours

2) Absence of averaging in order to acknowledge variable intensity of various rotations

Unlike some specialties, orthopaedic consultation and care is required often at night and weekends. In addition, the number of orthopaedic surgery residents is relatively small (average 4 residents per year) and most programs provide service to multiple institutions. It is not possible for small programs to incorporate the complex schedules that may be appropriate in the contained work environments of the Emergency Room and the Intensive Care Unit. (5) Sufficient workforce does not currently exist to accommodate the proposed changes in most orthopaedic surgery programs. Physician extenders do not take call and by privilege delineation are not able to provide the level of care (procedures) provided by an orthopaedic surgery resident. The proposed changes would require service to be provided by:

1) Increased number of attending surgeons who provide care without resident involvement. This option is not viable. The surgeons do not exist and the expense to attract those that do is not financially feasible.

2) More frequent in-house call by residents at all levels including expansion of night float responsibilities. More frequent call responsibilities, night float and time away from home will likely increase problems related to burnout. Resident burnout has more to do with lack of control and self-determination, low pay, and time away from family than fatigue. (10, 11) A mandated sleep time during duty would only intensify those issues that clearly have a negative effect on resident well-being, patient care, and the learning environment.

3) Significant increases in resident numbers to provide service. This can be done by increasing the number of residents per year or by lengthening the length of the resident educational program. Neither of these would be justifiable based on an educational rationale currently. Given present caps in resident numbers and lack of funding, this option appears to be neither credible nor viable.

4) Limit the availability of orthopaedic surgery consultation and care. This will exacerbate current challenges for patients with orthopaedic problems particularly in the emergency room setting and for those hospitals providing Level 1 trauma care.

There is also the problem of enforcement of mandated sleep. Adult learners will make decisions based on their own needs. In addition, most of us who have slept in hospitals recognize that it is not a restful environment. Shifts as described in the IOM report may work for rotations in the intensive care unit or the emergency room but will not fulfill the didactic and clinical requirements for surgical residents. Again, some modification of the guidelines is necessary to meet the goals of exemplary resident education and patient safety.

C. Dimensions of Resident Duty Hour Standards:

Rather than a "one size fits all" and in an effort to acknowledge the differences between specialties, the AOA would suggest that there be some flexibility in duty hour guidelines for programs accredited by the ACGME.

What may be optimal for a primary care resident in an ICU or an emergency room is not ideal for a resident in a surgical specialty like neurosurgery. There are tremendous differences in personal characteristics, learning environments, work intensity and levels of supervision that are necessary by the nature of the specialty.

The limited literature on resident work environments including shift optimization focuses on those in controlled environments like the intensive care unit or emergency room or on a single level resident in a particular primary care specialty. The recommendations would not apply to surgical specialties that have much different patient encounters and responsibilities.

D. Recommendation for ACGME / Residency Review Committee Oversight

In light of this variability, it is would seem reasonable that the individual Residency Review Committees arrive at the appropriate recommendations for their specialty.

It is also essential that the ACGME alone maintain oversight over the resident educational experience, and in that context also be held responsible for monitoring work hours and related matters. The AOA would argue against a significant role of the Joint Commission, whose charge does not include resident education and may likely evaluate work hours outside of the needed context of optimizing the learning environment for the resident. Using the Joint Commission to get the attention of hospital administration is at the very least inefficient and risks opening the door for excessive and counterproductive regulation of educational programs.

E. Funding and Success of Mandates

In the IOM report preamble, the committee notes that without the necessary restructuring in resource allocation, attempts to implement the recommendations will fail to have the desired effect and could even reduce patient safety. That is undoubtedly why the 2003 recommendations have not resulted in more tangible benefits to residents and patients. Those changes were costly to academic institutions and to orthopaedic programs financially, as AOA members have indicated. In these times of significant economic recession and uncertainty regarding health care reform and funding, it seems irresponsible to suggest that the money necessary to fund these recommendations will be made available without identified, specific, available funding sources.

To introduce an unfunded mandate would harm the viability of many academic health care centers, especially those who are the health care providers for the poor and those with complex diseases. Only financially robust institutions would be capable of sponsoring educational programs. This will have a negative effect on recent gains in cultural sensitivity and diversity education.

In addition, the effect of work hour restrictions on the teachers should be evaluated fully. (8,9) The work hour restrictions created significant increases in faculty work demands that resulted in a decrease in faculty morale and well being. Faculty burn out, especially among program chairs and directors, is a problem. Until the resources suggested in the report are made available, it would be a mistake to introduce further restrictions on resident duty hours.

F. Recommendations

The AOA suggests the following guidelines:

1. A decision by the ACGME to deliberately consider any changes in work hour restrictions in the common program requirements and allow for some flexibility based on input from the specialty residency review committees.

2. Support of maintenance of the 80 hour work week: the 80 hour work week limitation is a reasonable standard. On rare occasion, for residents on trauma rotations, an essential component of orthopaedic surgery education, that limit may be exceeded. An averaging allows for those rare instances. It also allows for some preservation of continuity of care important in fostering a culture of responsibility and professionalism.

3. Implementation of overnight in-house call limits, resulting in a continuous work day of 24-30 hours, for a maximum of six times per month. This standard (1.5 times per week) has been well tolerated by orthopedic residents and allows most programs to minimize the problems with frequent home call and night float rotations. Supervision must be provided by attending surgeons.

4. Support of a designated free period: five days per month free of duty as averaged over three months will improve resident well being, as indicated by AOA member Program Directors.

5. Programs should improve and document enforcement of work hour restrictions.
6. Programs should discourage moonlighting.
7. Programs should educate residents and faculty in effective communication regarding the "Hand off" of patient care
8. The ACGME should provide educational programming about fatigue to improve general understanding and recognition.
9. The source of funding available to programs to pay for the increased costs should be defined prior to implementing the recommendations of the IOM or other additional restrictions on resident duty hours.
10. Orthopaedic educators should define and update the essential knowledge and skills of a graduate of an orthopaedic surgery residency. In addition, they should identify outcomes measures that accurately determine a resident's competency in acquiring this knowledge and these skills prior to graduation. The current rotational model and the length of training may need to be fundamentally altered based on these measures.
11. Those that fund graduate medical education may need to separately consider time devoted to education and time spent in service. The current paradigm of resident funding based on service as currently provided by the federal government may require fundamental change.
12. Finally, academic medicine must advocate for the essential linkage between high quality and safe care for our patients and the professionalism that has come to be expected of medical practitioners. Any compromise in our ability to teach and model professionalism to our residents will intuitively result in a diminution in the quality of care and, ultimately, patient safety. To ignore the need to engender an ethos of professionalism in our residency education programs may result in a far greater threat to patient safety than arbitrarily limiting total duty hours.

Louis U. Bigliani

Louis U. Bigliani, MD
AOA President

Vincent D, Pellegrini, Jr., MD
First-President Elect

Gary Friedlaender, MD
Second-President Elect

Terrance Peabody

Terrance D. Peabody, MD
Chair, Academic Leadership Committee

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Executive Summary on Resident Work Hours

T. Peabody, MD and V. Pellegrini, MD, April, 2008

The American Orthopaedic Association, in an effort to determine the impact of further work hour restrictions on residency education in orthopaedic surgery, surveyed 254 program chairs and residency directors representing 168 programs in April, 2008.

One hundred twenty-four independent responses (49%) were received. Residency program characteristics are described in questions 1-3; 80% of respondents were from university based academic centers, and one-half represented designated Level 1 trauma centers. The same proportion described themselves as urban healthcare centers. The median size of the programs was from four to six residents per year at each postgraduate level: i.e., twenty to thirty trainees per program. Nine out of ten programs employed physician extenders (range 1 to 13 per program) to assist in the provision of patient care.

The program chairs and residency directors were asked to consider a restriction of resident work hours to less than 60 per week. The responses reflected a strong and clear consensus; further restrictions on resident work hours would have a deleterious effect on the cognitive, technical, and professional education of future orthopaedic practitioners. A significant majority of the respondents felt that the most substantial effect would be a negative impact on the competency of the graduate surgeon reflecting deficiencies in the educational program and erosion of the ethos of professionalism; both translate directly into a decline in the quality of patient care and the patient experience. This is evident not only on the pooled responses but also when one examines the plurality of responses (Question 4). Challenges concerning professionalism were most commonly cited, being ranked as one of the top three areas of concern by 86% of respondents. Although there would be a clear economic challenge of sizable magnitude (Question 6), the opinion of educators in orthopaedic surgery was that further restrictions on residency work hours would more seriously impair their ability to educate competent and professional practitioners capable of consistently providing high quality patient care.

Notably, 93% of respondents felt that a lengthening of the orthopaedic residency program would be a necessary response to further work hour restrictions (Question 5). This represents a meaningful shift in opinion compared with responses from the same group following implementation of the ACGME 80 hour guidelines. Many of these individuals support the current work hour limitations and the resulting clear focus on resident educational activities. Further restrictions would require a considerable restructuring of graduate medical education, possibly similar to the "registrar" model without a specified time frame for completion of residency. It will also introduce further challenges to the recruitment and retention of future orthopaedic surgeon educators (free text responses).

In summary, this survey portrays the overwhelming opinion that further restrictions on residency work hours would have a major, and potentially irretrievable, adverse effect on postgraduate medical education in orthopaedic surgery. While a deficiency in educational content may be mitigated by a lengthening of the term of the residency, the failure to impart an ethic of professionalism and altruism may be the most troubling loss to society.

Appendix
of
Cited Articles

Operative Experience in an Orthopaedic Surgery Residency Program: The Effect of Work-Hour Restrictions

By Michael A. Baskies, MD, David E. Ruchelsman, MD, Craig M. Capeci, MD,
Joseph D. Zuckerman, MD, and Kenneth A. Egol, MD

Background: The implementation of Section 405 of the New York State Public Health Code and the adoption of similar policies by the Accreditation Council for Graduate Medical Education in 2002 restricted resident work hours to eighty hours per week. The effect of these policies on operative volume in an orthopaedic surgery residency training program is a topic of concern. The purpose of this study was to evaluate the effect of the work-hour restrictions on the operative experiences of residents in a large university-based orthopaedic surgery residency training program in an urban setting.

Methods: We analyzed the operative logs of 109 consecutive orthopaedic surgery residents (postgraduate years 2 through 5) from 2000 through 2006, representing a consecutive interval of years before and after the adoption of the work-hour restrictions.

Results: Following the implementation of the new work-hour policies, there was no significant difference in the operative volume for postgraduate year-2, 3, or 4 residents. However, the average operative volume for a postgraduate year-5 resident increased from 274.8 to 348.4 cases ($p = 0.001$). In addition, on analysis of all residents as two cohorts (before 2002 and after 2002), the operative volume for residents increased by an average of 46.6 cases per year ($p = 0.02$).

Conclusions: On the basis of the findings of this study, concerns over the potential adverse effects of the resident work-hour polices on operative volume for orthopaedic surgery residents appear to be unfounded.

Section 405 of the New York Public Health Code and recent policies of the Accreditation Council for Graduate Medical Education (ACGME) have resulted in the implementation of resident work-hour restrictions[1,2]. The ACGME work-hour guidelines were implemented in 2002[3]. These policies restrict the hours worked by residents to eighty hours per week with a maximum of twenty-four hours in one shift. All work shifts require a separation of at least ten hours, and each resident is required to have at least one twenty-four-hour period of "non-working" time per week.

Much concern has been voiced regarding the operative experience of residents working under the new regulations. The goal of orthopaedic surgery residency training is to educate young physicians and to facilitate the acquisition of a comprehensive fund of knowledge, clinical judgment, operative skills, communication skills, and professionalism to practice orthopaedic surgery[4]. The amount of operative experience of the residents may impact the acquisition of these skills. As residents increase their operative surgical caseload, their operative decision-making skills and communication with colleagues, patients, and families improve. To date, it remains unknown whether the implementation of work-hour regulations detracts from the crucial operative experiences gained by residents who trained in the era preceding the work-hour policies.

Disclosure: The authors did not receive any outside funding or grants in support of their research for or preparation of this work. Neither they nor a member of their immediate families received payments or other benefits or a commitment or agreement to provide such benefits from a commercial entity. No commercial entity paid or directed, or agreed to pay or direct, any benefits to any research fund, foundation, division, center, clinical practice, or other charitable or nonprofit organization with which the authors, or a member of their immediate families, are affiliated or associated.

J Bone Joint Surg Am. 2008;90:924-7 • doi:10.2106/JBJS.G.00918

TABLE I Comparison of Operative Caseload per Resident Year Before and After Implementation of the Work-Hour Restrictions

	Before 80-Hour Work Week Restrictions		After 80-Hour Work Week Restrictions			
Year of Training	No. of Residents	Caseload*	No. of Residents	Caseload*	Difference	P Value
PGY 2 (n = 72)	24	263.3 ± 71.8	48	283.2 ± 106.7	19.9	>0.5
PGY 3 (n = 70)	22	549.8 ± 125.0	48	584.7 ± 159.4	34.9	>0.5
PGY 4 (n = 71)	23	386.7 ± 85.7	48	422.1 ± 97.3	35.4	0.14
PGY 5 (n = 71)	25	274.8 ± 74.7	46	348.4 ± 102.1	73.6	0.001
PGY 2-5 (n = 284)	94	363.6 ± 145.0	190	410.2 ± 163.6	46.6	0.02

*The values are given as the mean and the standard deviation. PGY = postgraduate year.

We conducted a formal review to assess the early effects of work-hour regulations on the operative experience of orthopaedic surgery residents in a large orthopaedic surgery residency training program. Since 2002, the program has been in strict compliance with the Code 405 regulations and resident work hours.

Materials and Methods

We used the operative case logs of the residents of our university-based orthopaedic surgery residency program from 2000 through 2006. Residents at the postgraduate year (PGY)-2 through PGY-5 levels were included for consideration. The PGY-1 residents were not included as their clinical experience is not limited to orthopaedic surgery. Formats for operative case logs were computerized from the ACGME resident case-log system after 2002 and from manual records maintained by the Department of Orthopaedic Surgery prior to 2002. All cases, including closed reductions of fractures, were included. Throughout the time frame of this study, compliance with both case-log recording systems was mandatory for all residents as a requisite for the completion of each postgraduate year and eventual graduation from residency.

From 2000 through 2006, there were no significant changes in the program in regard to required rotations, resident participation in the clinic or office, or the employment of physician extenders. There was no night-float system in place, and the residents worked within the same call schedule throughout the entire time. The PGY-4 and PGY-5 residents did not take in-house call, the number of junior residents in-house was the same, and the number of hours of in-house call taken by junior residents did not change in any year. The hospital affiliations of the program did not change throughout the time frame of this study and included New York University (NYU) Medical Center, NYU Hospital for Joint Diseases, Bellevue Hospital Center, Jamaica Hospital Medical Center, and the Veterans Administration Medical Center.

After receiving approval from our institutional review board, we administered a formal review of the operative case logs of 109 orthopaedic surgery residents (PGY-2 through PGY-5) during the period from 2000 through 2006. All residents were informed of the purpose of this study and were assured that their records would remain anonymous. Resident anonymity was maintained by blinding the authors to the identities of the resident author of each operative log.

We did not analyze the type of cases performed or the level of participation in each case, as surgical procedure codes were not available in the operative logs prior to the implementation of the ACGME resident case-log system. Operative case volumes were calculated before and after enforcement of resident work-hour restrictions. The statistical analyses were performed with use of a series of Student t tests.

Results

The operative case logs of 109 orthopaedic surgery residents were included in this study. Prior to the implementation of the work-hour restrictions, the operative experience consisted of a total of ninety-four individual resident years. The data on the operative volume after the adoption of work-rule policies consisted of 190 individual resident years. The average number of operative cases per resident prior to work restrictions was 363.6 per year compared with 410.2 per year following the new work rules (Table I). The mean increase of 46.6 cases per resident work year following the implementation of work-hour restrictions was significant ($p = 0.02$).

Prior to the implementation of the eighty-hour work week, the average number of cases per resident year was 263.3 for PGY-2 residents, 549.8 for PGY-3 residents, 386.7 for PGY-4 residents, and 274.8 for PGY-5 residents. The average number of cases per resident year after the adoption of the new work rules was 283.2 (PGY-2), 584.7 (PGY-3), 422.1 (PGY-4), and 348.1 (PGY-5) (Table I). After the implementation of the new policies, the average increases in cases performed per work year were 19.9 (PGY-2), 34.9 (PGY-3), 35.4 (PGY-4), and 73.6 (PGY-5) (Table I). A comparison of the cases per work year for each level of training showed no significant differ-

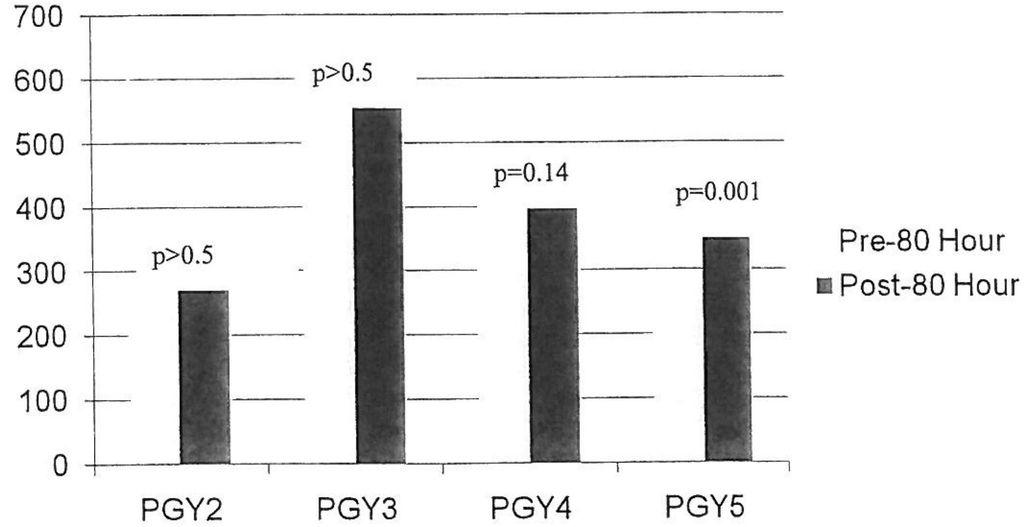

Fig. 1

Average operative caseload per postgraduate year (PGY) of training before and after the implementation of work-hour restrictions.

ence in the number of cases for residents at levels PGY-2 (p > 0.5), PGY-3 (p > 0.5), and PGY-4 (p = 0.14) (Table I, Fig. 1). There was a significant difference in the average number of cases performed per work year by PGY-5 residents (p = 0.001) as residents at this level reported a mean increase of 73.6 cases per work year following the implementation of the new work policies (Table I, Fig. 1).

Discussion

Our review was performed to evaluate the impact of work-hour restrictions on total operative case exposure in a large university-based orthopaedic surgery residency program in an urban setting. The collection period included two years prior to and four years following the initiation of strict compliance with the guidelines. The timing of the study was chosen to provide adequate data to evaluate the early impact of work-hour restrictions. In this analysis, we found that the total operative caseload was not negatively impacted by restrictions in work hours.

Residents, in addition to faculty and departmental administrators, are concerned about the potential negative impact of work rules on operative training[4]. Prior analyses have estimated that junior residents lose between twelve and twenty-four hours of operative experience per week because of the ACGME work rules[4]. However, in our comparison of each individual resident level, no significant change was detected in the number of operative cases performed at the PGY-2, PGY-3, and PGY-4 levels. The PGY-5 residents performed significantly more procedures after the implementation of the work-hour restrictions. Furthermore, on analysis of all residents as two cohorts (before 2002 and after 2002), the surgical volume for the residents significantly increased following the installation of and compliance with the new work rules. Between 2000 and 2006, the operative volume increased by 12.5% across the five hospitals of the residency program, which helped to meet the needs of residency training in the face of work-hour restrictions.

There are several potential explanations for the increase in the operative caseload reported by the PGY-5 residents following the implementation of the work-hour restrictions. Prior to the new regulations, on-call junior residents often stayed to participate in operative cases on days following a night of call-duty. Following the new work rules, these junior residents no longer remained on site. This required the more senior residents to assume increased operative responsibilities. It can be concluded that, with an increased responsibility in the operating room, the PGY-5 residents had to reallocate their time from other daily responsibilities including clinic coverage as well as personal and study time. Since there were no changes in senior resident coverage of the emergency department, we can deduce that the increase in operative case logs was for surgical procedures and not for closed reductions. Additionally, administrative chief residents and senior faculty members responsible for daily operating-room assignments were forced to maximize resident coverage of cases. The maintenance of operative volumes may reflect a more efficient use of available residents in the operating room, or it may be related to the increased volume across the residency program's hospitals after 2002. Lastly, following the implementation of the new work policies, junior-level residents may have made concerted efforts to compensate for lost time in the hospital by actively seeking to enhance their operative experience. It was likely that a combination of these factors allowed the absolute numbers of case exposures to be maintained for all levels of residents after the implementation of the work-hour restrictions.

Longer-term analysis of operative caseloads may provide further information that will help orthopaedic residency training programs to further adapt to the new policies. This represents the initial longitudinal study to evaluate the effect of the work rules on an important aspect of orthopaedic resident education in one residency program. Further study is required to determine whether the quality of the overall training had been compromised with the implementation of the work-hour restrictions.

The work-hour restrictions have had other positive, measurable effects on residency training programs. Barden et al. showed that residents achieved significant improvement in in-training examination scores with the implementation of the rules set forth by Code 405 ($p < 0.05$)[5]. Similarly, Hassett et al. showed that surgical residents in a university-based training program in an urban setting reported no substantial change in the number of procedures performed and that 90% of the residents were passing the qualifying examinations[6].

Studies in other surgical specialties have not shown that the eighty-hour work week has compromised operative experience. McElearney et al. showed that the numbers of cases were not significantly different for PGY-1 to PGY-4 residents after work week restrictions had been implemented in a general-surgery residency program[7]. However, the PGY-5 residents reported significantly fewer cases after the work-hour restrictions ($p = 0.03$)[7]. Ferguson et al. showed that work-hour limitations had no effect on case volume[8]. Similarly, they showed that changes in the daily work schedule to maintain compliance with work-hour restrictions did not affect operative case volume[8]. Our results are in accordance with an earlier report from the University of Oklahoma Health Sciences Center[9]. On the basis of a four-year collection of cases in their orthopaedic surgery residency program, the caseloads of PGY-2 through PGY-5 residents showed no significant difference before and after the implementation of work-hour restrictions[9].

Most of the studies[7-9] in this area evaluated the effects of the work rules on resident attitudes and education, patient care, in-hospital complications, and postoperative outcomes. Many studies were survey-based to evaluate resident attitudes with respect to operative experiences since the adoption of the new policies.

There are inherent limitations in our study. The resident case logs were authored by all residents who participated in the orthopaedic surgery residency program, and self-reporting of case volumes is an obvious weakness. The accuracy of the logs is dependent on the dedication of each resident to document accurately their experience. The different case-log systems, manual before 2002 and electronic after 2002, are also a limitation of the study. A possible explanation for the increased case volume after 2002 may be related to the conversion to an electronic case-log system. The increase in volume throughout the residency program may also confound the results of increasing caseloads after 2002.

To date, concerns over the potential adverse effects of the resident work-hour policies on operative volume for orthopaedic surgery residents appear unfounded on the basis of the findings of our study as well as others[9]. Although the objective of this study was to quantify the differences in operative case volumes, it would be important to analyze the quality of the operative experience following the implementation of the work-hour restrictions. This would require an analysis of the individual components of the residency training program to determine whether there are differences in the types of surgery performed by residents at each level with respect to the implementation of the work-hour restrictions.

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Effect of Duty Hour Standards on Burnout among Orthopaedic Surgery Residents

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We surveyed orthopaedic surgery residents and faculty from two university training programs to quantify quality of life measures including burnout, general health, and relationship issues. Residents exhibited high levels of burnout and emotional exhaustion but only average levels of personal achievement, while faculty showed lower levels of burnout and emotional exhaustion with above average scores for personal achievement. Resident burnout was positively correlated with number of hours worked while faculty hours worked was inversely related to burnout. The survey was readministered two years after implementing the Accreditation Council on Graduate Medical Education guidelines on residency duty hours. At this time resident scores for personal accomplishment had improved, while scores for emotional exhaustion showed a strong trend towards decreasing, and depersonalization scores also showed a possible trend towards decreasing. Resident duty hour limitation was associated with improvement in objective measures of burnout.

Residency training in orthopaedic surgery is known to be challenging and stressful. In a previous survey of residents and faculty in orthopaedic surgery, residents showed high levels of burnout, emotional exhaustion, and depersonalization. (Supplemental materials are available via the Article Plus feature at www.corronline.com. You may locate this article then click on the Article Plus link on the right.) Over 30% of residents showed psychological decompensation compared with only 8% of faculty.[5] A number of parameters correlated with the incidence and degree of burnout, most notably the number of hours worked per week.

In recent years the number of hours worked by residents has been under increased scrutiny. In 2003 the Accreditation Council on Graduate Medical Education (ACGME) implemented guidelines limiting the number of hours worked on average per week, the number of hours worked continuously on a single shift, and the number of days worked per week without a day free of clinical responsibilities.[3] This policy was implemented on July 1, 2003.

We wondered whether the change in work hours would achieve some of the goals of the ACGME by reducing measures of burnout.

MATERIALS AND METHODS

The first survey was completed in 2002, the year before ACGME duty hour standards went into effect. The study group for this first survey consisted of 21 orthopaedic surgery residents from a university-based training program and 25 full-time orthopaedic surgery faculty members from two institutions. The second survey was administered in 2005, two years after the duty hour standards had gone into effect. Twenty faculty and 34 residents from the same two institutions completed the second survey. The study was approved by the institutional review boards of both institutions.

The survey instrument was divided into six sections. Section one contained background information, such as age, gender, year in training, race, marital status, number of children, and family background information. Section two consisted of the Maslach Burnout Inventory, a validated instrument consisting of 22 questions that evaluate various aspects of emotional functioning affected by work stress. The three subscales of the Maslach Burnout Inventory assess emotional exhaustion, depersonalization, and personal achievement.[4] The first two correlate with burnout while the third is inversely related to burnout.

Section three comprised the General Health Questionnaire-12, a widely used validated grading scale, used to assess psychiatric morbidity. The questionnaire is a reliable indicator of anxiety, depression, somatic symptoms, and social dysfunction.[6] Scores of four or higher are consistent with decompensation.[2]

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Each author certifies that his or her institution has waived approval for the human protocol for this investigation and that all investigations were conducted in conformity with ethical principles of research.

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TABLE 1. Demographics of Study Groups Pre and Post Resident Duty Hour Implementation

	Pre Standards		Post Standards		Pre vs Post Faculty	Pre vs Post Residents
Demographic Factor	*Faculty*	*Residents*	*Faculty*	*Residents*	*p-Value*	*p-Value*
Age N	23	21	20	34	0.3600	0.6934
Mean	45.3	30.2	48.6	30.5		
Std	12.0	2.0	11.2	2.6		
Range	25–66	28–34	34–69	27–37		
Gender (male) N(%)	23/24 (96%)	17/20 (85%)	19/20 (95%)	29/34 (85%)	0.8949	0.9766
Marital (married) N(%)	21/25 (84%)	11/20 (55%)	18/20 (90%)	26/34 (76%)	0.5563	0.1009

Section four consisted of 23 questions that assessed subjective ratings of sources of worklife stress. Section five consisted of 18 questions focusing on stress coping methods. Section six consisted of the 14-item revised dyadic adjustment scale, which is another validated instrument that assesses marital adjustment on a 69-point scale. Scores of less than 46 are considered indicative of a distressed relationship.[1]

Descriptive statistics, including pair-wise correlations, on the graded questionnaires were computed. Bivariate relationships were tested with a simple correlation coefficient. Spearman correlations and the Pearson correlation coefficient were used to determine clinical significance. A p value < 0.05 was considered to be significant, p values between 0.05 and 0.1 were considered indicative of a trend, and p values < 0.15 were considered suggestive of a possible trend.

RESULTS

A detailed discussion of the results of the first survey have been previously published.[5] There were no significant differences in age, gender, or marital status among the groups between the pilot study and the current study, although there was a trend towards a higher percentage of married residents in the current study ($p = 0.1$, Table 1). A brief summary of the findings of the first survey follows. The residents rated in the upper third of the burnout scale for emotional exhaustion and depersonalization and the middle third for personal achievement, while the faculty scored in the lower third for emotional exhaustion, the middle third for depersonalization, and in the upper third for personal achievement. On the general health questionnaire, seven residents (33%) and two faculty members (8%) had a score ≥ 4, indicating psychiatric morbidity ($p < 0.05$).

Three residents and six faculty members scored in the distressed range, which was not a significant difference. Factors that significantly correlated positively with resident burnout included anxiety about competence, increased work hours, work/home life conflict, and stressed relationships with nurses, faculty and senior residents. Factors correlating positively with the presence of faculty burnout also included anxiety about competence, as well as alcohol use, worry about a future with orthopaedics, and stress in relationships with other faculty members. Factors that were inversely proportional to resident burnout consisted of potentially protective factors including having a father who was a physician, time alone with spouse, parenthood and satisfaction in talking with colleagues. Factors inversely proportional to faculty burnout included perceived support from faculty, increase in work hours, quality of marriage, and work-life balance, as well as hours that the spouse worked outside the home (Tables 2 and 3). A decrease in resident work hours, however, seemed to have a positive effect. It is interesting to note that an increase in reported work hours among faculty was inversely related to burnout and one can only speculate as to the reason for this. Faculty members certainly generally have greater control over their workload and it is possible that those faculty members that are busier and choose to work longer hours may have a greater sense of personal achievement and be less prone to burnout. It remains to be

TABLE 2. Correlating Positively with Burnout Measures

Survey Group	Emotional Exhaustion	Depersonalization
Residents	Anxiety about competence	Increased work hours
	Work/home life conflict	Stress with nurses and faculty
	Stressed faculty relationship	Debt load
	Stressed senior resident relationship	
Faculty	Anxiety about competence	Alcohol use
	Worry about future of orthopaedics	
	Stress in relationship with other faculty	
	Financial concerns	

TABLE 3. Factors Inversely Proportional to Burnout Measures

Survey Group	Emotional Exhaustion	Depersonalization	Personal Accomplishment
Residents	Physician father Time alone with spouse	Physician father	Parenthood Satisfaction in talking with colleagues
Faculty	Perceived support from faculty	Increased work hours More children	Marriage quality Work life balance Hours spouse worked

seen whether this finding will be substantiated by a larger, more broadly based study, but this is one of many questions that will be explored further in the follow-up study.

There was a decline ($p < 0.0001$) in the reported number of hours worked by residents between the first and second survey (70.4 versus 88.3). A decline in hours was seen at every year level with the greatest difference at Year 4 and the least at Year 3 (Table 4).

Results of the second survey showed improvements in several aspects of resident functioning, but not in faculty functioning. Compared to preduty hour standards, scores for emotional exhaustion were lower ($p = 0.056$) among the current group of residents (22.3 versus 27.5), while the score of the current faculty group remained virtually identical to those in the original survey (16.4 versus 16.2). The depersonalization score was also somewhat lower ($p = 0.14$) among residents in the more recent survey (12.5 versus 15.2) and this indicated a possible trend. A sample size calculation indicates that an increase in the study group size to 120 would be necessary to achieve statistical significance for emotional exhaustion and to 172 subjects for depersonalization. The score for personal accomplishment was higher ($p < 0.01$) among the current group of residents (40.4 versus 34.8), while again the scores among the faculty were essentially identical to the original survey (42.2 versus 42.8). The scores on the General Health Questionnaire indicated five of 34 residents (15%) scored ≥ 4 compared with seven of 21 (33%) in the first survey ($p < 0.2$). The incidence of scores ≥ 4 in the faculty group stayed essentially the same (15% vs 8%). There were no differences observed in the revised dyadic adjustment scale (assessment issues) of relationship between the first and second survey.

DISCUSSION

The ACGME duty hour standards include an 80-hour week limit averaged over four weeks, at least one day out of seven free of clinical and educational activities, continuous work hour limit of 24 hours plus an additional 6 hours of administrative time, and an on-call limit of every third night. The first survey was administered a year before the implementation of these standards when there was no formal tracking of resident duty hours. The results of the first survey indicated high levels of stress and burnout among residents, substantially more so than among the faculty. The duty hour standards had a number of potential benefits, including improving patient care and minimizing medical errors, minimizing sleep deprivation, and potentially improving the quality of life and educational experience of residents. Our results indicate it is likely the duty hour standards have had some positive impact on decreasing the burnout observed among orthopaedic residents. A positive impact on the score of all three subcategories of the Maslach Burnout Inventory was observed. The improvement in the score for personal accomplishment was high, the decline in emotional exhaustion showed a very strong trend toward association, and the decline in the depersonalization score also showed a possible trend towards association.

We note several limitations of these surveys. The sample size is small and there were only two training programs involved in the study. The same group of residents did not complete the survey before and after the implementation of the duty hours. It is possible other changes in the training programs could have had an impact on the scores between the two time intervals. A more robust study would have had a larger sample size, higher number of programs surveyed, and preferably the same group of residents and faculty completing the survey before and after the implementation of the standards. Finally,

TABLE 4. Average Reported Duty Hours

Year Training	Pilot Mean (SD)	Current Mean (SD)	Hours Decreased	p Value
2	94.3 (9.3)	79.3 (4.5)	15	0.0031
3	82.5 (12.6)	76.1 (9.9)	6.4	0.3744
4	92.5 (10.4)	69.4 (7.8)	23.1	0.0004
5	80.0 (0)	62.4 (8.4)	17.6	0.0066

SD = standard deviation

it was not possible to determine what percentage of faculty and residents completed both surveys because they were completed voluntarily and anonymously.

Despite these limitations, it is striking that changes were observed with such a small sample size. It does seem likely implementing the duty hour standards has been associated with a positive effect on the incidence of burnout among orthopaedic surgery residents. A larger scale survey has been recently completed involving 50 training programs and over 1000 responses from orthopaedic surgery residents, faculty, and their significant others to examine how coping methods are involved with orthopaedic surgery training.

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Review Article

Shiftwork: Safety, Sleepiness and Sleep

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Abstract: This brief paper reviews the available published literature on shiftwork and safety that allows the relative risk of "accidents" or injuries associated with specific features of shift systems to be estimated. Three main trends in risk are discussed, namely that (i) risk is higher on the night shift, and to a lesser extent the afternoon shift, than on the morning shift, (ii) risk increases over a span of shifts, especially so if they are night shifts, and (iii) risk increases with increasing shift length over eight hours. We discuss that some of these trends are not entirely consistent with predictions derived from considerations of the circadian variations in sleep propensity or rated sleepiness, and consider factors relating to sleep that may underlie the observed trends in risk. Finally, the practical implications of the trends in risk for the design of safer shift systems are discussed.

Key words: Sleep, Shiftwork, Work Schedules, Safety, Injuries, Accidents, Sleepiness, Fatigue

Introduction

Safety is a primary concern of both workers and their employers in most shiftworking situations, particularly in transport operations and the nuclear power or chemical industries where there may be a high "public" or "environmental" risk. A number of authors have noted that many of the "headline hitting" disasters of the last few decades, such as Three Mile Island, Chernobyl, Bhopal, Exxon Valdez, and the Estonia ferry, have all occurred in the early hours of the morning. Further, investigations of these disasters have concluded that they were, at least partially, attributable to fatigue and/or human error.

This brief paper reviews the available published epidemiologic studies on shiftwork and safety that allow the relative risk of "accidents" or injuries associated with specific features of shift systems to be estimated. We argue that these trends are not consistent with predictions derived from considerations of the circadian variations in sleep propensity or rated sleepiness and consider factors relating to sleep that may underlie the observed trends in risk. Finally, we consider the practical implications of the trends in risk for the design of safer shift systems.

Trends Associated with Features of Shift Systems

There are few published studies that allow for an unbiased calculation of relative risk estimates of "accidents" and/or injuries associated with specific features of shift systems due to non-homogeneous *a priori* risk. In the few studies of industrial situations where the *a priori* risk of incidents[1] appears to be homogeneous across the 24-h day, the probability of actually reporting an incident may still vary by shift. For example, the number of workers or the level of supervision may vary over the 24-h day, as may the safety associated with the nature of the job tasks being performed.

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[1] The term "incidents" is used from hereon to refer to injuries and/or accidents.

Nevertheless, there appear to be four consistent trends in incident risk associated with features of shift systems when confounding factors are taken into account. These trends could reasonably be assumed to reflect on variations in the likelihood of errors being made by the individual operators concerned. We have detailed the studies on which these trends are based elsewhere[1–3].

The first consistent trend relates to the relative risk of incidents on the morning, afternoon and night shifts on 8-h shift systems. There are several studies based on relatively large numbers of incidents that appear to have overcome the potential confounders and in which the incident frequencies are reported separately for the morning, afternoon and night shifts[1–3]. These frequencies were pooled across the available studies to estimate the general trend. Based on these results, risk increased by 18% on the afternoon shift and by 30% on the night shift, relative to the morning shift. This finding suggests that when the *a priori* risk appears to be homogeneous across the three shifts, there is a consistent tendency for the relative risk of incidents to be higher on the afternoon shift than on the morning shift, and to be highest on the night shift.

There is also a consistent trend in the risk of incidents over successive night shifts. Seven published studies were identified that have reported incident frequencies separately for each night over a span of at least four successive night shifts[1–3]. In order to compare across these studies, the frequency of incidents on each night was again pooled across the studies, and was then expressed relative to that on the first night shift. On average, the risk of an incident was about 6% higher on the second night, 17% higher on the third night, and 36% higher on the fourth night.

One important question regarding this substantial increase in risk over four successive night shifts is whether it is attributable to the night shift, or whether this increase in risk represents an accumulation of fatigue over successive workdays. Of the seven studies, five reported the risk over successive morning or day shifts[1–3]. Similar to the previous analyses, in order to compare across these studies the frequency of incidents on each shift was expressed relative to that on the first morning/day shift. On average, the risk was about 2% higher on the second morning/day, 7% higher on the third morning/day, and 17% higher on the fourth morning/day shift than on the first shift. There was evidence that risk increased over successive morning/day shifts, but it is important to note however that the increase was substantially smaller than that over successive night shifts.

The fourth trend compares the impact of different lengths of shift on incident risk. Four recent studies have reported the trend in risk over successive hours on shift and have corrected for exposure in some manner[1–3]. All four studies report fairly similar trends to one another and by setting the mean risk in each study for the first eight hours at one, (i.e. setting the relative risk for an 8-h shift at one), hourly relative risk value could be calculated for each study. The hourly values were then averaged across the four studies to obtain an average trend. Apart from a slightly heightened risk from the second to fifth hour (see [4, 5] for a discussion of this), risk increased in an approximately exponential fashion with time on shift.

Using this trend the relative risk on shifts of different lengths was estimated by averaging the hourly values involved in any given length of shift. Variations in shift length from about 4 to 9 h had little impact on these estimated relative risk values because of (i) the exponential nature of the time on shift trend and (ii) the increased risk from the second to fifth hours. However, most importantly, we can now estimate the change in risk associated with shorter or longer shifts than 8-h. Thus, for example, we can estimate that relative to 8-h shifts, 10-h shifts are associated with a 13% increased risk and 12-h shifts with a 27% increased risk.

Finally, it appears that the trend for hours on duty does not control for the influence of breaks during a duty period, and one possible explanation for the decrease in risk after the fifth hour may be that it reflects the influence of rest breaks. A number of laboratory studies on the effects of breaks have been conducted, e.g.[6], but there appears to be only a single, recent study that has examined the impact of rest breaks on the risk of incidents[7].

This study examined industrial injuries in an engineering plant in which breaks of 15, 45 and 10 min, respectively, were given after each period of two hours of continuous work. The number of incidents within each of the four 30-min periods between breaks was calculated, and the risk in each 30-min period was expressed relative to that in the first 30-min period immediately following the break. The results indicated that risk increased substantially, and approximately linearly, between successive breaks such that risk had doubled by the last 30-min period before the next break. There was no evidence that this trend differed for the day and night shifts, or for the three successive periods of two hours of continuous work within a shift.

Theoretical Considerations

Most authors have argued that safety may be compromised at night since normally people are asleep at this time, and if

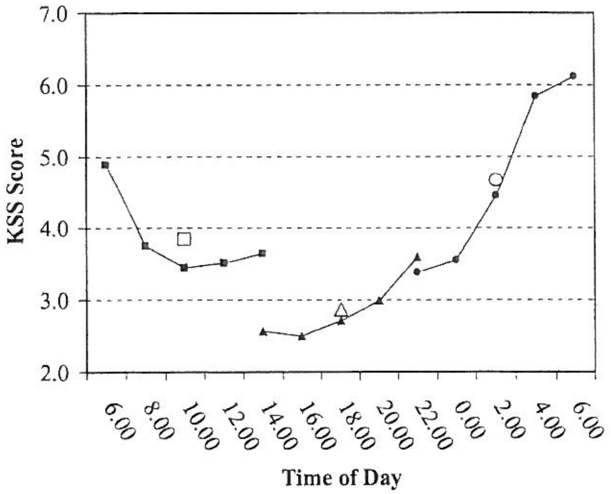

Fig. 1. The trend in sleepiness over the morning (■), afternoon (▲) and night (●) shifts and the mean values for each shift (large open symbols).

awake to work a night shift, their alertness and performance capabilities typically reach a low ebb in the early hours of the morning. Thus variations in risk are seen as reflecting on the circadian rhythms in alertness/sleepiness and performance capabilities. There are, however, two major problems with this interpretation.

First, sleepiness is usually higher on the morning shift than on the afternoon shift, despite the fact that the relative risk of incidents is lower on the morning shift (see above). A typical example of the trends in sleepiness over the three shifts is shown in Fig. 1. This figure is based on the averaged 2-hourly Karolinska Sleepiness Scale (KSS) ratings made by some 500 shiftworkers on a range of rotating 8-h shift systems, namely, continuous and discontinuous, and forward and backward rotating systems (see [8] for details). Sleepiness ratings were almost always higher on the morning shift than on the afternoon shift, and this is reflected in the mean ratings for the whole shifts (Fig. 1, large open symbols). Thus, although the increased risk on the night shift might be attributable to increased sleepiness, it is clearly not possible to account for the increased risk on the afternoon shift in this way.

An alternative explanation of the increased risk on the afternoon shift relative to the morning shift might be related to the sleep durations commonly associated with these shifts. For the 500 shiftworkers referred to above, workers slept an average of 5.9 (SD ± 1.1) hours between successive morning shifts and 8.4 (SD ± 1.3) hours between successive afternoon shifts. There is epidemiological evidence that both short and long habitual sleep duration are associated with an increased risk of mortality[9] and morbidity conditions such as diabetes[10] and coronary heart disease[11], and an increase in depressive symptoms[9]. There is also some evidence that injury risk may show a similar U-shaped relationship. Thus, for example, a case-control study[12] reported that excess sleep (9–10 h) on the night preceding a hand injury significantly increased risk (OR=2.7). Differences in the normal sleep duration between shifts cannot, however, account for the increased risk on the night shift relative to morning shift since they are typically rather similar (e.g. 6.2 versus 5.9 h in the sample described above).

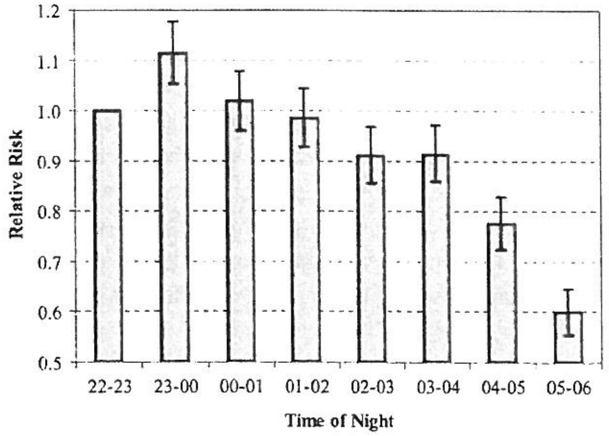

Fig. 2. The trend in Relative Risk over the course of the night shift. Error bars are 95% Confidence Intervals.

The second problem is the interpretation of the increased risk on the night shift in terms of the circadian rhythm in sleepiness. This explanation would predict that risk should increase over most of the night shift as sleepiness increases (see Fig. 1), however, studies of "accident" and injury rates over the course of the night shift have consistently found a rather different pattern to this. An early study in this area by Vernon in 1923[13] reported that the frequency of surgically treated lacerations occurring in two munitions factories decreased substantially over the course of the night shift. Vernon also showed that this decreasing trend, unlike that over the day shift, could not be accounted for in terms of variations in productivity.

A number of more recent studies have shown a similar trend[1, 3] and are summarised in Fig. 2. This figure is based on the summed frequencies across all the studies and the risk at 22:00 has been set at 1. Risk decreased fairly substantially after 23:00, with only a slight suggestion of an increased risk in the early hours of the morning between 03:00 and 05:00. The general trend over the night shift is essentially the opposite from that which would be predicted from sleepiness ratings (Fig. 1).

In summary, there are some relatively consistent trends in risk associated with features of shift systems but these are not always in line with predictions based on psychological factors such as sleepiness. In some cases it may be that we have yet to identify important psychological variables that underlie "accident" risk, or the nature of the relationship between sleepiness and risk[1]. Although the explanations for the discrepancies between risk and sleepiness are unknown, it would seem prudent to take the trends in risk seriously and to design shift systems in a manner that minimises the risk, especially in "high hazard" situations where there may be a danger to the general public or to the environment.

Practical Considerations

From a practical viewpoint, the trends in risk discussed in this paper could be used to design what should prove to be safer shift systems. Thus, for example, these trends suggest that shift length should be restricted, as should the number of successive shifts before a rest day. They also suggest that the use of frequent short breaks may reduce risk substantially. However, it is important to consider these features in combination rather than in isolation from one another. We have recently developed a "risk index" based upon a predictive model of the trends described in this paper[14]. The aim was to develop a tool that could be used to assess different work schedules with respect to their relative safety. Such a tool might also prove useful in injury and "accident" investigations to determine whether a particular injury or "accident" was at least in part, attributable to the work schedule.

In conclusion, there are consistent trends in incident risk associated with features of work schedules. In some cases, these trends are different from what would be predicted based on our knowledge of the circadian rhythm in sleepiness and clearly require further research to reveal the underlying mechanisms. Nevertheless, modelling the trends in risk may prove useful in designing safer work schedules.

Acknowledgement

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ORIGINAL ARTICLE

Effect of Reducing Interns' Work Hours on Serious Medical Errors in Intensive Care Units

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ABSTRACT

BACKGROUND

Although sleep deprivation has been shown to impair neurobehavioral performance, few studies have measured its effects on medical errors.

METHODS

We conducted a prospective, randomized study comparing the rates of serious medical errors made by interns while they were working according to a traditional schedule with extended (24 hours or more) work shifts every other shift (an "every third night" call schedule) and while they were working according to an intervention schedule that eliminated extended work shifts and reduced the number of hours worked per week. Incidents were identified by means of a multidisciplinary, four-pronged approach that included direct, continuous observation. Two physicians who were unaware of the interns' schedule assignments independently rated each incident.

RESULTS

During a total of 2203 patient-days involving 634 admissions, interns made 35.9 percent more serious medical errors during the traditional schedule than during the intervention schedule (136.0 vs. 100.1 per 1000 patient-days, $P<0.001$), including 56.6 percent more nonintercepted serious errors ($P<0.001$). The total rate of serious errors on the critical care units was 22.0 percent higher during the traditional schedule than during the intervention schedule (193.2 vs. 158.4 per 1000 patient-days, $P<0.001$). Interns made 20.8 percent more serious medication errors during the traditional schedule than during the intervention schedule (99.7 vs. 82.5 per 1000 patient-days, $P=0.03$). Interns also made 5.6 times as many serious diagnostic errors during the traditional schedule as during the intervention schedule (18.6 vs. 3.3 per 1000 patient-days, $P<0.001$).

CONCLUSIONS

Interns made substantially more serious medical errors when they worked frequent shifts of 24 hours or more than when they worked shorter shifts. Eliminating extended work shifts and reducing the number of hours interns work per week can reduce serious medical errors in the intensive care unit.

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IN A PIONEERING STUDY PUBLISHED IN the *Journal* 33 years ago, Friedman and colleagues reported that interns made almost twice as many errors reading electrocardiograms after an extended (24 hours or more) work shift than after a night of sleep.[1] More recent studies have similarly found that surgical residents made up to twice the number of technical errors in the performance of simulated laparoscopic surgical skills after working overnight than after a night of sleep.[2,3] Although many prior studies have been methodologically limited by the use of nonvalidated self-reports on the timing of sleep and inadequate accounting for circadian phase and chronic sleep loss, as reviewed elsewhere,[4-6] the literature as a whole suggests that sleep deprivation causes substantial decrements in physicians' performance of discrete neurocognitive and simulated clinical tasks.[4-8] The clinical importance of sleep curtailment has remained unclear, however,[4-6] owing to a lack of studies conducted in clinical care environments[4,9] and the possibility that scheduling interventions designed to mitigate sleep deprivation may simultaneously introduce discontinuities in care.[10,11]

Within hospitals, of all trainees, interns (postgraduate year 1) typically work the greatest number of hours per week.[12,13] The extended (24 hours or more) work shifts and long workweeks of interns may make them especially prone to fatigue-induced errors. In a survey of house officers, 41 percent reported fatigue as a cause of their most serious mistake. Most of these events occurred while they were interns, and 31 percent reportedly resulted in fatalities.[14]

To understand the effects of interns' sleep deprivation on serious medical errors, we conducted a comprehensive comparison of errors while interns followed a traditional work schedule and errors while they followed an intervention work schedule that was designed to reduce sleep deprivation. Our goals were to compare the rates of serious errors directly involving interns on the two schedules, since interns were the focus of our scheduling intervention, and to compare the overall rates of serious medical errors in order to track the effects of interns' schedules on the system as a whole.

METHODS

The Intern Sleep and Patient Safety Study was conducted as part of the Harvard Work Hours, Health and Safety Study from July 2002 to June 2003 in the medical intensive care unit (MICU) and coronary care unit (CCU) of Brigham and Women's Hospital, a large academic hospital in Boston, after approval by the institutional review board. The MICU and CCU were selected for study because they are the rotations of this internal-medicine training program with the longest work hours and because medical errors have been detected at higher rates in critical care settings than in other settings.[15,16] Both units have 10 adult critical care beds. Data were not collected on patients admitted for fewer than four hours, patients undergoing elective allergy desensitization, or the rare patients who boarded on the units but who were not cared for by the MICU or CCU team.

DESIGN OF INTERVENTION TRIAL

In collaboration with the leadership of the residency program and unit directors, we designed an intervention work schedule for interns that eliminated extended (24 hours or more) work shifts and reduced the number of scheduled hours of work to 63 per week (Fig. 1). The traditional MICU housestaff team consisted of three interns and three third-year residents, whereas the CCU team consisted of three interns and two second-year residents. Each intern and resident on these teams worked overnight in the hospital every third night. A resident from another hospital service assumed patient care responsibilities in the CCU on nights when neither of the daytime CCU residents was working. Under this rotation, interns' scheduled workweeks averaged 77 to 81 hours, depending on the clinic assignment, with up to 34 continuous hours of scheduled work when clinic occurred after they were on call (Fig. 1A).

During the intervention schedule, interns' work hours and overnight work schedules were changed. Interns' traditional extended work shifts were divided in two: a "day-call" intern worked the first half of a traditional call (from 7 a.m. to 10 p.m.); a "night-call" intern worked the second half (from 9 p.m. to 1 p.m. the following day). To effect this schedule, four interns shared patient care responsibilities during the rotation. The maximal scheduled hours of work were 60 to 63 per week, with consecutive hours of work limited to approximately 16 hours (Fig. 1B). The intervention did not alter the schedules or staffing of second- or third-year residents or other clinical personnel.

Our goal was to improve interns' opportunities to sleep while minimizing errors due to handoffs of patient care and cross-coverage.[10] To minimize cross-coverage errors, we developed a sign-out template for interns to use in all critical care rotations (both intervention and traditional schedules)[17] and incorporated an hour of overlap in the evenings for interns on the intervention schedule to sign out formally (see Figure A of the Supplementary Appendix, available with the full text of this article at www.nejm.org) under the supervision of the senior resident.

After providing written informed consent, interns were randomly assigned to work either the intervention schedule in the CCU and the traditional schedule in the MICU or the converse; these rotations were distributed throughout the year. Data collected during a pilot intervention schedule involving four interns that was discontinued after the first ICU rotation were not included. As detailed in the article by Lockley et al. in this issue of the *Journal*,[18] although actual work hours often exceeded those scheduled during both the tradi-

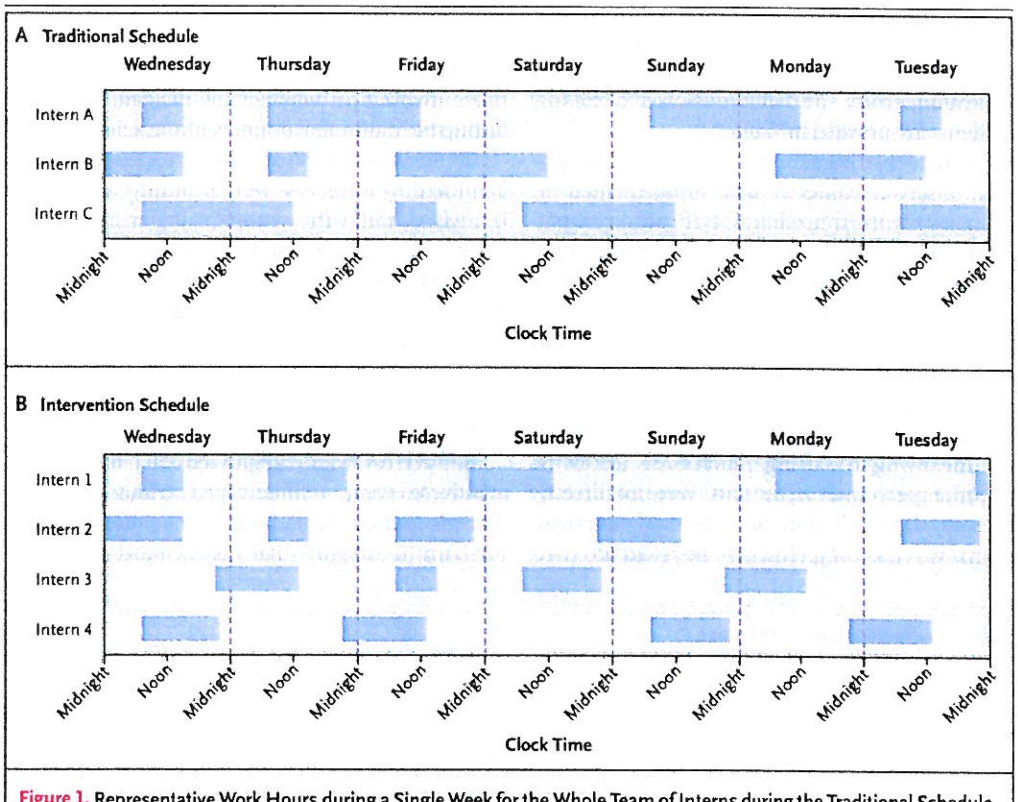

Figure 1. Representative Work Hours during a Single Week for the Whole Team of Interns during the Traditional Schedule (Panel A) and the Intervention Schedule (Panel B).

Scheduled work hours are indicated by the bars. Panel A shows the traditional rotation in which a team of three interns provided continuous coverage on a repeated three-day schedule, consisting of a daytime "swing" shift on day 1 (7 a.m. to 3 p.m.) (e.g., Wednesday for Intern A), followed by an extended on-call shift from 7 a.m. on day 2 to noon on day 3 (e.g., Thursday through Friday for Intern A). Interns had the day off when a swing shift was to occur on a Saturday, Sunday, or Monday (e.g., Saturday for Intern A). Interns staffed weekly ambulatory clinics when they coincided with a swing shift or the latter half of an extended on-call shift. Panel B shows the intervention rotation in which a team of four interns provided continuous coverage on a repeated four-day schedule. Day 1 is the standard swing shift (e.g., Wednesday for Intern 1); day 2 is "day call" from 7 a.m. to 10 p.m. (representing the first half of the traditional call) (e.g., Thursday for Intern 1); days 3 and 4 are "night call" from 9 p.m. on day 3 to 1 p.m. on day 4 (representing the second half of a traditional call) (e.g., Friday through Saturday for Intern 1). There is a one-hour scheduled overlap between the outgoing day-call intern and the incoming night-call intern (e.g., Wednesday from 9 p.m. to 10 p.m. for Intern 4 and Intern 3, respectively); this overlap was often extended as clinically required. Interns had the day off when a swing shift was to occur on a Saturday, Sunday, or Monday (e.g., Sunday for Intern 1). Interns only attended clinics when they coincided with the swing day.

tional and intervention schedules, the intervention successfully eliminated shifts of 24 hours or more, reduced the number of hours worked by interns by nearly 20 per week, increased the average daily duration of sleep by nearly an hour, and reduced attentional failures.

DATA COLLECTION AND CLASSIFICATION

To measure patients' safety during the two schedules, we developed an intensive system of data collection and evaluation that expanded on methods previously used in the study of medication errors[16,19] and also included continuous observation of interns by physicians. In this study, we focused on procedural and diagnostic errors in addition to medication errors. The definitions used to classify incidents are provided in Table 1.

A team of two nurse chart reviewers and six physician observers collected data, supplemented by voluntary reports from clinical staff and a computerized event-detection monitor. Direct observation was the principal means of detecting serious errors in which interns were directly involved; physician observers followed study interns continuously, day and night in the hospital. In the afternoons after work rounds, when more than one intern was working simultaneously, only one intern was observed at a time owing to staffing limitations. Residents and other personnel on the units were not directly observed. Data collection for personnel other than interns was less comprehensive and relied on chart review, voluntary reports, and computerized event-detection monitoring. Other methods of data collection, though less comprehensive, were designed to identify all serious medical errors — both those in which interns were involved and those in which they were not involved. Before beginning data collection, all staff received intensive training in the consistent, objective collection of data using standardized forms. Because it was not possible to blind data collectors to the study schedule, determinations of the preventability and classification of events were not made by the primary data collectors. Instead, each suspected error or adverse event identified was independently rated by two physician investigators who were unaware of the identity of those involved or whether the incident occurred during the traditional or intervention schedule.

In the vast majority of cases, the serious errors identified by observers were promptly addressed by medical staff with no need for action on the part of the observers. Nonintercepted serious errors were generally detected by observers when they were discussed by clinical staff. In the handful of cases in which observers identified possible errors in the making with substantial potential to cause harm, they immediately alerted clinical staff to prevent harm to the patient.

Blinded reviewers categorized each incident as an adverse event, nonintercepted serious error, intercepted serious error, or error with little potential for harm (a category that was excluded from the

Table 1. Definitions Used in the Study.

Term	Definition
Medical error	Any error in the delivery of medical care, whether harmful or trivial
Serious medical error	A medical error that causes harm or has substantial potential to cause harm, including preventable adverse events, nonintercepted serious errors, and intercepted serious errors, but not including errors with little or no potential for harm or unpreventable adverse events
Intercepted serious error	A serious medical error that is intercepted before reaching the patient
Nonintercepted serious error	A serious medical error that is not intercepted and therefore reaches the patient but causes no clinically detectable harm
Adverse event	Any injury due to medical management
Nonpreventable adverse event	Unavoidable injury resulting from appropriate medical care
Preventable adverse event	Injury due to a nonintercepted serious error in medical management
Serious medication error	A serious medical error related to the ordering or administration of pharmaceutical agents, blood products, or intravenous fluids
Serious procedural error	A serious medical error related to the performance of an invasive procedure, such as placement of a central venous or arterial catheter
Serious diagnostic error	A serious medical error related to history taking, the performance of a physical examination, or the ordering or interpretation of a diagnostic test

analysis) and rated the preventability of adverse events using a Likert scale (was prevented, was definitely preventable, was probably preventable, was probably not preventable, or was definitely not preventable); the preventability scale was dichotomized to include only "preventable events" and "nonpreventable events" before analysis. Events deemed more likely to be due to patients' underlying illness than to medical therapy were excluded. Disagreements were resolved by discussion; the interrater reliability was calculated before such discussion by means of the kappa statistic, as described below.

STATISTICAL ANALYSIS

Patients' characteristics and the mean daily census of the units during the intervention and traditional rotations were compared by means of Fisher's exact test; Wilcoxon's nonparametric test for dichotomous, nonnormally distributed continuous variables; and a t-test for normally distributed continuous variables. All statistical tests were two-tailed. The rates of diagnostic tests and procedures per patient-day were compared between the two schedules, and the distribution was assumed to be binomial. We compared the rates of medication orders per patient-day between the two schedules, assuming a Poisson distribution, since the presence of rates of more than one order per patient-day precluded the use of the binomial distribution.

We compared the rates of intern-associated serious medical errors per patient-day (for all interns combined) and of total serious medical errors per patient-day between the intervention and traditional schedules, assuming a binomial distribution. The rates of all serious medical errors include all intern-associated serious errors (those detected by direct observation and other methods) plus non–intern-associated errors (identified by chart review, staff reports, and the computerized monitor). We also compared the rates of type-specific errors (medication, procedural, and diagnostic) per patient-day, assuming a binomial distribution. For all tests, two-tailed P values of less than 0.05 were considered to indicate statistical significance.

The study was powered to determine differences in rates of serious medical errors. Analyses of the rates of adverse events were performed, but the results were considered exploratory since we had only 11 percent power to detect a 25 percent difference in intern-associated preventable adverse events. By contrast, the study was designed to have 80 percent power to detect a 16 percent difference in the rate of serious errors between groups.

We evaluated the reliability of the primary data-collection process by conducting dual direct observation for a total of 10 patient-days; there was 82 percent agreement between independent observers with respect to the occurrence of a serious medical error. At the review stage conducted by the blinded investigators, we performed comprehensive reliability testing of all incidents rated using the kappa statistic. For reviewers' judgments about whether an incident was an adverse event, an intercepted serious error, a nonintercepted serious error, or an excluded event, the κ was 0.90; the κ was 0.80 for the preventability of adverse events.

RESULTS

PATIENT POPULATION

The study involved 2203 patient-days (1294 during the traditional schedule and 909 during the intervention schedule), representing 634 admissions to the units (385 during the traditional schedule and 249 during the intervention schedule) and 5888 hours of direct observation of interns. The patients' characteristics and the units' characteristics were very similar during the traditional and intervention schedules (Table 2). The number of days included in the traditional schedule exceeded that of the intervention schedule primarily because four interns were required for the intervention schedule as compared with only three for the traditional schedule. Since all interns rotated through both schedules, more traditional than intervention rotations were required to allow each intern to spend three weeks on each schedule. The patients' length of stay and mortality rate did not differ significantly between the two schedules.

SERIOUS MEDICAL ERRORS BY INTERNS

Interns made 35.9 percent more serious medical errors during the traditional schedule than during the intervention schedule (136.0 vs. 100.1 per 1000 patient-days, $P<0.001$) (Table 3). Interns made 27.8 percent more serious errors that were intercepted during the traditional schedule than during the intervention schedule (70.3 vs. 55.0 per 1000 patient-days, $P=0.02$) and 56.6 percent more nonintercepted serious errors that reached the patients (44.8 vs. 28.6 per 1000 patient-days, $P<0.001$). The rates of preventable adverse events did not differ significantly between the two schedules.

ALL SERIOUS MEDICAL ERRORS AND ADVERSE EVENTS

The rate of all serious medical errors was 22.0 percent higher during the traditional schedule than during the intervention schedule (193.2 vs. 158.4 per 1000 patient-days, P<0.001) (Table 3). Intercepted serious errors occurred 37.2 percent more frequently during the traditional schedule than during the intervention schedule (95.1 vs. 69.3 per 1000 patient-days, P<0.001). The overall rates of nonintercepted serious errors did not differ significantly between the two schedules, nor did the rates of preventable adverse events. There was no significant difference in the rates of total adverse events (preventable plus nonpreventable) between the traditional and intervention schedules (85.0 vs. 93.5 per 1000 patient-days, P=0.31). Secondary analysis of the rates of serious medical errors in which interns were not involved revealed no significant differences between the traditional schedule and the intervention schedule (40.2 vs. 38.5 per 1000 patient-days, P=0.69).

TYPES OF SERIOUS MEDICAL ERRORS

Interns made 20.8 percent more serious medication errors during the traditional schedule than during the intervention schedule (99.7 vs. 82.5 per 1000 patient-days, P=0.03). Interns made 5.6 times as many serious diagnostic errors during the traditional schedule as during the intervention schedule (18.6 vs. 3.3 per 1000 patient-days, P<0.001). The rates of serious procedural errors among interns did not differ significantly between the two schedules (Table 3).

Analysis of the types of all errors (errors made by interns plus errors in which interns were not involved) showed similar patterns (Table 3). Serious medication errors occurred 17.1 percent more frequently during the traditional schedule than during the intervention schedule (135.2 vs. 115.5 per 1000 patient-days, P=0.03). The rates of serious procedural errors did not differ significantly between the two schedules. Serious diagnostic errors were nearly twice as common during the traditional schedule as during the intervention schedule (21.6 vs. 11.0 per 1000 patient-days, P<0.001).

Examples of each type of serious medical error and adverse event observed in the study are provided in Table 4. Subcategories of medication and nonmedication errors are available in Table A of the Supplementary Appendix.

Table 2. Characteristics of the Patients and the System.[*]

Characteristic	Traditional Schedule	Intervention Schedule
Patients		
No. of patients	354	227
No. of unit admissions	385	249
No. of patient-days	1294	909
Mean age — yr	64.9±0.8	63.2±1.10
Male sex — no./total no. of unit admissions (%)	214/385 (55.6)	126/249 (50.6)
Charlson comorbidity index[†]	4.0±0.2	4.1±0.2
APACHE II score[‡]	17.7±0.5	17.9±0.7
Length of unit stay — days		
Median	2.9	3.0
Interquartile range	5.1	5.7
No. who died in unit/total no. of unit admissions — %	49/385 (12.7)	36/249 (14.5)
CCU and MICU		
Daily censuses	9.2±0.1	9.4±0.1
Interns		
No. of medication orders/patient-day	8.2	7.8
No. of procedures/patient-day[§]	0.28	0.33[¶]
No. of interpretations of diagnostic tests/patient-day[‖]	0.28	0.29

[*] Plus–minus values are means ±SE.

[†] Scores for the Charlson comorbidity index can range from 0, indicating no serious coexisting conditions, to 6, indicating the presence of metastatic cancer or infection with the human immunodeficiency virus.

[‡] Acute Physiology and Chronic Health Evaluation (APACHE) scores can range from 0 to 71, with higher scores indicating an increased likelihood of death.

[§] Procedures performed by interns included placement (or rethreading) of central venous catheters, placement of arterial catheters, drawing of arterial blood, intubation, thoracentesis, placement of nasogastric and orogastric tubes, lumbar puncture, and removal of central catheters or tubes.

[¶] P<0.001 for the comparison with the traditional schedule.

[‖] Interpretations of diagnostic tests by interns included interpretation of chest radiographs, other radiographs, electrocardiograms, and arterial blood gas values.

DISCUSSION

Interns made 36 percent more serious medical errors during a traditional work schedule than during an intervention schedule that eliminated extended work shifts. These included significantly more serious medication errors and 5.6 times as many serious diagnostic errors. As a consequence, the overall rates of serious medical errors were significantly higher during the traditional schedule than during the intervention schedule. Fortunately, most of serious medical errors by interns will translate into a reduction in the rate of adverse events.

The prospective, randomized nature of this study allowed for a rigorous evaluation of the effects on patients' safety of an intervention designed to improve interns' sleep and thus decrease medical errors. Prior studies using before-and-after cohort designs to assess the effects of scheduling interventions have provided limited and conflicting data. A before-and-after analysis of a scheduling intervention in one hospital that reduced residents' work hours and decreased cross-coverage of unfamiliar patients by senior residents found that the efficiency of care increased and the rates of errors among residents decreased.[20] In contrast, an unblinded, retrospective study of a New York State regulation that decreased the number of hours worked by house staff but increased cross-coverage found that the efficiency of care declined and rates of medical complications increased.[11] Each was limited by a before-and-after design, which precluded the exclusion of secular trends, increasing experience of house staff, cohort effects, or other external confounders as possible explanations for the changes. Because of concurrent changes in work hours, cross-coverage, and other aspects of care in these studies, it was not possible to identify the elements that may have been responsible for the findings.

The overall incidence of serious errors and adverse events we detected is similar to that reported in other studies of patients' safety in the ICU. For example, Giraud et al.[21] and Rubins and Moskowitz[22] documented the occurrence of 13 to 40 preventable adverse events per 1000 patient-days. The Harvard Medical Practice Study[23] reported lower rates but used a less comprehensive method of data collection and a more restrictive definition of harm, since it sought to detect injuries due to negligence. Donchin et al. reported a higher rate of 1.7 errors per patient-day but included errors with little potential for harm.[15] The rates detected by Donchin et al. may also be higher because they focused on errors in the unit as a whole, whereas we directly observed only interns. Moreover, during daytime hours, when two or more interns were working simultaneously in different parts of the units, our staffing limitations allowed us to observe only one intern at a time. Consequently, the true rate of serious errors in the units as a whole may have been higher.

The article by Lockley et al.[18] demonstrates that eliminating extended work shifts and reducing the number of hours worked by interns led to signifi-

Table 3. Incidence of Serious Medical Errors.

Variable	Traditional Schedule	Intervention Schedule	P Value
	no. of errors (rate/1000 patient-days)		
Serious medical errors made by interns			
Serious medical errors	176 (136.0)	91 (100.1)	<0.001
Preventable adverse events	27 (20.9)	15 (16.5)	0.21
Intercepted serious errors	91 (70.3)	50 (55.0)	0.02
Nonintercepted serious errors	58 (44.8)	26 (28.6)	<0.001
Types of serious medical errors made by interns			
Medication	129 (99.7)	75 (82.5)	0.03
Procedural	11 (8.5)	6 (6.6)	0.34
Diagnostic	24 (18.6)	3 (3.3)	<0.001
Other	12 (9.3)	7 (7.7)	0.47
All serious medical errors, unit-wide			
Serious medical errors	250 (193.2)	144 (158.4)	<0.001
Preventable adverse events	50 (38.6)	35 (38.5)	0.91
Intercepted serious errors	123 (95.1)	63 (69.3)	<0.001
Nonintercepted serious errors	77 (59.5)	46 (50.6)	0.14
Types of serious medical errors, unit-wide			
Medication	175 (135.2)	105 (115.5)	0.03
Procedural	18 (13.9)	11 (12.1)	0.48
Diagnostic	28 (21.6)	10 (11.0)	<0.001
Other	29 (22.4)	18 (19.8)	0.45

serious medical errors were either intercepted or did not result in clinically detectable harm to the patient. Although the study was not designed to have sufficient statistical power to detect a difference in preventable adverse events, the incidence of intern-associated preventable adverse events was 27 percent higher during the traditional schedule than during the intervention schedule, a difference that was not statistically significant (20.9 vs. 16.5 per 1000 patient-days, $P=0.21$). The overall rates of preventable adverse events (intern-associated and non–intern-associated) were not significantly different during the traditional and intervention schedules (38.6 and 38.5 per 1000 patient-days, respectively; $P=0.91$), although our intervention and observations were focused on the interns. This study was not designed or powered to assess comprehensively the effect of the intervention on adverse event rates in the units as a whole. Therefore, it remains to be determined whether the decrease in the rate

Table 4. Examples of Serious Medical Errors and Nonpreventable Adverse Events.

Category and Type	Description
Intercepted serious error	
Procedural	As intern is preparing to perform a thoracentesis on the left side of the patient's chest, the senior resident enters the room and informs the intern that the pleural effusion is on right side of the patient's chest.
Diagnostic	Several days after a patient with a history of flash pulmonary edema is admitted for congestive heart failure, intern reports that patient is in clinically stable condition, having miscalculated that 24-hour input and output volumes are well matched (positive by 20 ml). The nurse is concerned that patient seemed overloaded with fluid and in mild respiratory distress and requests a reevaluation. A recalculation by the senior resident reveals an error by a factor of 100: the patient's input and output volume has, in fact, been positive by 2000 ml for the prior 24 hours. Furosemide is promptly administered and the patient's symptoms improve.
Medication	Intern orders an intravenous vasopressin drip at rate of 0.2 U/min (overdose by a factor of 10). Nurse intercepts the order, and the rate is changed to 0.02 U/min.
Nonintercepted serious error	
Procedural	Patient with defibrillator implanted on left side urgently needs central access for inotropic support. Intern inserts a central venous catheter in the left subclavian vein. Not recognizing that the vein contains the wire from the defibrillator, the intern is having repeated difficulty advancing the introducer. In the middle of the placement, the cardiology fellow enters and asks the intern to abort the procedure immediately. The catheter is removed before it can interfere with or dislodge the defibrillator wire.
Diagnostic	A middle-aged patient with a complete heart block is admitted to the CCU. The intern fails to examine the patient's back. The following day, the patient is noted to have a well-developed erythema migrans rash on the back, consistent with the presence of Lyme disease, which is later confirmed by serologic testing. Initiation of Lyme therapy is delayed.
Medication	Intern orders an antibiotic for a patient with a listed allergy to the medication. One dose is given before the error is detected, but the patient does not have an allergic reaction.
Preventable adverse event	
Procedural	A right-sided tension pneumothorax develops after a technical error during placement of a subclavian venous catheter leads to pleural-space puncture.
Diagnostic	The attending physician devised a plan to transfuse a patient for a hematocrit of <30. Despite these instructions, the intern fails to check laboratory results for 36 hours. When the laboratory results are finally checked, hematocrit is found to have been 26 in the interim. The patient has tachycardia for a protracted time as a consequence.
Medication	Bradycardia and hypotension develop owing to an inadvertent overdose of a benzodiazepine.
Nonpreventable adverse event	
Procedural	Transfusion is required for severe bleeding resulting from placement of a medically indicated nasogastric tube in a patient with coagulopathy. There is no error in placement or technique.
Medication	A rash related to nafcillin develops in a patient with no known drug allergies.

cant improvements in interns' sleep and reductions in attentional failures. Although causality cannot be established, it was our a priori hypothesis that increases in sleep resulting from the elimination of extended work shifts and reduction of work hours would lead to a decrease in serious medical errors.[24] There were no significant differences between the two schedules in the patients' severity of illness or other individual or systemic variables that could independently account for the observed differences in the rates of medical errors. Our randomized study design greatly diminished the likelihood of hidden confounding owing to secular trends, seasonal effects, learning over the course of the year, or other external factors unrelated to our study.

Before we initiated the intervention schedule, concern was expressed that decreasing the number of hours interns worked might diminish their role in the units, thereby shifting the burden of order writing and procedures and, hence, the risk of errors to more senior staff. Our results did not bear out this concern: the number of medications ordered and tests interpreted by interns per patient-day did not differ significantly between the two schedules, and interns performed significantly more procedures per patient-day during the intervention schedule. Moreover, the error rates among senior residents and other staff members were not increased during the intervention schedule. Thus, the substantially lower rates of errors by interns during the intervention schedule cannot be due to shifting of errors to more senior staff.

The Institute of Medicine's report "To Err Is Human"[25] was notably silent regarding the issue of sleep deprivation, largely because data directly linking sleep deprivation and medical error have been lacking. Our study helps to fill this knowledge gap and provides data suggesting that the sleep deprivation associated with the traditional extended shifts of 24 hours or more worked by interns may contribute to the high risk of medical errors in critical care units.

It is important to emphasize that not all interventions that reduce interns' work hours will increase interns' sleep[26] or improve patients' safety. Schedule design is a critical factor in determining the extent to which around-the-clock work schedules disrupt wake–sleep cycles, even when the number of weekly work hours remains the same.[27] Furthermore, any systemic intervention that reduces work hours necessarily increases either providers' workload (i.e., the number of patients covered by a provider at any time) or the number of hand-offs in care between medical personnel on shorter work shifts. Either can lead to increased rates of errors and adverse events.[10] "Night-float" systems, which use residents on night shifts to allow physicians working extended work shifts protected time for sleep, have their own set of risks. Night-float residents often know patients less well than do other team members (particularly if multiple residents share responsibilities as night floats over the course of a week, or if night floats are responsible for an increased number of patients), and may themselves be sleep-deprived and error-prone.[28] For these reasons, we ultimately decided not to implement a night-float system as a means of reducing interns' work hours, as originally planned.[24] Our data support the hypothesis that elimination of extended work shifts in a system that minimizes cross-coverage can improve patients' safety. These gains might not be realized in systems that use extensive cross-coverage.

Although our intervention decreased the rate of serious errors overall, our efforts to optimize the sign-out process were only partially successful. The computerized template was never fully adopted, and the effectiveness of the planned evening sign-out was frequently suboptimal. Although some groups of interns worked successfully as teams and effectively signed out every evening, even in the absence of formal training in team management, others did not. In the latter case, the night-call intern was often unaware of historical details regarding patients admitted by the day-call intern and sometimes performed poorly when describing these patients on morning rounds. This led to a widespread impression that communication on the intervention schedule was problematic, making the improvements in patients' safety we observed all the more remarkable. We suggest that future scheduling interventions address this issue by adding formal evening rounds for the entire team. Such improvements, coupled with the elimination of extended work shifts, could further improve patients' safety.

Our study has several limitations. The intervention schedule improved work hours but still involved shifts that were long enough to induce a number of attentional failures that was greater than would be expected among fully rested people.[18] We studied two ICUs in a single hospital, and our results may not be generalizable to other settings. In addition, although our study was very large as compared with prior observational safety studies,[15] the study was not powered to detect differences in the rates of preventable adverse events. Larger-scale, multicenter trials are needed to investigate this aspect.

Another important limitation was our inability to blind the medical observers to the schedule of the interns, an issue commonly encountered in investigations of systemic interventions to maximize patients' safety. We addressed this in two ways: first, we instructed observers — none of whom were study investigators — in the importance of consistent, objective detection of serious errors, regardless of study schedule. Second, all initial observations were also reviewed by two independent investigators who were blinded to the study's conditions and who classified incidents with extremely high reliability. Nonetheless, we cannot exclude the possibility that some bias may have resulted from the inability to blind the primary detection process, though our reliability data suggest that this bias was probably minimal.

Notably, our data on the high incidence of intercepted serious errors in ICU settings indicate that the ability of other personnel to act as interns' safety net — nurses, pharmacists, and senior medical staff — is very important in preventing injury to patients as a result of interns' errors. Therefore, future studies should seek to improve and measure objectively the sleep and performance of all clinical unit personnel, since team performance may critically affect patients' safety.[29] Having interns on a different schedule than supervising residents may have introduced discontinuities in education and interfered with the traditional resident–intern mentorship bond. We would recommend that future studies investigate the effects of eliminating the extended work shifts of interns and senior residents, both to avoid this problem and because it is unlikely that interns are uniquely susceptible to the adverse effects of sleep deprivation.

Prior interventions that have proved successful in reducing serious medical errors in ICU settings have included the use of computerized provider order entry (CPOE)[30] and on-site monitoring of orders by clinical pharmacists.[31] The higher intern-associated rate of serious medical errors during the traditional schedule, even in the presence of CPOE, clinical pharmacists, unrestricted use of caffeine by interns,[32] and a perceived increase in the risk of handoff errors, indicates the extent of impairment associated with extended work shifts. This observation corroborates the prior experimental finding that a single night of continuous sleep deprivation causes decrements in performance similar to those induced by a blood alcohol level of 0.10 percent.[33]

By reducing consecutive and weekly work hours, our scheduling intervention attempted to address both acute sleep deprivation and chronic partial sleep deprivation. By reducing interns' sleep deprivation and, hence, depth of subsequent sleep, we also indirectly addressed the adverse effects of sleep inertia (i.e., an increased tendency to err on awakening) on performance, since such impairment is a function of sleep depth.[34] The schedule was also designed to attenuate the circadian performance nadir by taking advantage of the blunting of this nadir that occurs when the homeostatic sleep drive is lower.[35,36] By providing interns with the opportunity to sleep in the afternoon before working overnight, the schedule thereby muted the effect of circadian misalignment on performance. Medical or surgical simulators could help isolate the effects of these interacting factors, since the relative importance of these variables remains unclear. Strategic use of a novel regimen of caffeine[32] or ambient light of specific intensity and wavelengths[37,38] may further mitigate the deterioration in performance resulting from circadian misalignment.

In conclusion, the rates of serious medical errors in two ICUs were lowered by eliminating extended work shifts and reducing the number of hours interns worked each week. Our results may have important implications for health policy, since more than 100,000 physicians are currently in training in the United States.[39] Most of these residents are regularly scheduled to work 30-hour shifts, since extended work shifts and long workweeks continue to be permitted, even under the scheduling reforms instituted last year by the Accreditation Council for Graduate Medical Education. Further modifications of these standards, particularly with respect to the duration of work shifts, may be needed to improve patients' safety in teaching hospitals nationwide.

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The Effect of Work Hour Restrictions on the Education of Orthopaedic Surgery Residents

Terrance Peabody, MD

In 2005 the Academic Leadership Group of the American Orthopaedic Association surveyed orthopaedic program directors, chairs, and members of the Resident Leadership Forum to gather information about the effect of the Accreditation Council for Graduate Medical Education work-hour restrictions on resident education. We compared these results with a similar survey performed 2 years ago. Ninety-four program directors and chairs and 59 senior residents responded to this survey. Overall, the respondents thought the duty hour restrictions had a negative impact on orthopaedic residency education but less so than in the previous survey. This conclusion was based on perceived negative effects on professionalism, resident operative experience, continuity of care, and increased workload for the faculty. Senior residents who worked before and after the work-hour limitations were instituted were more concerned about the negative effects than junior residents. Residents did seem more rested and content but not better prepared or necessarily more attentive. Respondents were not of the opinion resident performance had improved as measured by perceptions of performance on standardized tests. Orthopaedic departments had adapted to the work-hour limitations by scheduling night float rotations, converting in-house call to home call, and by hiring additional personnel in the form of physician extenders.

It has now been over 2 years since the Accreditation Council for Graduate Medical Education (ACGME) instituted work-hour limitations in response to public concerns regarding patient safety and resident welfare. These were based in part on New York laws resulting from the Bell Commission evaluation of patient safety and resident fatigue.[9,15] The limitations have been described as arbitrary but are more generous than limits in place in many European countries, many of which apply to practicing physicians and those in training.[8]

Resident work hours are now limited to 80 hours per week averaged over 4 weeks. Residents must go home after in-house call after 24 hours, with 6 hours allowed for transition of care, continuity clinics, or educational activities. The residents must have 1 day free of clinical responsibilities each week as averaged over 4 weeks. Ten hours must be allowed between regular scheduled shifts. In-house call must be no more frequent than every third night.[1] The ACGME will evaluate the impact of the work hour restriction and has stated another requirement may follow that may be higher or lower than 80 hours.

With little data collected before the work hour restrictions, it is difficult if not impossible to assess the impact they have had on residency education. Clearly, program faculty, including chairs, program directors, and all who teach residents, have had to make substantial adaptations. The residents have also had to change their behavior. Academic medical centers must provide additional resources at substantial expense for care previously provided by residents.

An earlier survey of program chairmen and residents was performed in order to identify the effect of the work hour restrictions on residency programs.[16] Overall, most were of the opinion the new restrictions had a negative impact due to lost educational opportunities and compromised patient care. No improvement in patient safety was noted. A bimodal response from residents was obtained that may have been related to year of training. Written comments expressed concern about negative effects on professionalism.

In order to see if opinions had in fact changed in the subsequent years we again surveyed program chairmen but this time sought opinions from program directors and senior residents from the Residency Leadership Forum (RLP). Were the negative opinions expressed in the first survey moderated by time and experience? We presumed

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with time, programs and residents had made accommodations to the new requirements and a more positive view of them would be expressed in this survey. Additional questions were asked about particular challenges raised by the new regulations including communication, teamwork, operative experience, and the effect on the faculty. New questions were asked about how the new rules on orthopaedic education influenced professionalism, resident operative experience, continuity of care, patient safety and workload. Last, we queried the group about coping mechanisms including physician extenders, night float, rotation deletion, and home call.

MATERIALS AND METHODS

To gauge the effect of the new rules on orthopaedic education, and specifically to identify particular challenges and unique coping strategies, the American Orthopaedic Association (AOA) undertook a second survey of program directors and chairs and members of the Resident Leadership Forum. Resident Leadership Forum members are senior level residents nominated by their programs who had participated in the jointly sponsored AAOS/AOA forum. We compared these results to the results of an initial survey completed shortly after the work-hour restrictions were instituted.[16] We surveyed 229 program directors and chairs of ACGME accredited residencies in orthopaedic surgery and 98 members of the Resident Leadership Forum with an electronic questionnaire designed by the members of the Academic Leadership Group of the AOA and reviewed and modified by the AOA staff. A reminder was sent two weeks following the initial submission.

Questions were written in such a way to elicit the overall effect of the work hour restrictions on the program as well as to solicit information about various effective and ineffective coping strategies. (Appendix 1) Because of disparities noted on the first survey, additional questions were added to provide clarity. In addition to standard responses, written comments were solicited from those surveyed. The early survey indicated a bimodal response from residents in their attitudes towards the work-hour limitations. To verify this, residents and chairs were asked if resident attitudes toward the duty-hour restrictions were neutral, positive, negative, or mixed based on resident level. Some survey questions were added related to unintended consequences of duty-hour restrictions (Table 1). To measure the effect on operative experience, the respondents were asked to comment on the effect of changes on the volume of operative and clinical experience.

The answers to the survey were then tabulated as a percentage of and compared to other responses. These results were later compared to choices made in the earlier survey. Written remarks were solicited separately in order to allow respondents to comment on related issues beyond what was contained in the survey responses. These were used to determine if common themes were present and if major issues were not addressed by the survey. (The methods and findings have been previously published[16] and are republished here in modified form.)

TABLE 1. Unintended Consequences

Consequence	Chair/PD	Residents
Hand-off problems	55%	59%
Uncovered cases	71%	58%
Increased faculty work	59%	29%

PD = program director

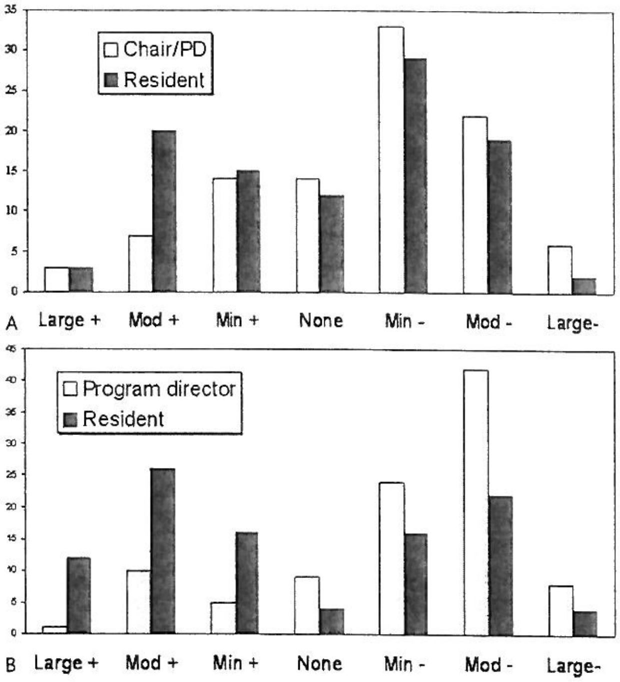

Fig 1A–B. (A) This graph shows the program directors', chairs', and residents' perceptions of the effect on the work-hour restrictions on the educational program. While the overall opinion is mildly negative, the results demonstrate a shift to a more favorable position compared to an earlier survey, especially on the part of senior orthopaedic surgery residents. (B) This graph shows the results of the earlier survey.

RESULTS

In comparison to the responses from the first survey, there were fewer strong negative opinions and a positive trend indicating some moderation and acceptance of the new regulations (Fig 1). Overall, however the general effect of the work-hour restrictions on orthopaedic residency education programs was described as negative by 61% of the responding program directors and chairs. Most believed this was a minimal effect. A few programs noticed no effect, and 24% thought the new regulations had a positive effect. In comparison, 38% of residents thought the changes had been good for the program, 12% were neutral, and 50% thought the effect was negative. One-half of the program directors and chairs and 58% of the residents believed attitudes were mixed based on resident level. Junior residents view the changes more favorably than more senior level trainees.

Problems related to communication and teamwork in patient hand-offs were commonly cited in the majority of resident and faculty surveys (Table 1). These problems may have in part mitigated any improvements perceived in patient safety as a result of the work hour limitations. An increased number of operative cases without resident involvement was also noted by program directors and residents. Of program directors, 42% thought residents had an inadequate volume of cases; 41% of residents agreed. The majority of program directors and chairs believed the faculty workload had increased. This perception was not shared by the residents. Faculty attitudes towards the work-hour restrictions were described as negative in 57% of program directors' and chairs' responses, neutral in 36%, and positive in 3%. Faculty attitudes were believed to be negative in 47% of the residents' responses, 37% believed the changes had a neutral effect on faculty attitudes, and 10% were described as positive.

Most (65%) residents believed the requirements resulted in improved resident satisfaction and contentment. Program directors and chairs did not share this assessment as strongly (Fig 2). Neither group believed residents were better prepared for cases and examinations, complained less, demonstrated improved teamwork, or were more attentive than they had been before the restrictions. The respondents were of the impression in-training examination scores and resident evaluations have not been affected by the work-hour limitations. No objective data was requested or available.

Addressing the issue most commonly cited for the regulations, patient safety, only 9% of program directors and 31% of residents agreed the changes made to accommodate the work-hour restrictions had resulted in fewer medical errors. Many believed the effect was neutral (30% and 39%). Sixty-one percent of directors and 30% of residents disagreed, saying the limitations had not resulted in fewer errors (Fig 3).

The most common reported adaptation to the work-hour restrictions was using physician extenders, such as physician assistants and similarly trained professionals (76%). This increased from the 51% previously reported. Interestingly, only 56% of the residents noted this accommodation. Not only were more departments using physician extenders, but the survey also showed an increased number of physicians' assistants and nurses hired in each institution, with 27% hiring three or more of these individuals. There was little change in the number of programs using other strategies. Thirty-seven percent of programs have changed call responsibilities from in-house to home call. This relieves the program of assessing the in-house call responsibilities and is fairly straightforward to implement but requires substantial oversight. Time spent in the hospital on-call still counts towards the work-hour limitations. The ACGME has had to subsequently comment on what is meant by home call. Other reported strategies included the design of night float rotations, where the residents' primary task is to assume night call responsibilities (34%). The educational value of this type of rotation varied based on the type of practice, the availability of conferences, and the level of supervision available after hours.

Written comments were largely negative towards the work-hour restrictions. Most mentioned concerns regarding the 30-hour restriction on continuous in house duty because residents are not able to participate in many procedures on patients they have evaluated the night before. This appears to affect mostly residents in the junior years. Also noted was a relative increase in operative trauma cases compared with other mostly elective orthopaedic subspecialty procedures. Some program directors also complained of a shift mentality among the residents, more work for faculty members and senior residents, and challenges related to funding, availability, and using physician

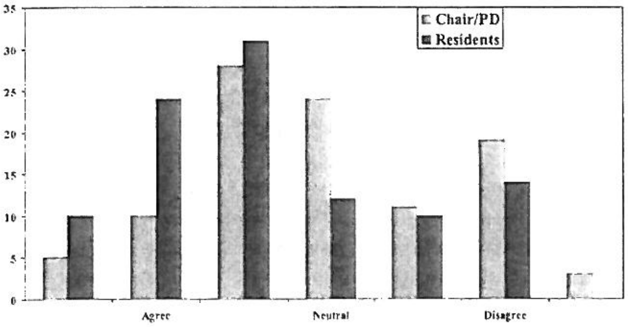

Fig 2. This graph of the program directors' and residents' responses illustrates the perception of the effect of work-hour restrictions on resident satisfaction. The residents are more content and satisfied.

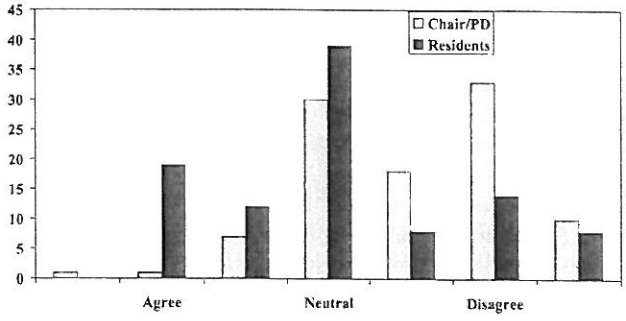

Fig 3. This graph shows program director and resident perception of the effect of work-hour restrictions on decreasing the incidence of medical errors. The possible benefit of being better rested may be mitigated by problems with communication and frequent hand-offs.

extenders. Problems were reported with the adoption of a night float rotation. Most importantly, program directors reported a problem with continuity of care. Positive comments included more rested residents improved lifestyle and morale. Program directors report an increased awareness of the effects of sleep deprivation. In addition, some commented the regulations forced them to address the various resident rotations' educational value and change or remove those not meeting the needs of the program.

The AOA received 94 responses (40% response rate) from program directors and chairs. Although not a majority, it was a larger number than those responding to the first survey. Fifty-nine out of 98 (60%) of the residents completed the questionnaire.

DISCUSSION

The decision of the ACGME to regulate work hours has had an impact on graduate medical education. Although legislation had already been in effect in the state of New York, the announcement of the proposed work-hour restrictions by the accrediting body caused hospitals, medical schools, and academic departments nationwide to rapidly arrive at strategies to accommodate the necessary changes. Surgical programs in particular were challenged because of the personality, culture, and educational needs of the residents.[4,6] The AOA used two surveys to study the early effects of the work-hour restrictions on orthopaedic residency education.

The program directors had a largely negative reaction to the work-hour restrictions. These sentiments appear to be softening with time. There are administrative problems in the implementation of necessary changes and in the documentation of compliance. Faculty members are asked to be more available than in the past and to be involved in patient care, often without resident involvement. Faculty attitudes toward the new rules are seen as negative by program directors and residents. Our findings are very similar to others. A single institution surveyed general surgery and surgical subspecialty faculty, including orthopaedic surgeons, and found 47% of faculty believed their work hours had increased. However, an increase in work hours could not be verified in comparing previously collected data to data collected 6 months after the implementation of the work-hour restrictions.[24]

Resident attitudes towards the work-hour restrictions were mixed based on postgraduate level. Senior level residents share the concerns and overall negative impressions of many faculty, which has been noted in studies of other specialties.[23] Junior level residents, not exposed to years without work-hour restrictions, may be better rested, more content, and have a better lifestyle. Other studies have also shown this result.[7,10,18,25]

More importantly, many faculty are concerned about the effect of the restrictions on the development of the resident as a professional whose commitment to their patients is paramount. Responsibility and accountability are essential characteristics of the physician.[6,13] There is concern residents educated in an atmosphere of restricted work hours will be poorly prepared for the practice of medicine, which, at times, requires long hours and an ability to work despite fatigue.[17] The criticism noted most frequently in this survey related to the work-hour restrictions themselves was the 24 plus 6 mandate requiring residents go home after 30 hours of continuous duty. Many commented this restriction had a deleterious effect on education and was not consistent with the practice of orthopaedic surgery. It precluded resident involvement in educational activities, including operative procedures on patients evaluated by the resident the night before. Faculty are also concerned residents and physicians of the future will consider themselves shift-workers.[9] Given the popularity of certain subspecialties, such as emergency medicine, anesthesiology, and radiology, it is more likely this goes beyond the issue of work hours and involves generational differences between faculty members and the residents.

In fact, surgical specialties may see more interested students. In the past, students may have been interested in the field but sought other opportunities because of the traditional perception surgical training programs were too rigorous for all but those with a willingness to sacrifice a personal life and work long hours. The duty hour restrictions may change this perception. Recent National Resident Matching Program match information, showing an increased number of American medical graduates seeking positions in general surgery residencies and subspecialties like plastic surgery, may support this hypothesis but it is not proven.[19] One study indicated the duty hour restrictions have had a positive impact on students' perceptions of surgeons' lifestyles but does not necessarily increase their interest in a surgical career.[3]

The work-hour restrictions may have additional important workforce implications. Many programs in orthopaedic surgery have attempted to enlarge their residencies in an effort to meet the requirements with variable success. Increases in resident numbers will require an educational rationale, not one based on service. Small programs with few residents or those with multiple sites of practice are particularly challenged to comply with the requirements. An increased number of residents or a consolidation of programs may result.

The effect of the work-hour limitations on education will likely not be known for years to come. Many program directors and residents expressed concern about the lack of clinical experience resulting from the new rules. The impact of the duty-hour restrictions on the number of patient encounters and operative cases in orthopaedic surgery is not known. Many respondents to the survey believed the residents would do fewer cases. At least one study looking at a general surgery resident program suggested the work-hour restrictions had a substantial negative impact on operative experience. This was measured by missed cases as recorded by the on call residents who had to go home the day after call.[11] On an individual case basis this may be true. Overall though, early data from the residency review committee after 1 year of implementation in general surgery found no effect of the work-hour restrictions on the overall surgical experience for major cases or for the experience of the chief residents, which was confirmed in an independent study at a single institution.[5,14] Some have suggested the reduction in work hours comes at the expense of outpatient clinic experiences rather than operative experience. Spencer found resident participation in outpatient clinic dropped from 66 to 17%.[20] It will have to be seen whether there is a negative impact on the residents' operative case load and patient care experience of sufficient severity to warrant additional years of residency training.

In a similar way, there has been insufficient time to measure the restrictions' effect on patient safety. Studies have reported fewer attention errors in residents who get more rest.[12] There was no consensus in our survey. Some residents believed there had been a positive impact. When compared with attending surgeons, in many instances, the residents may be closer to and aware of common but relatively minor medical errors in patient management. Most program directors and an equal number of residents disagreed. Many cited problems with communication inherent with frequent turnover of patient care responsibilities. Many program directors and some residents cited the negative impact of the work-hour restrictions on continuity of care as a patient safety issue. This has been noted in other studies looking at the negative effects of work-hour limitations in other specialties.[21] In general surgery, 70% of residents perceived problems with continuity of care and 43% believed the quality of care had deteriorated.[10] A survey similar to this found 50% of the faculty believed duty-hour restrictions had resulted in worse patient care with only 2% reporting better care.[24] This negative perception was higher among general surgeons as compared with other surgical specialists and those attending surgeons who worked over 80 hours per week.

Positive attitudes toward the work hour restrictions were also noted in the survey. The new rules have compelled program directors to carefully evaluate the educational value of each component of the residency program. They have been asked to eliminate noneducational tasks traditionally delegated to house staff, which facilitated their ability to finish their work. These included phlebotomy, patient transportation, film and medical record recovery, and housekeeping among other duties more appropriately performed by others but often not provided on a reliable basis by the academic medical center. In addition, institutional support has been provided to some programs to meet their service needs, although not universally. Residents appear to be better rested and content and may be spending more time on personal development. Similar to the findings of other studies, the respondents to this survey noted no measurable improvement in resident learning documented by improvement in conference participation or evaluations.[22]

Orthopaedic residency programs have responded to the new regulations in a variety of ways. Most programs have had to make certain adaptations to comply. Most orthopaedic departments have sought support for the recruitment of physician extenders to meet the service needs of the residency program. This survey showed not only had more programs adopted this strategy, but more physicians' assistants and nurses in each department were required than was noted on the first survey. There have been problems in implementing this adaptation. First, there are not a large number of competent individuals with the desire or training to do this type of work. Second, the relatively high salaries and benefits these individuals require creates increased financial burden on departments and, in cases where the medical center provided funds, increased dependency on hospital administration. Many of the program directors and chairs commented on problems related to the lack of institutional support and availability of adequate personnel. In addition, many found physician extenders did not provide the service a resident traditionally had. Often, multiple personnel were necessary to perform the tasks previously performed by a single resident. This further increased costs. Last, many programs lacked the experience to know how to use these individuals in an effective way. Without guidance and protocols, the systems were not in place to allow these practitioners to care for patients independently and many physicians' assistants became underused and dissatisfied.

Many programs chose to change call responsibilities from in-house to home call. This relieves the program of assessing the in-house call responsibilities and is fairly straightforward for many to implement. However, it is a strategy that calls for oversight and may in selected cases increase resident fatigue. In busy trauma centers, the resident may be called so often they may not be able to leave the institution or may be covering a number of institutions. In addition, the frequency of home call may be increased compared with in-house call. The 24 plus 6 rule does not necessarily apply to residents taking home call. All of these factors may mean residents are in fact on call more often, or worse, are driving to and from home or other locations while fatigued.[2]

The use of night float rotations to provide night service is another coping strategy used by many programs. The residents at times enjoy relative independence and there may be some improved continuity of care if the rotation is structured so residents consistently follow the same patients each night. There are, however, important concerns about the educational value of the night float rotation, the lack of attending supervision, and the feeling of alienation by some residents.

Three limitations of the study are the low response rate, selection bias, and the lack of objective data. Program directors and residents have been asked to complete multiple surveys on this topic and others. Many may have chosen not to respond based on the lack of available time or confusion over having already completed the same survey (ie, the earlier survey). The potential result is the responses of those with strong opinions regarding the issue dominate our results. As a result many of the conclusions are at times speculative and not fully evidenced by objective data. Without baseline information a comparison before and after the 80 hour work week is not possible. Future tracking of patient safety measures, OITE and Board scores, operative case logs, and patient satisfaction information may provide more concrete observations to be made about future changes in resident education.

The effects of the work-hour restrictions mandated by the ACGME on residency education and patient safety needs to be continuously assessed. In addition, it is important for the organizations involved in postgraduate education to coordinate their activities to obtain reliable information and convey their findings in a constructive manner. For practicing surgeons, there is a need to be attentive to this process. There are regulating bodies charged with patient protection that may wish to expand work-hour restrictions to all physicians, not just those in training programs.

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SYMPOSIUM

RESIDENT WORK-HOUR GUIDELINES

A SENTENCE OR AN OPPORTUNITY FOR ORTHOPAEDIC EDUCATION?*

BY VINCENT D. PELLEGRINI JR., MD, MODERATOR, TERRANCE PEABODY, MD,
DAVID F. DINGES, PHD, JENNIFER MOODY, AND PETER J. FABRI, MD

Not since 1910, when Abraham Flexner established a set of standards and an accreditation process for schools of medicine in the United States[1], has the foundation of American medical education been so shaken as it has by the 2001 Accreditation Council for Graduate Medical Education (ACGME) Outcome Project. Predicated on imperatives derived from a public call for regulation and accountability in support of patient safety and an evolving appreciation of the education process and the optimal learning environment, the ACGME instituted standards and limitations for the work hours of residents participating in accredited programs[2]. Amid protest largely from the sector of surgical specialists during the period of preparation and review, these restrictions were approved in February 2003 and became effective on July 1, 2003.

Averaged over four weeks, resident duty hours are now limited to eighty hours per week, in-house call frequency cannot exceed once every third night, and one twenty-four-hour day in seven must be free of patient-care responsibilities. There is a twenty-four-hour continuous duty limit with a supplemental six-hour transition period to accommodate patient transfer and debriefing logistics as well as didactic activity. A minimum of ten hours must be allowed between scheduled duty periods. Included in the eighty-hour weekly tally are hours spent in-house while on home call as well as moonlighting hours, provided that such activity is approved by the program director. Anticipating resistance to change in the implementation of these guidelines, the Outcome Project also mandated an educational program for faculty and residents on the effects of fatigue, support to reduce time on routine tasks, and a rigorous enforcement program that held program directors, rather than the residents themselves, accountable for performing within the work-hour restrictions. While a 10% increase in duty hours has been offered on a case-by-case basis for specific rotations through the respective Residency Review Committees, no exceptions to the eighty-hour weekly limit have been granted or entertained at a specialty level[2].

After the first year of experience with these new regulations, the ACGME made some early observations, which included identification of anticipated challenges in the area of patient care and some interesting and unanticipated effects on resident life[3]. A concern

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Presented at the Annual Meeting of the American Orthopaedic Association, Boston, Massachusetts, June 25, 2004.

over the risk of medical error focused on the increasingly frequent patient-care "handoff," as a by-product of truncated and rigidly defined work shifts of house-staff physicians. Faculty and attending physicians, functioning outside the umbrella of the work-hour guidelines, assumed a more prominent role in patient-care continuity but experienced an unregulated increase in work hours at an age arguably more at risk for sleep deprivation and resulting medical error. Residents, on the other hand, reported no increase in sleep hours, demonstrated no change in test performance, and expressed a greater job satisfaction based on more available personal time.

The previous priorities, which included continuity in patient care to provide experience in observing the course of disease[4], the need to instill an ethos of obligation and professional service, and the development of sheer endurance, are no longer justifications for the old order. To continue the protest could be viewed largely as a misdirected effort. Rather, our challenge is to reengineer residency education to conform to a new social order that no longer tolerates the extended work shifts that were once thought essential to a medical, especially a surgical, residency education. Our formidable challenge is to meet the cognitive and ethical professional needs of postgraduate medical education while reducing medical error and acting in the best interest of our patients as perceived by the lay public.

The American Orthopaedic Association Survey of Program Directors and Residents

BY TERRANCE PEABODY, MD,
AND VINCENT D. PELLEGRINI JR., MD

An important issue identified by the Graduate Medical Education Committee of the American Orthopaedic Association (AOA) is how orthopaedic surgery program directors, chairs, and residents perceive the work-hour restrictions. In an effort to gauge the effect of the new rules on orthopaedic education, and specifically to identify particular challenges and unique coping strategies, the Committee undertook a survey of program directors, chairs, and residents in the 152 accredited orthopaedic residency programs. The survey provides a starting point for a dialogue on the topic of assessing orthopaedic surgery resident education.

Methods. A survey tool was designed by the members of the Graduate Medical Education Committee and was reviewed and modified by the staff of the American Orthopaedic Association. An electronic questionnaire was distributed early in the fall of 2003 to 152 program directors of ACGME-accredited residencies in orthopaedic surgery. A reminder was sent two weeks following the initial solicitation. Program directors were asked to identify a resident at each level of postgraduate training. The same survey was subsequently sent to these individuals electronically. In addition to standard responses, written comments were solicited from those surveyed.

Results. The AOA received responses from seventy-eight (51%) of the 152 program directors. The program directors submitted the names and e-mail addresses of 261 residents. A total of 185 addresses (71%) were valid, and fifty (27%) of the 185 residents completed the questionnaire. Most of the responses were from programs that had fewer than six residents per year.

Overall, the effect of the work-hour guidelines on orthopaedic residency programs was described as *negative* by nearly three-quarters (fifty-eight) of the seventy-eight responding program directors (Fig. 1), and half of all responders (thirty-nine) felt that this negative effect was moderate to severe. The two most commonly cited negative issues related to (1) lost educational opportunity, both clinical and didactic, resulting from noon dismissal of residents after a night of in-house call in accor-

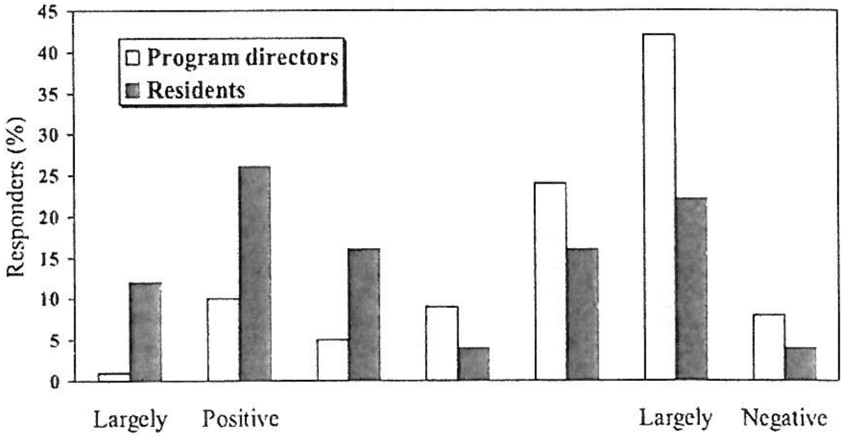

Fig. 1

The general effect of the work-hour restrictions on the educational program as perceived by the program directors and the residents.

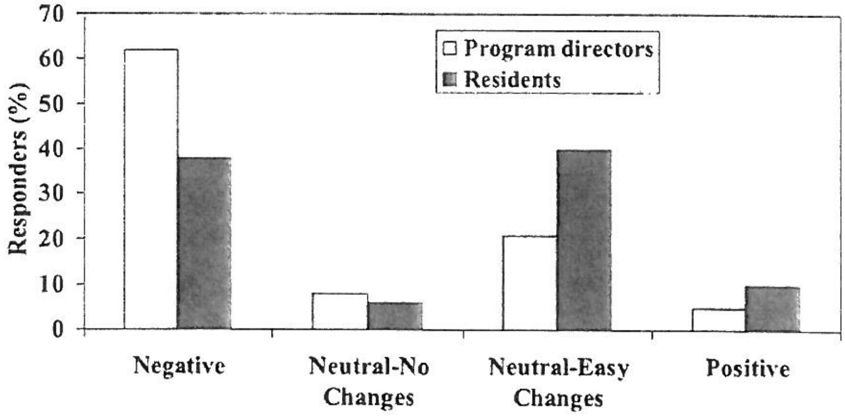

Fig. 2

The attitudes of the faculty toward the work-hour regulations as perceived by the program directors and the residents.

dance with the thirty-hour continuous duty rule, and (2) a compromise in patient care resulting from an overall disruption in continuity of care, specifically, more frequent handoffs in care responsibility. Some program directors voiced concern about a shift mentality among the residents; a majority noted the increase in work for faculty members and senior residents as well as technical challenges related to funding, availability, and utilization of physician extenders; and many cited problems with the adoption of a "night float" rotation. A minority of program directors (9%) had noticed no effect, and only 17% thought that the new regulations had a positive effect, most commonly noting less fatigue, greater alertness, and improved morale of the residents. Program directors reported an increased awareness of the effects of sleep deprivation, and some commented that the regulations forced them to evaluate the educational value of various rotations more critically and to address those not meeting the needs of the program. Faculty attitudes toward the work-hour restrictions were described as negative by 62% of the responding program directors, as neutral by 29%, and as positive by 5% (Fig. 2). In contrast, only 38% of the responding residents perceived negative faculty attitudes, 46% thought they were neutral, and 10% described them as positive. Conversely, resident attitudes were described as negative by 53% of the program directors (Fig. 3) and positive by only 14%, whereas 34% of the residents described their own attitudes toward the work-hour restrictions as positive and 38% described them as negative. From the perspective of the fifty residents, 54% (twenty-seven) thought that the changes had been good for the program, citing greater satisfaction and morale (52%), more rest, and more independent studying opportunities, while 4% were neutral and 42% expressed a negative impact (Fig. 4).

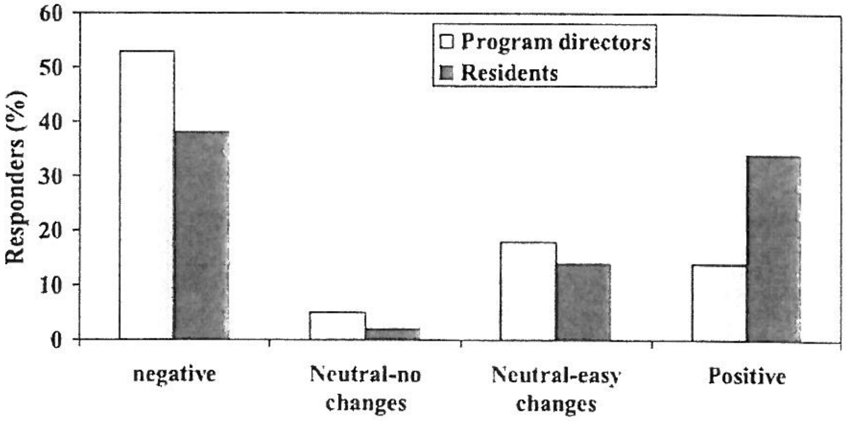

Fig. 3

The attitudes of the residents toward the work-hour regulations as perceived by the program directors and the residents.

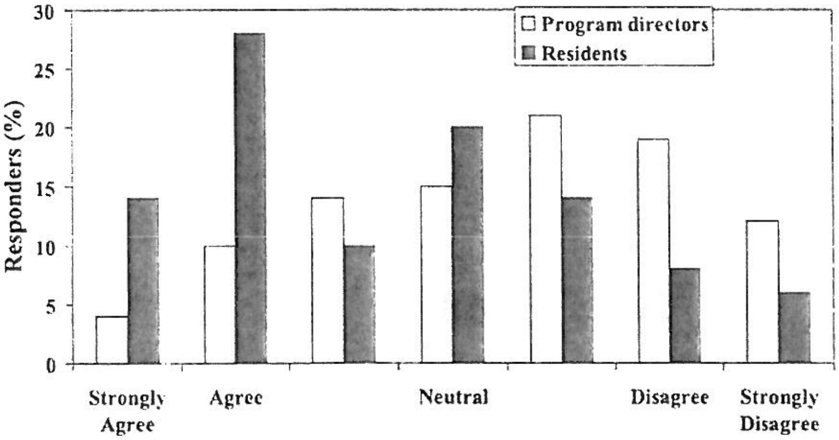

Fig. 4

The opinions of the residents and the program directors as to whether the work-hour regulations resulted in greater resident satisfaction.

Beauty clearly remains in the eye of the beholder, strongly influenced by the shading of the viewer's spectacles.

In view of harsh fines recently levied on prominent university programs over the role of the teaching physician, it was no surprise that the practical mechanics of conforming to the work-hour guidelines attracted the immediate attention of program directors in their quest to become compliant with the new regulations. The most commonly reported adaptation to the work-hour restrictions was the hospital employment of physician extenders in the form of physician assistants and similarly trained professionals (51%); interestingly, only 28% of the residents acknowledged this accommodation. While 46% of the responding program directors reported no additional providers of care, 14% described one additional caregiver, 17% had hired two, and 12% had employed three. Other reported strategies included the design of "float" rotations (31%), in which the residents' primary task is to assume night call responsibilities. Such an approach has been controversial and has prompted considerable debate, largely over the educational value of the "night float" system in view of the fact that the affected resident is usually not primarily assigned to a specific service and the continuity of the experience in observing the course of illness is lost. Alternatively, 39% of the programs have shifted call responsibilities from in-house to a call-from-home system in order to sidestep the thirty-hour rule and avoid lost and disrupted educational opportunities resulting from resident dismissals at noon.

While the issue of patient safety is widely acknowledged as being largely responsible for the birth of the regula-

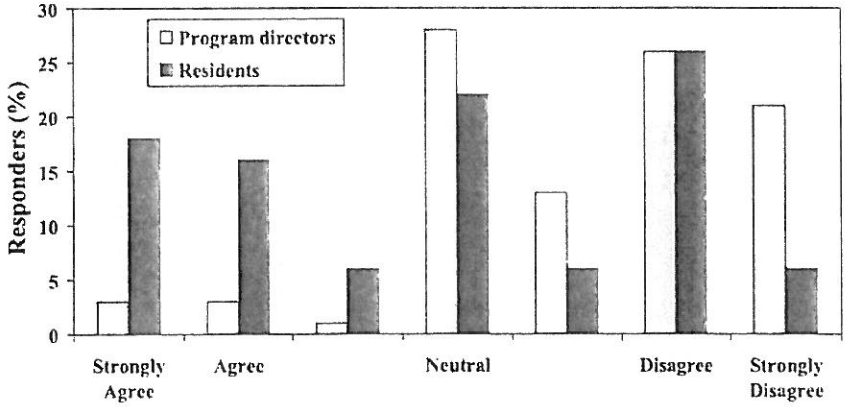

Fig. 5

The opinions of the residents and the program directors as to whether the work-hour regulations resulted in fewer medical errors.

tions, only 6% of the program directors and 40% of the residents thought that the work-hour restrictions had resulted in fewer medical errors (Fig. 5). Indeed, a majority (60%) of the program directors and 38% of the residents disagreed that the limitations had resulted in fewer errors.

Among the unintended consequences of the duty-hour restrictions, an increased number of operative cases without resident involvement was most frequently cited by both program directors and residents. Residents are often not able to participate in procedures on patients whom they had evaluated during the previous night on call; this most materially affects residents in the junior years and contributes to a relative increase in the number of operative trauma cases, compared with elective orthopaedic cases, in the overall resident case log. As a result, 46% of the program directors and 42% of the residents thought that the surgical case volume was inadequate. Neither group felt that residents were better prepared for cases and examinations or that they complained less, demonstrated improved teamwork, or were more attentive than they had been prior to July 2003.

Discussion. The decision of the ACGME to regulate work hours has already had a tremendous impact on graduate medical education. Although legislation had already been in effect in the state of New York, the announcement of the proposed work-hour restrictions by the accrediting body caused hospitals, medical schools, and academic departments nationwide to rapidly develop strategies to accommodate changes imposed by the new rules. Surgical programs, in particular, were challenged because of a long-held surgical personality and culture, as well as the arguably unique and compelling educational needs of the residents in managing surgical illness[5]. The American Orthopaedic Association undertook this survey in order to study the early effects of the work-hour restrictions on orthopaedic residency education. While other surveys have been undertaken during the same period, this survey is unique in its ability to compare the responses of both program directors and residents to the same questions. Nonetheless, the low response rate was likely adversely affected by the large number of similar surveys circulated in the past year by many other organizations. A potential selection bias may result, with responses dominated by those with strong opinions regarding the issues and, therefore, possessing the stamina and conviction to complete several similar surveys.

Administrative issues in the implementation of necessary changes and the documentation of compliance have preoccupied program directors. Adaptations were required of nearly all programs, and most sought support for the recruitment of physician extenders to meet the service needs of the residency program. Many commented on problems related to the lack of institutional funding and the availability of adequate personnel. Common responses included changed call responsibilities from in-house to home call, noneducational rotations were modified or deleted, and some programs instituted a night-float system that has had varied early reviews. Interestingly, some programs have requested additional residents from the ACGME with mixed responses. Not surprisingly, the reaction of program directors and faculty to the work-hour restrictions was noted to be largely negative. Faculty members were asked to be more available and involved in patient care without resident participation, contributing to further erosion of the perceived perquisites of a faculty appointment. These technical and logistical matters dominated the program directors' landscape for the early period after introduction of the regulations, but, after compliance was achieved, more philosophical and deeper concerns have predominated among educators.

Notwithstanding these early administrative challenges, positive attitudes toward the work-hour restrictions were also noted in the survey. The new rules have compelled program directors to evaluate more carefully the educational value of each component of the residency program. In addition, although not universal, institutional support provided to some programs to meet service needs has refocused attention on residents as students rather than as employees. Faculty perceived that residents were better rested and content and may be spending more time on personal development. Interestingly, resident attitudes toward the work-hour restrictions were bimodal in distribution: one-third of the respondents described their attitude as positive and nearly an equal number described it as negative. Unfortunately, the survey was blinded as to the educational level of the residents who responded, but, on the basis of the written comments, senior residents shared the concerns and overall negative impression of many faculty while junior residents, who were not exposed to prior years without work-hour restrictions, expressed positive sentiments about being better rested, feeling more content, and having a better lifestyle. These findings are in agreement with the assessment of others who have attempted to measure similar outcomes[6].

Among the philosophical and more far-reaching concerns that were noted, the deterioration in clinical experience that has resulted from the new rules was cited by many program directors and residents. It remains to be seen whether the negative impact on operative case load will be of a sufficient degree to warrant additional years of residency training. More difficult to measure, as well as a more troubling philosophical issue, is the effect on professional behavior. The most frequently noted criticism related to the work-hour restrictions was the need for residents to go home after thirty hours of continuous duty. It precluded resident involvement in educational activities other than early morning conferences and limited exposure to operative procedures on patients evaluated by the resident during the previous night on call. Many commented that this restriction not only had a deleterious effect on education but was inconsistent with the real practice of orthopaedics and a physician's sense of obligation to patient care. A deeper concern focused on the impact of encouraging a mentality of shift work among residents, i.e., one in which punching a clock and prospectively defining limits to patient-care responsibilities seemingly encouraged a mindset that prioritized personal schedules over patient well-being. Moreover, while there has been insufficient time to measure the real impact of the new guidelines on patient safety, there was skepticism among both faculty and residents that a perceived improvement in patient safety or a reduction in medical errors could be claimed at this early juncture. Many cited problems with communication exacerbated by an increased number of handoffs to transfer patient-care responsibilities.

Clearly, the impact of the work-hour restrictions on residency education and patient safety will require ongoing assessment. One popular recommendation derived from this survey is to allow residents additional time (beyond the six hours already granted) after in-house call for the express purpose of participating in activities that enhance the continuity-of-care experience, specifically, operative procedures on patients previously admitted by the on-call resident. Among all of the issues with an adverse impact on orthopaedic resident education, this issue seems to have been the most noticed. The ultimate effect of the work-hour limitations on the quality and effectiveness of graduate medical education, patient safety, and professionalism of the physician workforce will not be known for many years to come, but there is cause for concern, and a need for careful observation and monitoring of outcomes has been identified.

Sleep Deprivation, Impairment of Resident Performance, and Medical Error

By David F. Dinges, PhD

The resident duty-hour guidelines were intended to reduce the risk of performance errors due to sleep loss. It is therefore noteworthy that the ACGME "chose 80-hours as the upper limit to safeguard against the negative effects of *chronic sleep loss,* and selected a limit of 24 hours plus up to six hours to address the effects of *acute sleep loss,* and to allow for adequate time for patient hand-off and didactic learning [italics added]."[2,3] The question herein addressed is whether these duty-hour limits achieve the stated goals of safeguarding against acute and chronic sleep loss.

Sleep deprivation and performance. There is abundant scientific evidence that *acute sleep loss*—defined as continuous wakefulness beyond sixteen hours—results in a range of neurobehavioral and cognitive performance deficits[7-10]. These impairments increase the risk of accidents related to human error while driving and on the job[11-13]. In recent years, scientific studies have also documented that *chronic sleep loss* (i.e., sleep deprivation) in healthy adults results in dose-response adverse effects on neurobehavioral and cognitive functions, especially when sleep duration is chronically less than 6.5 hours per day[14-16]. Importantly, in these experiments, the deficits were cumulative across days, such that a week of sleep restriction to six hours per night resulted in neurocognitive performance deficits equivalent to those found after acute total sleep deprivation of similar magnitude.

Sleep and medical errors in residents. The current ACGME duty-hour limit of twenty-four hours, which can be extended to thirty hours, is well in excess of the scientifically established performance limit of sixteen hours of wakefulness[7,15]. One can reasonably expect, therefore, that cognitive deficits and the risk of fatigue-related performance errors will increase when resident physicians work to this duty-hour limit. Similarly, the current ACGME limits permitting eighty hours of work per week (averaged over four weeks) and mandating only one day in seven free from duty (averaged over four weeks) could easily result in chronic sleep loss. A recent survey of 3604 first and second-year resident physicians indeed found this to be the case[5,17]. Among all subspecialties, 66% of the residents reported that they had an average of six hours of sleep per night or less, and 22% reported that they had an average of five hours of sleep per night or less. Surgical residents reported the least amount of sleep of all subspecialties. For example, 84% of orthopaedic surgery residents reported that they obtained an average of six hours of sleep per night or less and 40% reported that they obtained an average of five hours of sleep per night or less. Among all residents, a sleep duration of five hours or less was associated with elevated odds ratios for serious accidents and injuries, working in an impaired condition, and having made serious medical errors[17]. Sleep durations were substantially shorter for interns than for second-year residents, suggesting that impairments would likely be greater in the less experienced house staff, which could further exacerbate the risk of a serious medical error.

A recent comprehensive study that relied on physician-based documentation of medical errors confirmed that *acute and chronic sleep loss* in interns occurred within the current ACGME duty-hour limits, and they were associated with meaningful increases in attentional failures[18] and serious medical errors in intensive care units[19]. In contrast, an intervention schedule that limited scheduled work hours to sixteen consecutive hours and reduced the number of hours worked each week to fewer than eighty hours was associated with increased sleep time. Most importantly, it substantially reduced both attentional failures[18] and serious medical errors[18].

It appears that the ACGME limits of eighty hours of duty per week "to safeguard against the negative effects of chronic sleep loss,"[3] and of twenty-four hours (and up to six hours) of extended duty "to address the effects of acute sleep loss,"[3] do not adequately prevent acute and chronic sleep loss and their contribution to medical errors. While these guidelines have taken an important, and painful, first step in the right direction, it may be time to study alternative schedules to ensure that residents (and their faculty supervisors, perhaps?) obtain the needed sleep to prevent fatigue-related serious medical errors.

Young Physicians—Generation X and Millennials

By Jennifer Moody

One of the unique contemporary challenges facing health-care administrators and educators is the expanding number of generations currently present in the workforce[20]. At no other time in history have four distinct generations, with such disparate perspectives on work and life in general, worked together. There are two reasons for this. First, people are living longer and they are staying active longer. For economic and personal reasons, many people are extending their careers into their sixties and beyond. Second, the speed at which our culture changes is accelerating. Each emerging generation develops its own tastes and its own perspective more rapidly than in the past. What is fresh to one generation quickly becomes "old school" to the next.

In order to create intergenerational harmony, it is critical to know who the generations are and what motivates them[21]. Using demographic studies, one can roughly define the four generations currently in the workforce as the Veterans (sixty years or older), Baby Boomers (forty to sixty years old), Generation X (thirty to forty years old), and the Millennials (less than thirty years old).

Veterans comprise 5% to 10% of today's total workforce, and, in many instances, they still run the show as chief executive officers, board members, or controllers of capital. Their historical frame of reference is World War II and the most intense phases of the Cold War. "Can-do" icons such as John Glenn are their heroes. Conforming to the company line is an ingrained trait. "Rules are there for a reason," "Do it right the first time," and "Work first" are some of the mottos they live by. Gender roles were sharply defined in their formative years, and they have been instructed to believe that the benefits of sacrifice are worth waiting for.

Baby Boomers comprise 40% to 45% of today's workforce, and, in many cases, hold key managerial positions. Their historical frame of reference is the Vietnam War, Woodstock, and the civil rights and women's movements. Their icons are entrepreneurs with a socially conscious agenda such as Ted Turner or Bill Gates. Baby Boomers changed the shape of the workforce by embracing diversity and by their sometimes self-absorbed quest for a better quality of life. Personal growth, "meaningful work," and health and fitness are central to their values. They expect that work itself should be its own reward, and, while they may still question authority, they are comfortable working within the team concept.

Generation X comprises 35% to 40% of the workforce, and they typically hold entry-level jobs or are moving into middle management. Their historical frame of reference is the destruction of the Berlin Wall and the early 1990s recession, and their icons include socially or politically aware entertainers such as Bono or Sting. A product of media saturation and latchkey parenting, Generation X expects continual stimulation, and they have more loyalty to their friends and to themselves than to organizations or leaders. They believe that work should be fun; they are technologically savvy, practical to the point of being cynical, deride "micromanagement," and prefer managers who point the way and then step aside.

Millennials comprise 10% to 15% of today's workforce, and they usually represent interns, residents, and new staff physicians. Their historical frame of reference is Columbine, the September 11 attacks, and corporate scandals, and they look up to those who have achieved fame such as rock stars and movie stars. They are devoted to the Internet and cell phones, they are the most diversity-tolerant group ever, and they are adaptable, goal-oriented, and bred on instant feedback and communication.

Because they are "coming from different places," the various generations sometimes do not understand each other and conflicts arise in work as well as education. Veterans often put forth the message "Do as I say," to which the three other generations respond, "Give us a reason." Baby Boomers often declare, "You have no loyalty to the organization," to which Generation X and Millennials respond, "Why should I? So you can downsize me or outsource my job when it suits you?" Veterans and Baby Boomers say "Work harder," while Generation X and Millennials respond, "Not if it hurts my quality of life or relationships." In the health-care setting, the new generation of physicians—Generation X and Millennials—often exhibit starkly different values and behaviors than their Baby Boomer and Veteran teachers and mentors. Eight general characteristics define Generation X and Millennial physicians: they are more likely to be female, lifestyle is a core concern, they seek immediate stability, they resist hierarchical dominance, they are technologically savvy, they have a skills-based mindset, they are loyal to principles rather than to organizations, and they seek conflict resolution. Each of these areas has particular implications for the education and employment of medical professionals that cannot be ignored by educators and health-care leaders[22].

Female physicians. While more than 75% of all physicians are male, about 40% of all Generation-X physicians and 50% of Millennial physicians are female. In addition, female physicians dominate the ranks of certain residency programs. Approximately 50% or more of the residents in family practice, psychiatry, dermatology, pediatrics, and obstetrics-gynecology are female. This tendency to choose certain fields, particularly those that are known for being low or no call, may shift the quantity and quality of candidates traditionally attracted to the most competitive programs as well as change those programs conventionally considered to be most desirable.

According to the American Medical Association, female physicians work seven fewer hours per week than do male physicians and they see slightly fewer patients. Therefore, more full-time employees may be required as women begin to assume a greater number of positions on a medical staff. More importantly, younger female physicians often are married to physicians or to other professionals. This greatly restricts the geographic flexibility of these physicians in choosing training programs or practice opportunities, unless the professional needs of their spouses can be accommodated.

Lifestyle. Younger physicians approach medicine in a fundamentally different way than their teachers and superiors. To younger physicians, medicine is a profession, not a lifestyle. These physicians view lifestyle as what happens outside the office or hospital, whereas older physicians blur the distinction between home and work. Young physicians seek defined practice hours, limited call, reasonable patient loads, and set vacations. If they are not satisfied, they will seek alternative settings that promote quality of life, such as charting days, which are days exclusively devoted to completing paperwork. Charting days allow physicians to focus on seeing patients for the majority of the week, while taking one day to complete charts and other paperwork without distractions. Reduced call and practice-sharing—an increasingly popular option in which two physicians work the same practice—also appeal to young physicians.

Immediate stability. Younger physicians are seeking stable situations as soon as the ordeal of medical education and training is over. They are less likely to be attracted to entrepreneurial environments in which they must bear the load of both running a business and seeing patients. Younger physicians prefer group practice settings or hospital employment, where management structure and stability are provided. Immediate stability also means being relieved of educational debt, obtaining a secure guaranteed salary, and working in a stable practice environment.

Hierarchical dominance. Younger physicians want to focus on their practices and on patient relationships. Increasingly, they are less apt to embrace the hurly-burly of medical politics by asserting dominance on medical staffs. However, they will seek leadership roles if it is apparent that real patient-care issues are at stake, rather than medical "politics as usual." To involve younger physicians in leadership roles, it is important that they see that larger goals will be accomplished rather than the personal aggrandizement of a select group of physicians.

Technologically savvy. Much of the medical and cultural information younger physicians have absorbed has come through the Internet, and they assume that Internet technology will be integrated into the workplace. Educators and administrators need to get wired and not overlook the obvious—such as Internet access in the physician's lounge, palm technologies, and high-speed T1 lines—to ensure that younger physicians have the access they expect and that they can communicate with colleagues and patients through e-mail. Moreover, it is critical that hospitals and training programs be aware of how they are represented on the Internet. Younger physicians will research a community online, and any data they find there can influence their decisions.

Skill-based. Young physicians are accustomed to using all of their skills in academic medicine, and they want to use all of their knowledge in practice. Even in the face of turf wars, ways should be found to accommodate the special interests of young physicians, or they are likely to move on. As well, academic professionals should work to prepare physicians for the routine cases they will find in most practice environments outside academic centers.

Loyalty to principles. Like other members of their generation, young physicians saw their parents downsized over the last twenty years. They, therefore, are leery of investing their loyalties in an organization. Their loyalties are to principles, not institutions, and it is important to them to be able to maintain these principles, most of which are tied to patient-care issues. Rather than mold themselves to organizational beliefs they do not share, they will seek locations that are compatible with their beliefs.

Conflict resolution. The majority of older physicians grew up in single-income families in which the mother was the homemaker. Most young physicians, by contrast, come from two-income homes or from single-parent environments. They have endured conflict and division at home and prefer not to encounter it at work. Rather than traditional medical politics, which can be adversarial, they prefer conflict resolution. They also appreciate a nonadversarial management style.

Fostering generational unity is a difficult balancing act, but it can be accomplished by treating everyone equally and uniquely, rather than treating all individuals in exactly the same way. Communication is always the key, and all forms—written, oral, and electronic—should be employed. Generation X and Millennials expect primary communication—instructions, follow-up, and verbal rewards—to be conveyed through e-mail. Baby Boomers prefer personal, one-on-one interaction, while Veterans like to get things in writing. Veterans and Baby Boomers are more open to "grinding it out," that is, repeating tasks or behaviors that they believe will ultimately lead to rewards. Generation X and Millennials require more varied routines and quicker feedback regarding performance. Veterans and Baby Boomers often are more committed to the concept of "professional pride"—doing things a certain way based on the established tradition in their profession. Generation X and Millennials may be more committed to the concept of "just getting it done" in the most expedient way possible.

While there are differences between the generations, fundamental human behavior does not change and people usually have more in common than they might originally expect. Leaders and educators today have to be sociologists, to a certain extent, listening to and interacting with the generations to understand what they have in common and what sets them apart. They also need to create an environment where the generations can interact and work to achieve common goals—whether on work-related projects or during social activities such as staff softball games or golf outings.

Much has been written about the supply of physicians in the United States and whether we have too many physicians or too few. Often these arguments focus on patient demographics, payment systems, disease incidence, medical education, and related issues. Rarely do people consider physicians themselves and the ways they have changed. The fact is that medical students, residents, and doctors today are different. They have different priorities, different practice patterns, and face different challenges than their forebears did. Effective medical education and health-care provision in the next decade will require acknowledgement of these differences and accommodation of the needs of the younger physicians who will soon determine the future of medicine.

Lions and Tigers and Bears

BY PETER J. FABRI, MD

The problem with modern graduate medical education is that medical educators are convinced that the only way to train residents is the way *they* were trained. Much like Dorothy and her three friends in *The Wizard of Oz*, whose fear of lions and tigers and bears hindered their progress to Oz, our fear of this new approach to medical education may be unfounded and unrealistic. So when the ACGME introduces a duty-hours requirement, the response of the typical academic surgeon is to resist, deny, and then try to do all of the same old things in a compressed time-period. This "solution" might be likened to stuffing five pounds of manure into a three-pound bag. Many solutions have been "invented" to address the duty-hours dilemma, e.g., night float, home call, use of fellows or allied health professionals, and increased involvement of attending physicians, to name a few. But each assumes that the method being used to educate and train the residents is appropriate and getting around the hours limitation is the goal. The frequent complaint resulting from this is whether the residents will get shortchanged in clinical experience and whether the patients will get shortchanged in quality of care. It can be postulated that none of this is real, because duty-hours limitation is a *symptom* of the problem and not the problem. The problem is that the paradigm for educating residents, which dates back almost 100 years, is outdated and inappropriate in a modern world, where new information is being produced at an exponential rate and information science puts data and solutions at our fingertips. If we could just re-engineer our graduate medical education programs, then we would find new ways to educate and train and new ways to take care of the routine tasks in patient care that have been delegated to residents *simply because they are there!* If we could reinvent the residency on the basis of a clear definition of what we want the residents to know, to be able to do, and the qualities we wish them to have (knowledge, skills, and attitudes), we could create a progressive and logical sequence of learning that would parallel the work product that residents produce for their attendings and their hospitals. Perhaps we should redefine the eighty-hour work week as forty hours of work and forty hours of education.

A common complaint in the academic workplace is "Why are they doing this to me when we do so well already?" This is a particularly difficult position to support since we have never actually measured the effectiveness of our training programs except for the results of structured examinations. We do not assess how well prepared our residents are for the marketplace, how well they perform in the first two years of practice, how often they get sued or lose their privileges, or whether they develop a chemical dependency or get divorced. These would be useful outcome measures, with direct implications for patients and society, but none are measured.

The residency can be traced back directly and continuously to the efforts of Sir William Osler and William S. Halsted at Johns Hopkins a century ago, and to the British and Germans before them. Little change occurred over the subsequent years. The apprenticeship model was the dominant theme, and it worked as long as patients were inpatients and hospital stays were long. House staff did not rebel against long hours, as long as they were single white males who lived in the hospital.

The introduction of quality management by W. Edwards Deming in 1948[23] (which revived the Japanese economy and later became the essential tool for reengineering heavy industry, service industries, banking, and airlines in the United States) and the description of the competency-based education process by Bloom in 1956[24] (which has served as the basis of all higher education in the United States for the last forty years or more—except for medicine) went largely unnoticed by medical educators. Today, they are contained within the Outcome Project of the ACGME as the six "Core Competencies" of graduate medical education and are rapidly becoming assimilated into the objectives of the undergraduate curriculum as well as continuing medical education. Medical education is a continuum of life-long learning, and the operative paradigm focuses on how to interpret and utilize information rather than on being able to memorize it as a walking repository of knowledge. The Dreyfus brothers[25] described a logical progression of competency acquisition from novice to advanced beginner to competent to proficient to expert to master and identified the characteristics of each step. Our graduate medical education programs would seem to span the range from advanced beginner to competent. Undergraduate medical education encompasses the transition from novice to advanced beginner, and continuing medical education serves to project the competent new practitioner through proficiency, expertise, and mastery. Combined, they span the learning continuum and lead to a lifelong search for knowledge and wisdom, a quest that demands new learning skills, advanced problem solving, and a solid infusion of probability and decision theory, database management, and information science.

But the task immediately before us is controlling duty hours. Will we focus our efforts on finding ways to just do what we currently do in the way we currently do it, by hiring additional employees and getting other people to help, or will we ask ourselves what we really want our residents to learn during the residency so that they are truly competent at completion? We must reengineer graduate medical education with the goal to produce competent graduates, competent by *our* definition of the knowledge, skills, and attitudes or behaviors necessary for us to vouch for this individual before our peers. Only then can we begin to ask ourselves how much of what residents do is really necessary. How much of the time spent on a task is really wasted time, redundant time, or waiting time? How much of their "education" is really designed to assist the progressive acquisition of competencies rather than just "fit" into a schedule? How much of rounds is adult-based education, and how much is just watching me do what I usually do? On point, a recent graduate of one training program was asked if he thought a surgical resident could be trained adequately in eighty hours per week. He responded that it would be no problem if someone would spend ten hours per week looking for radiographs and another ten hours per week waiting for the attending to show up.

A competency-based curriculum that maps new knowledge, skills, and acquisition of core qualities with a new set of privileges within the scope of residency education can dispel the "magic," set the tone, create benchmarks, and define outcomes for an evolving process of graduate medical education.

Overview

The mandated constraint of duty hours for resident physicians will thankfully refocus the process of physician training on the resident as learner and student rather than as employee. Yet, it simultaneously threatens to radically unravel the fabric of the professionalism of medicine and the physician work ethic; nearly one-half of symposium attendees identified concerns related to endorsing a "shift mentality" as outweighing any potential benefit from increased rest and preparedness resulting from the duty-hour limits[26]. The opportunity for fundamental change in the medical education process has never been greater, and, at the same time, never have medical educators felt the future of their profession to be at such a critical crossroads. If the reduction of medical errors by encouraging wakefulness is the genesis of the duty-hour restrictions, then it would appear that we have taken only a meaningful first, yet inadequate, step in the proper direction. Alertness and greater attention span would be better served by additional reductions in work hours, so as to wholly remove the effects of sleep deprivation from the equation. And if such guidelines are good for the resident learner and the safety of their patients, why should they not also apply to the faculty and staff physicians—those teaching the resident learners—who are ultimately in charge of the care of the patient? Indeed, in a symposium pretest, 44% of the attendees concurred with the concept of restricted work hours for faculty and staff physicians in an attempt to eliminate performance impairment attributable to the effects of chronic sleep deprivation; after the symposium, 60% had become convinced of the need to limit duty hours for staff and faculty physicians[26]. Such pressure for a more controlled and finite work-hour exposure is not inconsistent with the expectations of Generation X and the Millennials as they enter the physician workforce. The days of long work hours, delayed gratification, and selfless dedication to patient care in the name of medical professionalism are numbered as much by the perspective of tomorrow's physicians as by the work-hour guidelines. Indeed, the wave of duty-hour limitations must soon extend to the staff physicians before today's residents enter their ranks and become confused and overextended in a way to which all are unaccustomed!

How we meet the conflicting challenges of duty-hour restrictions and the mandates for patient safety and resident education, concurrent with the emergence of a new generational outlook on medicine that challenges the traditional model of professionalism, will determine not only the scope of the physician workforce but the course of the medical profession for the coming century. We can only hope that Sir William Osler (1849-1919) would have made the same musings about our profession 100 years later[27]: "The practice of medicine is an art, not a trade; a calling, not a business; a calling in which your heart will be exercised equally with your head."

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ORIGINAL ARTICLE

Recognizing and Preventing Burnout among Orthopaedic Leaders

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Abstract Stress, emotional exhaustion, and burnout are widespread in the medical profession in general and in orthopaedic surgery in particular. We attempted to identify variables associated with burnout as assessed by validated instruments. Surveys were sent to 282 leaders from orthopaedic surgery academic departments in the United States by e-mail and mail. Responses were received from 195 leaders for a response rate of 69%. The average surgeon worked 68.3 hours per week and more than ½ of this time was allocated to patient care. Highest stressors included excessive workload, increasing overhead, departmental budget deficits, tenure and promotion, disputes with the dean, and loss of key faculty. Personal-professional life imbalance was identified as an important risk factor for emotional exhaustion. Withdrawal, irritability, and family disagreements are early warning indicators of burnout and emotional exhaustion. Orthopaedic leaders can learn, and potentially model, ways to mitigate stress from other high-stress professions. Building on the strength of marital and family bonds, improving stress management skills and self-regulation, and improving efficiency and productivity can combine to assist the orthopaedic surgery leader in preventing burnout and emotional exhaustion.

Introduction

The prevalence and impact of burnout have been investigated in various medical specialties, including orthopaedic surgery [22], with the conclusion that burnout is present and widespread in the medical profession. Burnout is physical, emotional, or mental exhaustion, especially in one's job or career, accompanied by decreased motivation, lowered performance, and negative attitudes toward self and others [28]. The primary component of burnout is emotional exhaustion and a principle cause is job stress [11].

The American Institute of Stress indicates job stress has reached epidemic proportions in the United States, the United Kingdom, and other industrialized nations and suggests people working in almost every sector in the United States are overworked, negatively affecting job performance [25]. Although it is unclear if there is sufficient evidence that stress and burnout are at epidemic

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proportions in medicine in general or in orthopaedic surgery in particular, there are important advantages in preventing burnout among leaders in the medical profession. Prevention is always the preferred mode of intervention for diseases and disorders that may become epidemics [21]. Preventive stress management and the associated stages of primary, secondary, and tertiary prevention are key concepts accepted in the lexicon of psychology and the behavioral sciences [11, 28].

It is not necessary to settle for tradeoffs between stress and performance or between health and productivity [10]. These conditions and attributes should compliment each other and, in the long run, be mutually reinforcing. Therefore, traits and risk factors that lead to burnout should be identifiable and potentially modifiable. Leiter and Maslach [11] reported the most extensive research on burnout and its prevention worldwide, and their methods can be adapted for the practicing orthopaedic surgeon.

A previous study of orthopaedic leaders showed high levels of stress and burnout (as measured by standardized instruments) among department chairs and program directors, with the highest stressors being excessive workload, budgetary concerns, disputes with hospital and medical school administration, and night and weekend work hours [27]. These stressors can lead to medical errors and stress-related illness and ultimately have led some physicians to leave the practice of orthopaedic surgery [15, 22]. Because all of these results of stress are unacceptable, we hypothesized potential risk factors that lead to burnout can be identified, and there are prevention and coping strategies that can avert the onset of burnout before negative manifestations arise.

We therefore examined the relationships between emotional exhaustion, as defined by a standardized behavioral assessment, and self-reported satisfaction with key personal indicators to describe the experiences of orthopaedic leaders and help to provide insight into the key drivers of burnout. We presumed using an emotional exhaustion scale as a marker for potential severe burnout would help define strategies to mitigate negative effects before irreversible burnout occurs. We specifically report on (1) the degree of emotional exhaustion felt by orthopaedic leaders, and (2) compare how that emotional exhaustion is enhanced or decreased based on the respondents' perceptions of family support (especially spousal support) and personal actions.

Materials and Methods

We used data from a cross-sectional questionnaire-based survey of past, current, and acting chairs, division chiefs, and residency program directors from academic departments of orthopaedic surgery as designated by the 2004–2005 directory of the American Orthopaedic Association. After receiving approval from the University of Virginia Institutional Review Board (2005-0193-00), 282 surveys were distributed by e-mail and regular postal mail by a third-party survey group (Leever Research Services Inc, Naperville, IL). An academic department was defined as an orthopaedic unit associated with an approved orthopaedic surgery training program. The responses were kept confidential and the data double-entered into a password-protected computer file. We removed control numbers from the data file at the time of analyses, and the hard copy surveys were destroyed. The demographic and incidence rates from this sample were reported previously [27]. For the entire survey, 195 final data records from the 282 surveys were received and processed, representing a final response rate of 69%. Because response rates to the Maslach Burnout Inventory–Human Services Survey (MBI-HSS) [14] questions (see below) were low in the program directors group and with division chiefs (n = 85) and because the distribution of respondents in each emotional exhaustion category were statistically similar between respondent types, we focused on the data from department chairs (which includes current, acting, and former chairs) to help predict risk factors for severe burnout. One hundred ten of 169 surveys originally sent to department chairs were returned for a response rate of 65%. The number of valid responses on individual questions ranged from 102 to 104 of a possible 110 completed and returned surveys.

The questionnaire was developed and validated using a format similar to that used by Gabbe et al. [6] for the American Gynecological and Obstetrical Society. The eight-page questionnaire was divided into six sections and included 30 major questions. (Editors note: the holder of the copyright of this questionnaire, CPP, Inc., Mountain View, CA, does not permit reproduction of the actual survey questions and therefore the questions are not included; however a sample of the types of questions included in the MBI-HSS was provided by CPP, Inc, and is available for viewing as supplemental material with the online version of CORR.) A letter accompanied the questionnaire requesting the participation of each individual and although the letter expressed the principal investigator's concerns about the well-being of orthopaedic leaders in academic departments, the word burnout was not used. The first 17 questions collected information about program size, demographics, income, the orthopaedic leader's subspecialty, and hours worked per week. The second portion asked the respondents to select from a list of 19 stressors and to grade them on a 5-point Likert scale from "not at all" to "extreme amount" and an open-ended question at the end asking how these affected them [6]. Other sections included questions about job satisfaction, family life, work-family balance, family and spousal support, and how the individual dealt with stress. The questionnaire also asked if the institution where the individual worked had a support group for departmental leaders and for a personal appraisal of his or her professional life and reported self-efficacy. The questionnaire included 22 questions from the MBI-HSS [14]: nine for emotional exhaustion, five for depersonalization, and eight for personal accomplishments. We calculated a subscale for each of the three components. To further examine the relationships between emotional exhaustion and severe burnout, we categorized the orthopaedic chair responses based on their overall scores on the emotional exhaustion component of the MBI-HSS of low (scoring less than 17 points), medium (scoring between 17 and 27 points), and high (scoring more than 27 points).

The results for individual survey questions were tabulated and standard confidence interval formulas for proportions were used. We used chi square tests to compare responses among leaders in the different burnout categories with a focus on exploring relationships between the emotional exhaustion component of the MBI and answers to other questions. Correlations were used to assess associations between burnout scores and other questions.

Results

On average, the orthopaedic leaders had held faculty positions at two prior institutions before becoming a chairperson or program director. The average surgeon worked 68.3 hours per week (range, 10–120 hours/week), and on average, more than 55% of this time was allocated to patient care.

Among current or acting department chairs 22% reported low emotional exhaustion, 39% reported moderate emotional exhaustion, and 38% reported high emotional exhaustion. The lack of personal-professional life balance is correlated with emotional exhaustion (Table 1). More frequent withdrawal from family, irritability, and disagreements with spouse and family members were associated with higher levels of emotional exhaustion (Tables 2–4).

We observed no relationship between how the department chairs rated their spouses' willingness to listen to these leaders' work-related problems and emotional exhaustion (Table 5). We also found no relationship between the department chairs' perceptions regarding whether their spouses understand about of the extra hours

Table 1. Correlation between dissatisfaction with personal-professional life balance and emotional exhaustion*

Satisfaction level	Emotional exhaustion subscale					
	Low		Medium		High	
	Number	Percent	Number	Percent	Number	Percent
Very dissatisfied	1	4.3%	0	0.0%	11	27.5%
Somewhat dissatisfied	5	21.7%	12	29.3%	19	47.5%
Neutral	1	4.3%	8	19.5%	6	15.0%
Somewhat satisfied	9	39.1%	13	31.7%	3	7.5%
Very satisfied	7	30.4%	8	19.5%	1	2.5%
Total	23	100%	41	100%	40	100%

* Chi square test, $p < 0.0001$.

Table 2. Correlation between withdrawal from family and emotional exhaustion*

Withdrawal frequency	Emotional exhaustion subscale					
	Low		Medium		High	
	Number	Percent	Number	Percent	Number	Percent
Never	4	17.4%	1	2.4%	1	2.6%
Once in a while	15	65.2%	18	43.9%	4	10.3%
Sometimes	2	8.7%	17	41.5%	14	35.9%
Frequently	2	8.7%	5	12.2%	20	51.3%
Always	0	0.0%	0	0.0%	0	0.0%
Total	23	100%	41	100%	39	100%

* Chi square test, $p < 0.0001$.

Table 3. Correlation between irritability with family and emotional exhaustion*

Irritability frequency	Emotional exhaustion subscale					
	Low		Medium		High	
	Number	Percent	Number	Percent	Number	Percent
Never	3	13.0%	2	4.9%	2	5.1%
Once in a while	13	56.5%	24	58.5%	7	17.9%
Sometimes	6	26.1%	14	34.1%	21	53.8%
Frequently	1	4.3%	1	2.4%	9	23.1%
Always	0	0.0%	0	0.0%	0	0.0%
Total	23	100%	41	100%	39	100%

* Chi square test, $p < 0.0007$.

Table 4. Correlation between disagreements with family and emotional exhaustion*

Disagreement frequency	Emotional exhaustion subscale					
	Low		Medium		High	
	Number	Percent	Number	Percent	Number	Percent
Never	3	13.0%	8	19.5%	4	10.3%
Once in a while	14	60.9%	15	36.6%	11	28.2%
Sometimes	5	21.7%	13	31.7%	11	28.2%
Frequently	1	4.3%	5	12.2%	9	23.1%
Always	0	0.0%	0	0.0%	4	10.3%
Total	23	100%	41	100%	39	100%

* Chi square test, $p = 0.04$.

Table 5. Correlation between spouses' willingness to listen to work-related problems and emotional exhaustion*

Spouses' willingness to listen frequency	Emotional exhaustion subscale					
	Low		Medium		High	
	Number	Percent	Number	Percent	Number	Percent
Never	0	0.0%	0	0.0%	0	0.0%
Once in a while	2	8.7%	2	5.0%	3	7.7%
Sometimes	4	17.4%	8	20.0%	9	23.1%
Frequently	8	34.8%	18	45.0%	10	25.6%
Always	9	39.1%	12	30.0%	17	43.6%
Total	23	100%	40	100%	39	100%

* Chi square test, $p = 0.71$.

leaders may have to work in their jobs and the leaders' emotional exhaustion (Table 6). We did observe a relationship between the chairs' perception of spousal encouragement for the leaders to take advantage of professional opportunities and emotional exhaustion (Table 7); when chairs reported their spouses were more encouraging of them taking on new opportunities they more often reported low or medium emotional exhaustion, and conversely higher emotional exhaustion was related to a perception of less frequent spousal encouragement. The chairs' overall satisfaction with family life was not related to emotional exhaustion (Table 8).

Discussion

Preventing burnout in orthopaedic surgeons in general, and their leaders in particular, should be an important priority

Table 6. Correlation between spouses' understanding of working extra hours and emotional exhaustion*

Frequency of spouses' understanding of working extra hours	Emotional exhaustion subscale					
	Low		Medium		High	
	Number	Percent	Number	Percent	Number	Percent
Never	0	0.0%	0	0.0%	1	2.6%
Once in a while	1	4.3%	4	10.0%	6	15.4%
Sometimes	1	4.3%	6	15.0%	7	17.9%
Frequently	9	39.1%	20	50.0%	10	25.6%
Always	12	52.2%	10	25.0%	15	38.5%
Total	23	100%	40	100%	39	100%

* Chi square test, p = 0.18.

Table 7. Correlation between spousal encouragement and discouragement for professional opportunities and emotional exhaustion*

Frequency of spouses' encouragement and discouragement	Emotional exhaustion subscale					
	Low		Medium		High	
	Number	Percent	Number	Percent	Number	Percent
Never	2	8.7%	2	5.0%	5	12.8%
Once in a while	1	4.3%	4	10.0%	10	25.6%
Sometimes	6	26.1%	12	30.0%	12	30.8%
Frequently	10	43.5%	18	45.0%	3	7.7%
Always	4	17.4%	4	10.0%	9	23.1%
Total	23	100%	40	100%	39	100%

* Chi square test, p = 0.012.

Table 8. Correlation between satisfaction with family life and emotional exhaustion*

Satisfaction with family life	Emotional exhaustion subscale					
	Low		Medium		High	
	Number	Percent	Number	Percent	Number	Percent
Very dissatisfied	1	4.3%	0	0.0%	4	10.0%
Somewhat dissatisfied	2	8.7%	4	9.8%	12	30.0%
Neutral	1	4.3%	3	7.3%	2	5.0%
Somewhat satisfied	6	26.1%	19	46.3%	10	25.0%
Very satisfied	13	56.5%	15	36.6%	12	30.0%
Total	23	100%	41	100%	40	100%

* Chi square test, p = 0.035.

for healthcare institutions, especially as the demand for orthopaedic services increases [27]. We examined risk factors and early warning signs of burnout and emotional exhaustion among orthopaedic leaders, specifically current department chairs. We also collected data on preventive stress management factors, such as the spouse, family, social support systems, and positive communication attachments. Previously work-home balance was examined and results suggested relationships, and especially family relationships, can be among the most powerful antidotes to burnout and emotional exhaustion [24]. This becomes an issue of managing energy more than it is an issue of managing time [12].

Readers should keep in mind the following limitations. We had a 69% response rate from department chairs, therefore nonrespondents potentially could lead to bias in the data. Nonetheless, we believe the sample is representative and our results reflect the experiences of orthopaedic leaders in general. However, we realize the experiences and stressors among leaders may be somewhat different from those of the rank and file surgeon who mostly is treating patients. Perhaps a more extensive study of burnout should be conducted to assess severity and prevalence in the orthopaedic surgery population at large, with the aim of identifying potential risks at earlier stages in the surgeon's career. Starting prevention efforts during residency could lead to great benefits in the future. In addition, the limitation of any survey is that it reflects the perceptions of the respondents, which might be very different from the viewpoints of others intimately involved with the lives of these orthopaedic leaders. We thought it was important to present this information, but we acknowledge that a more global assessment of burnout, including responses from coworkers and spouses, could add to the picture and provide greater insight into the extent of the problem of burnout.

Based on the perception of the chairs who responded to the survey, the data suggest spouses are available and not pushed away when emotional exhaustion gets high for the leader (Tables 5, 6). Therefore, spouses' willingness to listen could be seen as a preventive resource and buffer to burnout and emotional exhaustion Unfortunately, even when the spouse and family realize what is happening to their loved one and try to seek help, the overstressed or workaholic surgeon may deny there is a problem, which is a behavior often seen in people with substance abuse or other type of addictions [17]. Once the spouse and/or family has exhausted all means of obtaining help for their loved one and sees no hope, the relationship may fall apart. Thus, care and support for the spouse and family as caregivers are central to the health and well-being of orthopaedic leaders. Balance becomes a key in the long-term maintenance and vitality of the marital and family relationships and should be encouraged.

Despite the potentially negative impact of stress, the caveat is well-managed stress can lead to positive effects, such as peak performance and the energy to address legitimate emergencies. However, as a known risk factor, stress is directly linked to heart disease, stroke, injury, suicide, and homicide [30]. No one is immune to the possible adverse health risks that constitute distress in any of its medical (eg, coronary vascular disease), behavioral (eg, substance abuse), or psychologic (eg, burnout) forms. Although some individuals are more stress-resistant than others, everyone has one or more vulnerabilities that may be exploited when subjected to stress that is too intense, too chronic, or too frequent. This is known as the Achilles heel, or organ inferiority, hypothesis, which states stress causes the individual to experience illness, disease, or health problems at the weakest and most vulnerable points of their lives [29]. However, before the leader gets to that point, there are some early warning signs as we have shown. Dissatisfaction with the work-personal life balance, irritability, and withdrawal are the same early warning signs reported in other clinical research with senior executives in health care, manufacturing, the military, and service organizations [14, 19].

From a prevention perspective, early warning signs are powerful and important because they allow for early intervention to avert serious or debilitating disorders, problems, or disease.

Prevention is a highly appropriate response to a health epidemic, and in the case of stress, the approach becomes one of preventive stress management [23]. There are two ways to translate the public health notions from preventive medicine into a stress process framework. One approach focuses on the degree of risk for individuals and groups in a population. In this approach, preventive interventions may be aimed at individuals not at risk (primary), those who are at risk (secondary), or those with health decrements as a result of the disease (tertiary; ie, symptomatic). The other approach to prevention focuses on health risks and the asymptomatic and symptomatic responses to these health risks. We would choose this second approach to prevention in the case of stress. When translated in the case of stress, primary prevention aims to address the source of the stress or the causes of stress, such as job demands. Secondary prevention aims to alter the individual's response to stress, such as thorough reality testing, relaxation, or exercise. Tertiary prevention aims to aid those experiencing distress and therefore includes a range of medical, psychologic, and behavioral treatment interventions.

So what does the orthopaedic surgeon do to reduce stress? What can orthopaedic surgeons learn, and potentially model, from other high-stress professions? As an example, air traffic controllers (ATCs) have looked carefully at their work and workloads, including psychologic workloads, as a key vehicle for stress management [3, 4, 18]. The effects of high stress manifest epidemiologically in this group; approximately 10% to 15% of ATCs report burnout and stress symptoms from work spillover into their personal lives [31]. In addition, cardiovascular problems, endocrine disorders, and hypertension have been linked to the stresses experienced by the members of this profession [16, 26]. The orthopaedic profession and chairs can, either individually or collectively, benefit from similar review of the work and workload in their profession. This is one preventive stress management that may prove cost-benefit-effective for orthopaedic surgeons. The 80-hour work week is an excellent example of a strategy of moderating the workload. This has naturally led to strategies, such as the introduction of more physician assistants and nurse practitioners, to help fill the gap between what physicians were doing before compared with what they are able to do in the

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The Prevalence and Severity of Burnout Among Academic Orthopaedic Departmental Leaders*

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Burnout has many definitions but the most commonly accepted is "a state of physical, emotional or mental exhaustion caused by long-term involvement in situations that are emotionally demanding."[1] It tends to be most common among medical professionals as a result of long working hours, stresses associated with the responsibilities of patient care, and emotional contact with patients[2]. According to Jones, burnout—a syndrome of progressive emotional, attitudinal, and physical exhaustion—is a critical occupational hazard for people in a wide range of helping professions[3]. Those who are affected find themselves plagued by chronic fatigue, low energy, irritability, and a negative attitude toward themselves, toward others, and toward their jobs. Because they are emotionally depleted and cynical, they may have a negative impact on those around them, including the individuals with whom they work and the patients they treat. Among the members of the so-called helping professions, physicians are clearly most afflicted with burnout and, as we noted in our previous report[4], they have by now been quite intensively studied. Characteristically, burnout syndrome involves the development of a cynical attitude and the loss of concern for people with whom one is working. In addition to physical exhaustion, which harms physical health through many pathways[5], burnout is also characterized by an emotional exhaustion wherein the professional experiences growing negative feelings, cynicism, or disrespect for patients and colleagues. "A very cynical and dehumanized perception of these people often develops in which they are labeled in derogatory ways and therefore treated accordingly."[6]

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Gabbe et al.[7] undertook a cross-sectional study, in which a questionnaire was sent to 131 chairs of academic departments of obstetrics and gynecology in the United States and Puerto Rico, and had a 91% response rate. The study found that 22% of the chairs were very dissatisfied with their positions. Using the Maslach Burnout Inventory-Human Service Survey (MBI-HSS), the study revealed a high subscale score for emotional exhaustion, together with a moderate-to-high level of depersonalization or cynicism, yet with a high score for personal accomplishment. More importantly, burnout was more common in new chairs and in those who had less spousal support.

Leaders in orthopaedics, such as department chairs, past chairs, acting chairs, and program directors, may be experiencing substantial yet different stress as a result of increased oversight and bureaucracy associated with patient care, teaching, and research; decreased reimbursement for patient care services; and a reduction in protected time for undertaking such activities. We therefore wanted to ascertain the prevalence and severity of burnout among orthopaedic leaders in the United States. This is important because of the adverse effects that burnout among leaders may have on the quality of department work, morale, attendance, turnover, mental and physical health, and family relationships[8].

Materials and Methods

After obtaining approval from the University of Virginia institutional review board, a cross-sectional questionnaire-based survey was undertaken with use of the 2004-2005 membership directory of the American Orthopaedic Association. Two hundred and eighty-two past, current, and acting chairs—along with program directors from academic departments of orthopaedic surgery in the United States—were contacted by e-mail and mail. For our study, we classified an individual as an acting chair if that individual was at an institution that had an active search for a chair and if that individual checked the "acting chair" box on the questionnaire.

The chairs were contacted directly through a third-party survey group (Leever Research Services, Naperville, Illinois). The responses were kept confidential, and the data were double-entered into a password-protected computer file. A second mailing of the questionnaire was sent to those who had not responded initially and was followed by an e-mail reminder. Control numbers were removed from the data file at the time of analysis, and the hard copy surveys were destroyed.

The questionnaire was developed with use of a format similar to that utilized by Gabbe et al. and the American Gynecological and Obstetrical Society[7]. The eight-page questionnaire was divided into seven sections and included

TABLE I Stressors and Their Impact as Rated by the Respondents

"During the past year, to what degree have you and your department been affected . . . by the following problems?"	Not at all (1)	Slight Amount (2)	Moderate Amount (3)	Large Amount (4)	Extreme Amount (5)
Excessive workload	5%	17%	37%	34%	7%
Increasing overhead (i.e., malpractice rates, rent, etc.)	12%	20%	28%	29%	10%
Union disputes	80%	15%	2%	2%	1%
Substance abuse	90%	8%	2%	1%	0%
Bioethics violation	73%	23%	3%	1%	0%
Medicare-Medicaid billing audits	53%	33%	11%	1%	1%
Loss of key faculty	33%	27%	24%	13%	3%
Tenure or promotion dispute	68%	19%	10%	3%	0%
Faculty or resident dismissal	64%	21%	9%	5%	0%
Staff dismissal	59%	26%	11%	2%	1%
Dispute(s) with dean	52%	24%	11%	8%	4%
Department budget deficits	33%	23%	21%	16%	7%
Hospital budget deficits	33%	27%	16%	17%	8%
Credentialing dispute	77%	17%	4%	1%	1%
Defendant in malpractice case	63%	29%	5%	2%	1%
Sexual harassment	88%	9%	2%	1%	0%
Verbal abuse	67%	23%	8%	2%	1%
Physical abuse	93%	7%	1%	0%	0%
Overall impact of these problems	3%	27%	40%	23%	7%

thirty major questions. There were also sixty-four minor questions that delved into some of the major topics but in greater detail. A letter accompanied the questionnaire requesting the participation of each individual and, although the letter expressed the principal investigator's concerns about the well-being of chairs in academic departments of orthopaedics, the word "burnout" was not used.

The first section was composed of sixteen questions collecting information on program size, demographic data, income, subspecialty, and hours worked per week. The second section explored effectiveness or self-efficacy and asked, "On a 0 to 10 scale, how would you rate your effectiveness as a chair?"

The third section asked, "During the past year, to what degree have you and your department been affected (i.e. with decreased morale, productivity, or collegiality or fiscally) by the following problems?" The respondents were instructed to select from a list of nineteen stressors and to grade them on a 5-point Likert scale from "not at all" to "extreme amount" and to answer an open-ended question at the end asking how these affected them (Table I)[7].

The fourth section (questions 19 and 20) asked the respondents to rate job satisfaction currently, one year ago, and five years ago and to anticipate what it would be in one year. In addition, in order to quantify the likelihood that the chair would step down in the next one to two years, the questionnaire asked the respondents to rate that variable from "very dissatisfied" to "very satisfied."

The fifth section had questions about the balance between personal life and professional life and about satisfaction with family life, and the individual was asked to list three positive and three negative ways in which he or she dealt with stress. The questionnaire also asked whether the institution where the individual worked had a chair support group that assessed the individual's control of his or her professional life and reported self-efficacy.

TABLE II Descriptive Data from 195 United States Orthopaedic Department Chairs and Program Directors

	Average	Range
Age *(yr)*	53.7	32-83
Duration as chair *(yr)*	7.2	0.5-40
Duration that previous person held that position *(yr)*	10.5	0-32
No. of faculty in department		
Full-time	16.9	0-72
Part-time	6.8	0-60
No. of division chiefs in department	3.6	0-11
No. of residents in department	7.5	2-52
No. of fellows in department	4.3	0-40
Income earned in current leadership position *(%)*	44.2	0-100
Hours worked per week:	68.3	10-120
Time spent on patient care *(%)*	55.3	10-95
Time spent on teaching *(%)*	14.9	0-60
Time spent on research *(%)*	6.7	0-30
Time spent on administration *(%)*	23.1	4-80
No. of nights worked		
Weekdays	2.5	0-2.8
Weekend nights per month	2.1	0-2.4

The sixth section of the questionnaire had twenty-two questions from the MBI-HSS[8]. Nine of those questions evaluated emotional exhaustion; five, depersonalization; and eight, personal accomplishments. A subscale was calculated for each of the three components.

The seventh, and final, section asked three questions that assessed family and spousal support of the respondent's position.

Statistical Analyses

The results for individual survey questions were tabulated, and standard confidence interval formulas for proportions were used. Scores on the MBI-HSS were categorized into low, medium, and high according to established definitions. Chi-square tests were used to compare responses among chairs in the different burnout categories. Correlations were used to assess associations between burnout scores and other survey questions.

Results

One hundred and ninety-five final data records from the 282 surveys were received and processed, representing a final response rate of 69%.

Demographic data are summarized in Table II. On the average, the chairs had held faculty positions at two prior institutions before becoming a chairperson. Only 6% of the responding surgeons described themselves as specializing in general orthopaedics; 19%, as specializing in traumatology; 19%, in hip and knee reconstruction; 19%, in sports medicine; 7%, in orthopaedic oncology; 14%, in pediatric orthopaedics; 12%, in hand surgery; and 7%, in shoulder and elbow surgery. The surgeons worked an average of 68.3 hours per week (range, ten to 120 hours per week), and, on the average, >55 % of this time was allocated to patient care.

The highest stressors, in order of decreasing frequency, were excessive workload, increasing overhead, departmental budget deficits, tenure and promotion, disputes with the dean, loss of key faculty, staff dismissal, night and weekend work, and hospital budget deficits.

When asked how much these

problems affected their lives, 70% of the respondents indicated that the stressors had a moderate to extreme impact. Of the 147 emotionally exhausted respondents, thirty-seven (25%) reported frequent irritable behavior with their spouses, significant others, and family members when they were preoccupied with work matters. Eighty-eight percent of the 147 respondents reported that they were sometimes irritable with the people in their lives.

The respondents were asked to list three positive and three negative ways in which they managed stress; 218 responses were listed. The most frequent positive responses were physical activity and exercise (42%), family support (18%), leisure activity (15%), and hobbies (9%). Fifteen percent responded that they would work harder at addressing the source of the stress. The most frequent negative responses were irritability (31%), sleep disturbance (17%), withdrawal (15%), overworking (10%), procrastination (7%), alcohol use (7%), and overeating (5%).

Survey responses suggested that perceived job satisfaction had declined substantially over the previous five years, and there was anticipation that, in a year, the job satisfaction would decrease even further. Twenty-six percent of the respondents reported that they were currently dissatisfied with their position compared with 22% who had been dissatisfied one year earlier and 10% who had been dissatisfied five years earlier. Only 20% reported that they were satisfied with their current position.

When asked how satisfied they were with the balance between their personal life and their professional life, only 15% of the respondents noted that they were satisfied and 45% responded that they were somewhat dissatisfied to very dissatisfied. With regard to their family life, 20% of the respondents were somewhat dissatisfied or very dissatisfied. Seventy-two percent reported that the long hours hurt their family life or other relationships. Eighty-nine percent responded that they took work home because of the concern that it would not otherwise get done. Sixty-nine percent reported that their friends and family have given up expecting them to show up for family or social events on time. Seventy-two percent took work activity on vacation. Only 13% responded positively to the question regarding the availability of a support group in their institution for persons in their position.

When the respondents rated their effectiveness as a leader, considering all facets of the job, on a scale from 0 (least effective) to 10 (most effective), they had a mean score (and standard deviation) of 7.3 ± 1.5. Ten percent of the twenty-one past chairs, 25% of the eight acting chairs, 18% of the 110 current chairs, and 37% of the fifty-four residency program directors felt that they had either slight control over their personal lives or none at all. Thirty-four percent of the past chairs, 13% of the acting chairs, 38% of the current chairs, and 60% of the program directors felt that their professional life would get worse over the next several years, with the majority (19% to 50%) believing that this was due to factors beyond their control. Unfortunately, 30% of the present chairs, 38% of the acting chairs, and 45% of the program directors felt that their current professional role got in the way of developing their own life goals.

As has been described previously, burnout is defined as a high level of emotional exhaustion, a high level of depersonalization and/or cynicism, and a low level of personal accomplishment[5]. Table III summarizes the overall results on the MBI-HSS for this study. Sixty-seven percent of the past chairs, 75% of the acting chairs, 81% of the current chairs, and 72% of the residency program directors scored high on the personal accomplishment subscale. However, 76% of the past chairs, 88% of the acting chairs, 73% of the current chairs, and 82% of the program directors reported moderate-to-high emotional exhaustion. On the depersonalization scale, 66% of the past chairs, 88% of the active chairs, 61% of the current chairs, and 76% of the residency program directors had moderate-to-high scores. No significant differences were identified between positions.

TABLE III Results on the Maslach Burnout Inventory-Human Services Survey

	Scores of Respondents		
Subscale	Low	Moderate	High
Personal accomplishment*			
Past chair or chief (n = 21)	0%	33%	67%
Acting chair or chief (n = 8)	0%	25%	75%
Chair or chief (n = 110)	4%	15%	81%
Residency program director (n = 54)	2%	26%	72%
Emotional exhaustion†			
Past chair or chief (n = 21)	24%	33%	43%
Acting chair or chief (n = 8)	13%	50%	38%
Chair or chief (n = 110)	26%	37%	36%
Residency program director (n = 54)	19%	30%	52%
Depersonalization‡			
Past chair or chief (n = 21)	33%	33%	33%
Acting chair or chief (n = 8)	13%	63%	25%
Chair or chief (n = 110)	39%	34%	27%
Residency program director (n = 54)	24%	52%	24%

*A score of >38 indicated a low level; 31 to ≤38, a moderate level; and ≤31, a high level.
†A score of <17 indicated a low level; 17 to <27, a moderate level; and ≥27, a high level.
‡A score of <7 indicated a low level; 7 to <13, a moderate level; and ≥13, a high level.

TABLE IV Comparison of the Average Scores on the Maslach Burnout Inventory-Human Services Survey Subscales for United States Orthopaedic Chairs and Other Groups

Subscales	Orthopaedic Chairs	Otolaryngology Chairs	Obstetric-Gynecology Chairs	Family Physicians	Emergency Physicians	Normative Data Medicine
Emotional exhaustion*	24.0	17.5	29.9	23.2	26.2	22.2
Depersonalization†	9.2	4	9.1	10.2	16.5	7.2
Personal accomplishments‡	28.0	32.8	41.5	40.9	37.2	36.5

*A score of <17 indicates a low level; 17 to <27, a moderate level; and ≥27, a high level. †A score of <7 indicates a low level; 7 to <13, a moderate level; and ≥13, a high level. ‡A score of >38 indicates a low level; 31 to ≤38, a moderate level; and ≤31, a high level.

Of the 147 respondents with moderate-to-high emotional exhaustion, 77% reported that they were somewhat dissatisfied with the balance between their personal life and professional life and 40% were somewhat to very dissatisfied with their family life. Of the emotionally exhausted respondents, 26% reported being frequently irritable with their spouses, significant others, and family members when they were preoccupied with work matters, and another 88% of the emotionally exhausted respondents reported that they were sometimes irritable with their spouses or family members. Forty-three percent of the emotionally exhausted respondents reported that spousal support was available sometimes, and another 13% reported that it was available once in a while.

The American Psychological Association defines self-efficacy as an individual's capacity to act effectively to bring about desired results, especially as perceived by the individual[9]. In our survey, there was a significant relationship between the self-efficacy score and burnout. As self-efficacy increased, burnout decreased ($p < 0.01$). Table IV compares subscale scores on the MBI-HSS between United States otolaryngology chairs, obstetric-gynecology chairs, as well as other physician groups including normative data for the medical profession. Excessive work ($p < 0.01$), overhead ($p < 0.01$), departmental and hospital budget deficits ($p < 0.01$), tenure and promotion issues ($p < 0.05$), disputes with deans ($p < 0.05$), loss of key faculty ($p < 0.05$), and staff dismissal ($p < 0.05$) correlated significantly with emotional exhaustion. Excessive work ($p < 0.01$), staff dismissal ($p < 0.01$), credentialing issues ($p < 0.01$), and spousal support ($p < 0.01$) correlated significantly with depersonalization and cynicism (Table V). There was a 100% rate of being a so-called workaholic. When the respondents (not including past chairs) were asked what the likelihood was that they would step down from their position over the next two years, 14% indicated that it was moderately likely; 13%, that it was very likely; and 10%, that it was extremely likely.

Discussion

Our study provides the first investigation into burnout in orthopaedic leadership, focusing on departmental chairs and program directors. The strengths of the study are that it is a prospective investigation that uses validated psychometric measures, and we attained a fairly high response rate (69%). The 31% nonresponse rate was probably related to the respondent burden of completing a long questionnaire in an already busy group of individuals. For completeness, other members of the field of orthopaedics should have been surveyed as it would be important to know the views of residents, fellows, and members of the private orthopaedic community as well.

Burnout syndrome appears to be a response to chronic stress as opposed to acute stress. The medical literature began to address the problem of physician distress some twenty years ago[2]. Although the problem is common among academic faculty (among whom 37% to 47% experience burnout), it is also prevalent in private practice[10]. This may reflect the degree of dissatisfaction, which is common to all practicing orthopaedic surgeons, with regard to third-party payers and government

TABLE V Correlations of Burnout Subscales to Stressor Variables*

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	Excessive Work	Overhead	Department Budget Deficits	Tenure or Promotion	Disputes with Dean	Loss of Key Faculty	Staff Dismissal
Emotional exhaustion *(r value)*	0.467†	0.306†	0.284†	0.256‡	0.250‡	0.248‡	0.232‡
Depersonalization *(r value)*	0.267†	NS	NS	NS	NS	NS	0.289†

*NS = not significant. †The correlation was significant ($p < 0.01$). ‡The correlation was significant ($p < 0.05$).

agencies, paperwork, community demands, isolation from other physicians, and poor working relationships with medical colleagues. Burnout was once thought to be a late-career phenomenon, but studies have now suggested that younger physicians experience it nearly twice as frequently as their older colleagues and the onset may occur as early as residency[10]. Burnout has many consequences including absenteeism, turnover in personnel, cynicism, and decreased job satisfaction as evidenced by our survey. More concerning effects include the spillover into personal life. When physicians return home, they are tense, unhappy, or upset, leading to friction in personal relationships and isolation from significant others or family members. Perhaps the most compelling report on stress among medical personnel came from the more than 3500 physicians who responded to a Canadian national survey, which revealed that the majority of physicians thought that their workload was too heavy (62%), that their family and personal life suffered because they had chosen medicine as a profession (55%), and that opportunities to change careers were limited (65%)[11]. Our data appear to concur with these results.

Although we did not delve into the question of the quality of care provided by the respondents, burnout may also have other serious implications including effectiveness as a caregiver. Measured depersonalization has been associated with an increased frequency of physicians reporting suboptimal patient care practices[11]. As is evident from our data, an important role is played by such factors as workload, malpractice suits, lack of control over the practice environment, and problems with the balance between personal and professional life and practice setting. Other studies have shown that characteristics, such as sleep deprivation, personality type, and methods of dealing with death and/or suffering, can lead to burnout[12].

Only 13% of the respondents reported that their institution had suppor groups for chairs or program chairs. There is clearly a need to develop and evaluate effective interventions to maintain leaders in these roles. That is why we recommend that institutions provide the foundation for the development of support groups among their departmental leaders. The weakness in this approach, though, is that institutional support groups will be less effective in dealing with field-specific issues, and that is why we recommend that orthopaedic societies also provide this similar support for its members.

Many of those surveyed felt that they had either slight or no control over their personal lives, and many felt that their professional life would get worse over the next several years, with a large proportion (≤50%) believing that this was due to factors beyond their control. A number of new guidelines that have added considerable restrictions to academic health centers have been instituted over the last five years, and they have affected every aspect of academic orthopaedic practice including, but not limited to, research practices (i.e., HIPAA [the Health Insurance Portability and Accountability Act]), education programs (the eighty-hour workweek), and clinical practice (the Center for Medicare and Medicaid Services Pay for Performance guidelines). These new restrictions, combined with the increasing demand for reporting, transparency, and audits, have given the chair or program director less control over his or her role. Karasek developed the stress-disequilibrium theory, which proposes that low levels of control can cause chronic disease through chronic deregulation of our highly integrated physiological systems[13].

Specifically, burnout (or its alternative, "engagement") mediates the relationship between the characteristics of one's work environment (such as workload, control, rewards, community, fairness, and values) and the important results of work (such as quality of work results, absenteeism, turnover, health-care costs, and others). Burnout can be the first stop on the way to depression, cardiovascular problems, stroke, and other debilitating health problems[14]. It can also serve as an important call to action to restructure work into a positive experience that results in positive outcomes, rather than burnout and negative outcomes.

It is important to point out that 26% of the respondents reported that they were currently dissatisfied with their position compared with 22% who had been dissatisfied one year earlier and 10% who had been dissatisfied five years earlier. This may correlate to a number of health-care issues and processes that have taken place over this period or it may be an issue of recall bias, i.e., remembering the so-called good old days. It was also surprising to us that only 20% of the respondents reported that they were satisfied with their current position. This is certainly not consistent with the commonly perceived orthopaedic leader's persona.

TABLE V ***(continued)***

Medicare Audits	Nights and/or Weekends	Credentialing	Hospital Budget	Spousal Support	Verbal Abuse	Malpractice Defendant	Self-Efficacy	Percent Administrative Time
NS	0.289†	NS	0.284†	NS	NS	NS	NS	NS
NS	NS	0.241†	NS	0.342†	NS	NS	NS	NS

The opportunity to respond anonymously and with confidentiality may have allowed these leaders to feel that they could truly express their views.

Job stress can have spillover effects into the surgeon's family, home, and personal life. For all leaders, it is important to maintain a balance among the competing demands of work and home. The problems associated with a lack of balance are not isolated to the individual doctor; rather, they affect the physician's family and the organization in which the physician works. Indeed, 77% of those with moderate to high emotional exhaustion reported that they were somewhat dissatisfied with the balance between work and family.

Work-family conflict can cause stress and suffering for spouses and children and for colleagues in the work environment. We described in our previous report that regardless of whether the work-family conflict originates primarily from job pressures, family demands, or self-imposed expectations, there are accelerants that can amplify or inflame the conflict[4]. These accelerants were reported by the respondents in this study and included alcohol, sleep disturbances, overwork, toxic departmental and institutional cultures, and withdrawal. A large number of the respondents (119) reported that they handled stress negatively by taking it out on their family, either displacing themselves from family situations or delving into more work. Identifying these accelerants within the family and then knowing the early warning signs of their impending activation can go a long way toward early detection and prevention of conflict within the family and workplace. Emotional exhaustion and depersonalization are common among those working in the health-care profession, especially in the medical field, and the best antidote is a well-structured work organization, which ensures efficiency and a collaborative team in the operating room, the laboratory, and the office. When these factors are ignored, the impact of stress on the individual is revealed through its negative effect on family relationships, personal productivity, and the quality of care for the patient.

At the professional level, peer support and unity around pressing issues are useful in reducing the negative impact on both occupational and personal stress. Support can be provided to assist subordinates, such as office staff, residents, and fellows, as well as peers and colleagues. Peer counseling and occupational health and safety measures, including occupational and mental health services, have proven to be effective. One important obstacle to achieving success with these programs is a lack of acceptance, which may lead to a substantial communication barrier. Work groups that provide workshops and presentations for all levels of the orthopaedic community need to be formed. These presentations should focus on topics such as violence in the workplace, suicide awareness, and stress management. They should be offered at the hospital as well as off-site and during conferences. Individuals should be assured that these presentations are informal and that discussion is welcomed. The informal setting and educational nature of these sessions should encourage involvement and participation. One such program that was effective in implementing this strategy was the Kelly Air Force Base occupational health psychology program[15].

At the personal level, leaders can be proactive by taking steps to ensure that burnout is avoided and that, when burnout occurs, recovery is possible. We need to emphasize that there is no magic, no surefire cure, no standard protocol, and no quick fix. People do not burn out overnight, and they do not recover overnight. The long-term solution is lifestyle change and the determination to break out of a rut. Some useful steps include the following: (1) Take regular pit stops. We all know when we need a rest break. Arrange for a time-out to take a deep breath and recharge. (2) Practice good self-control. Develop awareness of increasing tension, signs of getting toward the edge, and the development of poor interpersonal communication exchanges. You need to know yourself, but it is just as important to remember that your spouse and family are your best resource to help you to make sure that you are attuned to your own mind and body. (3) Pay attention to how you talk to yourself. Thoughts and ideas have consequences in behavior and action. How we talk to ourselves, positively or negatively, can be the leading edge of how we act and behave. If you do not like what you say to yourself, change and start talking more constructively and positively. (4) Burn hot but stay cool. Take your work seriously, but do not take yourself too seriously; lighten up and stay cool. There is a time for high-intensity work and a time to cool and recover. (5) Protect your investment. You are the most important and valuable asset you have. Take good care of yourself and your loved ones, and then they will take good care of you.

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TOPICS IN TRAINING

STRESS AND COPING AMONG ORTHOPAEDIC SURGERY RESIDENTS AND FACULTY

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Background: Evaluations of physicians and residents have revealed concerning levels of psychosocial dysfunction. The purposes of this study were to determine the quality of life of orthopaedic residents and faculty and to identify the risk factors for decompensation.

Methods: Twenty-one orthopaedic residents and twenty-five full-time orthopaedic faculty completed a 102-question voluntary, anonymous survey. The survey consisted of three validated instruments, i.e., the Maslach Burnout Inventory, the General Health Questionnaire-12, and the Revised Dyadic Adjustment Scale; and three novel question sets addressing background and demographic information, stress reaction and management, and the balance between work and home life. Descriptive statistics, pairwise correlations, simple t tests, and Pearson and nonparametric Spearman correlations were calculated. The simple correlation coefficient was used to assess bivariate relationships.

Results: The mean overall quality-of-life score, on a scale of 0 to 4 points, was 2.5 points for residents compared with 3.6 points for faculty members. Residents reported considerable burnout, showing a high level of emotional exhaustion and depersonalization and an average level of personal achievement, whereas faculty reported minimal burnout, showing a low level of emotional exhaustion ($p < 0.0003$), an average level of depersonalization ($p < 0.0001$), and a high level of personal achievement ($p < 0.0001$). Only two of twenty-five faculty members (compared with seven of twenty-one residents) scored over 4 points on the General Health Questionnaire-12, indicating significant symptomatology ($p < 0.01$). The majority of subjects reported that a partner or spouse showed nondistressed levels of marital adjustment and satisfaction. All residents and nine of the twenty-five faculty members had mentors but judged the resource to be minimally beneficial. Resident burnout and psychiatric morbidity correlated with weekly work hours; conflict between the commitments of work and home life; discord with faculty, nursing staff, and senior residents; debt load; and work-related stress. Protective factors included being a parent, spending time with a spouse, having a physician father, and deriving satisfaction from discussing concerns with colleagues, friends, and family.

Conclusions: In pursuit of our goal of determining the quality of life of orthopaedic residents and faculty, we identified a large disparity between the two groups. The resident group reported much greater levels of dysfunction particularly with regard to burnout and psychiatric morbidity. Furthermore, with regard to our second goal; our data revealed a number of risk factors for resident decompensation, most notably, increased workload, high debt levels, and discord with superiors. In addition, our research revealed that the current support interventions by the residency program, including mentoring and facilitation of spousal adjustment, are viewed as being of little help.

Residency is known to be a stressful, demanding undertaking, and orthopaedic training can be particularly challenging physically, intellectually, and emotionally. Recent studies have drawn attention to some potentially adverse effects of residency training[1-6]. While a number of researchers have evaluated the quality of life among residents and physicians, none have focused on orthopaedic surgeons or orthopaedic residents. Studies of other medical specialties have described depression, drug abuse, loneliness, marital disruption, cognitive impairment, and suicidal thoughts or actions occurring during training in more than one-third of residents[3]. While research addressing psychological disturbance among American physicians is sparse, studies from the United Kingdom have found that the prevalence of such disturbances in practicing physicians was as high as 27% and the suicide rate for doctors was twice that of the general population[7].

In addition to general assessments of psychiatric morbidity, a number of researchers have focused on the work-related distress syndrome of burnout among physicians and residents[7,8]. Burnout, as defined by Maslach et al., is a syndrome of emotional exhaustion, depersonalization, and a reduced sense of personal accomplishment among individuals who work with people in some capacity[9]. Factors identified as contributing to burnout among workers in a variety of fields include work overload, lack of control, insufficient rewards, lack of community, lack of fairness, and conflicting values[10]. By contrast, high levels of job satisfaction appear to protect an individual's mental health against job stress[7]. Problems associated with burnout scores above the norm include physical and emotional illness, increased turnover, absenteeism, poor performance, drug abuse, and negative attitudes[8].

Physicians and other health-care professionals are believed to be particularly susceptible to burnout[7]. In 1996, Ramirez et al., in a report on the mental health of 882 hospital-based specialists in the United Kingdom, noted that insufficient communication and management training correlated with increased depersonalization and reduced personal achievement scores[7]. Ramirez et al. noted a corollary finding that the quality of the physician's relationships with patients, family, and support staff was directly proportional to job satisfaction[7]. High levels of burnout in medical professionals may result in poor performance and a decreased quality of medical care[11].

Research in other specialties has revealed a number of features of residency training that contribute to resident stress[1-4,6,12-15]. Factors that increase the risk of dysfunction and those that protect against toxic stress reactions have also been identified[1,3,13] (Table I).

In light of the recognized negative impact of the aforementioned stressors, we hypothesized that orthopaedic residents are at high risk of burnout, psychiatric morbidity, and a diminished quality of life. In addition, we hypothesized that the increased autonomy, financial compensation and security, and sense of clinical competency and responsibility attained by practicing academic orthopaedic surgeons would render them less susceptible to burnout and psychiatric morbidity and would afford them an improved quality of life. Our goals in conducting this study were to determine the quality of life of current orthopaedic residents and faculty and to identify risk factors for decompensation.

Materials and Methods

Participants

Our primary study group was composed of twenty-one orthopaedic surgery residents from a large university training program. The second study group consisted of twenty-five full-time orthopaedic surgery faculty members from two institutions; sixteen were at the same large university training program, and nine were at a second large university training program. Upon review and approval of our project by the institutional review boards of our participating institutions, each study group was surveyed in a voluntary, anonymous fashion. Each participant received a random code number, records of which are confidentially maintained by the study administrator.

Survey Instrument

Participants completed a 102-question survey consisting of six sections:

- Background and demographic information.
- Job satisfaction, assessed with use of the Maslach Burnout Inventory (twenty-two questions), a validated and accepted instrument[9]. It consists of three subscales: nine items measuring emotional exhaustion, i.e., a drained, depleted feeling arising because of excessive psychological and emotional demands; five items assessing depersonalization, i.e., the tendency to view others in an excessively detached, impersonal, even cynical manner; and eight items appraising personal achievement, i.e., a sense of competence and accomplishment. Maslach Burnout Inventory norms for medical workers were developed from the responses of a sample of 1104 American doctors and nurses[9]. Scores are compiled for each subscale and are categorized by thirds in accordance with the normative distribution[9]. Emotional exhaustion and depersonalization correlate with burnout, while personal achievement is inversely proportional to burnout[9].
- Psychiatric morbidity, assessed with use of the General Health Questionnaire-12, a validated, widely used mental disorder screening instrument that has been translated into

TABLE I Residency Stressors and Factors

Residency Stressors	Risk Factors for Distress	Protective Factors
Financial pressures[1,3,12]	Personal psychiatric history[3]	Camaraderie with peers[3,13]
Heavy work and call schedules[4,14]	Family psychiatric history[3]	Sense of clinical competency[1]
Lack of free time[3,13]	Inadequate support systems[1]	Helpful social support systems[1]
Daily microstressors[1]*	Length of residency training[1]	Clinical responsibility[1]
Harassment[15]	Female gender[1,3]†	
Sleep deprivation[2,3,4,12]		

*Frustrating, daily hassles encountered in the health-care workplace[1]. †Studies assessing the impact of gender on stress levels of residents yield conflicting results. Female gender has been associated with higher reported levels of stress; however, studies have disagreed about whether female residents actually experience more emotional distress or dysfunction[1,3].

TABLE II Background and Demographic Data

	Resident Group (N = 21)	Faculty Group† (N = 25)
Age* *(yr)*	30 (28-34)	45 (32-66)
No. *(%)* of subjects who were female	3 (14)	1 (4)
No. *(%)* of subjects who were married or in a committed relationship	16 (76)	21 (84)
No. *(%)* of subjects who were single	5 (24)	3 (12)
No. *(%)* of subjects who were divorced	0 (0)	1 (4)
No. *(%)* of subjects with a physician father	7 (33)	9 (36)
No. *(%)* of subjects with a physician mother	1 (5)	1 (4)
Work hours per week*	88 (70-120)	70 (40-105)
Debt anticipated at completion of training*	$76,000-$100,000 (0->$150,000)	NR

*The values are given as the average, with the range in parentheses. †NR = not reported.

eleven languages and used in more than fifteen countries[16]. It has been found to be a highly reliable indicator of depression, social dysfunction, anxiety, and somatic symptoms[12]. The twelve items are symptoms of psychiatric morbidity that receive a score of 0 or 1 on the basis of the frequency with which the subject has experienced the symptom in the recent past, yielding a maximum score of 12[17]. Scores of 4 or higher have been shown to be indicative of substantial psychiatric morbidity[17].

- Stressful aspects of life and work, assessed with use of twenty-three items specifically designed for this instrument. Included were questions identifying specific stressors (e.g., sleep deprivation, financial concerns, and relationships with staff) as well as questions regarding perceptions of harassment, discrimination, and overall life and career satisfaction.
- Responses to stress, with use of eighteen novel questions related to self-care and stress management strategies.
- Relationship issues encountered by married participants and those in ongoing committed relationships, assessed with use of the Revised Dyadic Adjustment Scale (fourteen questions) and self-reported descriptions of the balance between work and home life (fifteen questions). The Revised Dyadic Adjustment Scale is a validated instrument assessing marital adjustment on a 69-point scale[18]. In the Revised Dyadic Adjustment Scale format, "adjustment" is considered a neutral term that refers to the quality of the relationship as determined by the individual[18]. In the normative data for the scale, the mean score (and standard deviation) for couples who scored in the not-distressed range was 52.3 ± 6.6, while the mean score for those in the distressed range was 41.6 ± 8.2; a score of ≤ 46 is considered to reflect a distressed relationship[18]. In addition, fifteen questions pertaining to the balance between work and home life were adapted from the work of Geurts et al., who evaluated work-home interference as a "critical mediating pathway in the relationship between work and home characteristics and work-related and general psychological health indicators."[6]

Statistical Analysis

Statistical analysis was performed on all completed questionnaires. Descriptive statistics and pairwise correlations were calculated. The simple correlation coefficient was used to estimate the strength and to test the significance of bivariate relationships. The Pearson and nonparametric Spearman correlations were calculated, and similar results were obtained with use of the two methods. Pearson correlation coefficients are presented for consistency. Simple t tests were used to compare mean responses on standardized scales. Differences generating p values of <0.05 were considered significant, while those generating p values between 0.05 and 0.1 were considered to suggest a trend.

Results

The first five sections of forty-six questionnaires (twenty-one from residents and twenty-five from faculty) were completed and analyzed. In addition, thirty-seven subjects (sixteen residents and twenty-one faculty) who reported that they were married or involved in an ongoing committed relationship completed section six of our survey, and these results were also analyzed for data pertaining to relationship issues. The decision to include the relationship data from nonmarried subjects who reported ongoing committed relationships as well as from married persons is supported by the fact that only one-quarter of American households consist of what most people think of as a traditional family: a married couple and their children[19]. Furthermore, cohabitors are at least as likely as individuals in their first marriage to remain together after five years[20,21].

Background and demographic results are reported in Table II.

Job Satisfaction: The Maslach Burnout Inventory

In comparison with the norms for American health-care workers[7], the resi-

TABLE III Burnout Subscales

	Norms*†	Faculty†	Residents†	P Value‡
Emotional exhaustion	22 ± 9.5	16.6 ± 9.5	27.7 ± 9.7	<0.0003
Depersonalization	7.1 ± 5.22	6.6 ± 5.1	15.1 ± 6.3	<0.0001
Personal achievement	36.5 ± 7.3	42.8 ± 4.4	36.3 ± 5.3	<0.0001

*Based on a study of 1104 doctors and nurses[9]. †The values are given as the mean and the standard deviation. ‡The differences between the groups were assessed for significance with use of the t test.

dent group showed high levels of burnout, scoring in the upper third for emotional exhaustion and depersonalization and in the middle third for personal achievement. In contrast, the faculty group showed low levels of burnout, scoring in the lower third for emotional exhaustion, the middle third for depersonalization, and the upper third for personal achievement (Table III).

Psychiatric Morbidity

Seven residents (33%) and two faculty members (8%) had a score of ≥4 (range, 4 to 7) on the General Health Questionnaire-12, indicating significant psychiatric morbidity ($p < 0.01$)[3].

Life and Work Stress

The average overall quality of life, as rated on a scale that ranged from 0 to 4 points, fell within the "moderately satisfying" range (mean, 2.5 points) for the resident group. By contrast, the faculty group rated their overall quality of life in the "very satisfying" to "extremely satisfying" range (mean, 3.6 points). Both groups rated the overall stress level of their work as "moderately stressful" (mean, 2.6 points for residents and 2.2 points for faculty); however, both groups unanimously reported that they would again choose to pursue a career in orthopaedic surgery.

Responses to Stress

All residents reported having faculty mentors; however, with use of a 0 to 3-point scale, the residents reported that their mentors were of "little help" or "no help" (mean, 0.9 point). Nine (36%) of twenty-five faculty participants reported having mentors and that talking with those mentors helped "a little" (mean, 1.6 points). Residents discussed concerns with their colleagues "quite a bit," whereas faculty did so "a little" (mean, 2.1 and 1.2 points, respectively). Both groups stated that they talked about their concerns with family, friends, and/or partners "quite a bit" (mean, 2.6 points for residents and 2.0 points for faculty).

With regard to self-care, neither group reported difficulty unplugging from work. Neither group reported that they used relaxation techniques or sought formal counseling to help to cope with stress. Both groups claimed that they drew on religion or faith in God "a little" (mean score, 1.2 points for residents and 1.7 points for faculty on a 0 to 3-point scale). Residents reported that they exercised an average of two and one-half times each month, while faculty reported exercising approximately four times each month. Both groups denied cigarette use and reported "a little" alcohol use (mean, 1.2 points for residents and 1.0 point for faculty).

Relationship Issues

Sixteen residents (76%) and twenty-one faculty members (84%) reported being married or in an ongoing committed relationship. Responses to relationship inquiries are scored on a 0 to 5-point scale with a maximum score of 70 points and with a score of <46 points indicating relationship distress. The majority of subjects from each group scored above the distressed range on the Revised Dyadic Adjustment Scale with regard to marital adjustment and satisfaction; the mean score (and standard deviation) was 49.7 ± 7.3 points (range, 38.0 to 62.0 points) for residents and 51.7 ± 6.6 points (range, 39.8 to 66.0 points) for faculty. However, three residents and six faculty members scored within the distressed range.

Residents reported, on the average, being "fairly satisfied" (mean, 5.3 points on a 1 to 6-point scale) with the overall quality of their marriage or relationship, whereas faculty reported being "extremely satisfied" (mean, 5.8 points). Both groups reported that work conflicted with family life "occasionally" (mean, 2.7 points for residents and 2.4 points for faculty on a 0 to 4-point scale).

The residents with a committed relationship reported that their spouses worked an average of 31.8 hours (range, zero to sixty hours) each week outside the home. The faculty members with a committed relationship reported that their spouses worked an average of twenty hours (range, zero to fifty hours) per week outside the home. Both groups reported spending an average of forty-five to ninety minutes alone and awake with their spouse on a typical workday. Neither group viewed the work schedules or commitments of their spouses as a substantial source of family stress. Additionally, both groups perceived that their spouses had more frequently made career sacrifices. Both groups perceived that their families paid attention to their feelings (mean, 1.9 points for each group on a 0 to 3-point scale) and appreciated the way that the subject handled his or her work "quite a bit" (mean, 1.6 points for residents and 1.8 points for faculty members).

Regarding support outside their family or relationship, both groups reported that their colleagues and their colleagues' families were "a little" supportive (mean, 1.3 points for each group on a 0 to 3-point scale). However, the department was perceived by both groups as being "not at all" helpful in facilitating their spouses' adjustment (mean, 0.5 point for residents and 0.6 point for faculty). In fact, potential efforts by the department to assist the spouse in understanding the work stress of the subjects were predicted by the residents to be only "a little" helpful (mean, 0.8 point, on a scale of 0 to 1 point), while the faculty predicted that these efforts would help "not at all" (mean, 0.4 point).

Finally, the resident group rated the overall balance between work and home life as "somewhat satisfying" (mean, 4.1 on a scale of 1 to 6 points), while the faculty rated the balance as "fairly satisfying" (mean, 4.6 points).

Positive Correlations

The Pearson and nonparametric Spearman correlations were calculated, and similar results were obtained with use of the two methods. The Pearson correlation coefficients are presented for consistency.

Burnout

Emotional Exhaustion

Among residents, high levels of emotional exhaustion were correlated with anxiety about clinical competence ($p < 0.02$; correlation coefficient, 0.50), increased conflict between work and home life ($p < 0.001$; correlation coefficient, 0.66), stress in relationships with faculty ($p < 0.01$; correlation coefficient, 0.51) and senior residents ($p < 0.07$; correlation coefficient, 0.41), and increased perceptions of work as stressful ($p < 0.002$; correlation coefficient, 0.62).

Among the faculty members, increased emotional exhaustion correlated with anxiety regarding clinical competence ($p < 0.002$; correlation coefficient, 0.57), worry about the future because of the number of orthopaedic surgeons in the field ($p < 0.02$; correlation coefficient, 0.23), stress in relationships with other faculty ($p < 0.003$; correlation coefficient, 0.63), financial concerns ($p < 0.02$; correlation coefficient, 0.45), increased perception of work as stressful ($p < 0.006$; correlation coefficient, 0.53), and increased conflict between work and home life ($p < 0.08$; correlation coefficient, 0.35).

Emotional exhaustion tended to be reduced by increased time alone with their spouse ($p < 0.09$; correlation coefficient, –0.41) in the resident group and by increased perception of support from colleagues and colleagues' families ($p < 0.06$; correlation coefficient, –0.39) in the faculty group.

Depersonalization

For residents, as their reported number of work hours increased, so did their score on the burnout subscale for depersonalization ($p < 0.01$; correlation coefficient, 0.55). The opposite pattern was observed with faculty. As their work hours increased, faculty members had decreased levels of depersonalization ($p < 0.02$; correlation coefficient, –0.44). Stress in relationships with nursing staff correlated with increased depersonalization in residents ($p < 0.039$; correlation coefficient, 0.46) and faculty ($p < 0.03$; correlation coefficient, 0.43). For residents, increases in anticipated debt load at the completion of training ($p < 0.001$; correlation coefficient, 0.66) increased the level of depersonalization. For faculty, higher scores were correlated with increased alcohol use ($p < 0.02$; correlation coefficient, 0.47) and greater levels of concern regarding alcohol and drug abuse ($p < 0.007$; correlation coefficient, 0.53).

For residents, having a father who is a physician correlated with lower ratings on emotional exhaustion ($p < 0.05$; correlation coefficient, –0.42) and depersonalization ($p < 0.04$; correlation coefficient, –0.46). Among faculty, the levels of depersonalization decreased as the number of children they had increased ($p < 0.07$; correlation coefficient –0.38). Depersonalization scores also were lower among faculty members who reported a better quality relationship with their mother ($p < 0.07$; correlation coefficient, –0.37).

Personal Achievement

For residents, being a parent was found to correlate with increased scores on personal achievement ($p < 0.05$; correlation coefficient, 0.47). The scores on personal achievement also increased as satisfaction from talking with colleagues informally increased ($p < 0.05$; correlation coefficient, 0.43) or as satisfaction from talking with friends and family about concerns increased ($p < 0.007$; correlation coefficient, 0.58).

The levels of personal achievement among faculty members correlated with their ratings of the overall quality of their marriage ($p < 0.04$; correlation coefficient, 0.41) and overall work-family balance ($p < 0.05$; correlation coefficient, 0.39). Surprisingly, for faculty, the personal achievement level increased as the number of hours that his or her spouse worked outside the home each week increased ($p < 0.002$; correlation coefficient, 0.58).

Psychiatric Morbidity

Among residents, increased stress in relationships with senior residents correlated with increased scores on the General Health Questionnaire-12 ($p < 0.04$; correlation coefficient, 0.45) indicating psychiatric morbidity, whereas satisfaction from speaking with a mentor was associated with decreased scores ($p < 0.02$; correlation coefficient, –0.48). For faculty, increased General Health Questionnaire-12 scores were found to correlate with increased levels of worry about the number of orthopaedic surgeons in the field ($p < 0.0004$; correlation coefficient, 0.67).

Relationship Issues and Conflict Between Work and Home Life

In the resident group, increased conflict between work and home life was found to correlate with increased levels of emotional exhaustion ($p < 0.001$; correlation coefficient, 0.66), General Health Questionnaire-12 scores ($p < 0.0075$; correlation coefficient, 0.57), and depersonalization ($p < 0.01$; correlation coefficient, 0.54).

As faculty made more time for hobbies, their emotional exhaustion levels diminished ($p < 0.04$; correlation coefficient, –0.41), personal achievement levels increased ($p < 0.03$; correlation coefficient, 0.44), and psychiatric morbidity (General Health Questionnaire-12) levels declined ($p < 0.07$; correlation coefficient, –0.37).

Discussion

This study is the first, as far as we know, to examine job stress and satisfaction and the psychological and social functioning of orthopaedic residents and faculty. Our study group was small and included residents from only one institution, so it is difficult to generalize our results. Our results showed a great disparity in burnout and psychiatric morbidity between the resident group and the faculty group. Whether this variance arises from generational differences or stage of career development cannot be determined from these results alone. Age may influence the vulnerability to burnout. In a study by Campbell et al. that surveyed 582 practicing surgeons, substantially higher levels of burnout were identified in younger surgeons[8]. Longitudinal follow-up of this population is planned to evaluate the changes over time; furthermore, we hope to expand the current study to include other orthopaedic residency programs as well as orthopaedic surgeons in private practice in an effort to fortify our findings.

Our results revealed a substantial level of burnout in this resident population, with scores in the upper third on both emotional exhaustion and depersonalization. These results reflect a tendency toward cynicism and a view of patients as inanimate objects by doctors who feel overwhelmed, drained, and depleted[9]. An average level of personal achievement was maintained in this population; however, a study by Schaufeli and van Dierendonck supported a two-dimensional conception of burnout including only emotional exhaustion and depersonalization[22]. Thus, the preservation of an average level of personal achievement may not temper the resident burnout level to any substantial degree. Indeed, despite maintaining a reasonable sense of personal accomplishment, the respondents who showed greater levels of burnout also reported increased levels of anxiety concerning their own clinical competence.

Other factors associated with burnout among the residents in our study included increases in work hours per week; conflict between work and home life; stress in relationships with faculty, nursing staff, and senior residents; debt load; and perceptions of work as stressful. Protective factors included being a parent, spending more time alone with a spouse, having a father who is or was a physician, and deriving greater satisfaction from speaking about concerns with colleagues, friends, and family.

The faculty group, by contrast, showed low levels of burnout, scoring below average for emotional exhaustion, within the average range for depersonalization, and above average for personal achievement. These findings contradict those of Campbell et al., who noted that orthopaedists are more likely than other surgeons to suffer from high degrees of burnout, particularly on the subscale of depersonalization[8]. It is tempting to attribute the low level of burnout in the faculty group to practicing in an academic setting; however, Campbell et al. also investigated the impact of caseload, practice setting, and percentage of the patient population covered by health maintenance organizations but found no correlation between these practice characteristics and the prevalence or degree of burnout[8].

Factors associated with burnout among the faculty members in our study included increases in anxiety with regard to clinical competence, worry about the future because of the growing supply of orthopaedic surgeons, stress in relationships with other faculty, financial concerns, perceptions of work as stressful, alcohol use, concerns with regard to drug and/or alcohol abuse, and conflict between work and home life. Protective factors included increases in the number of children, spouse's work hours per week, perceptions of support from colleagues and colleagues' families, overall quality of the marriage or relationship, and time spent on hobbies.

Residents showed high levels of psychiatric morbidity, as assessed by the General Health Questionnaire-12, in comparison with the faculty group. However, the finding of significant psychiatric abnormalities in one-third of our resident group is similar to levels reported among other resident groups[3]. In a 1991 study of anesthesia, pediatric, and psychiatry residents at Jefferson Medical College, Samuel et al. reported that the prevalence of psychiatric morbidity, as assessed by the Beck Depression Inventory, was only 17%[23]. However, they suspected that symptoms were underreported because of participant statements questioning the anonymity of the study or revealing a belief that "it was best to always present themselves in a positive light for fear of a negative performance evaluation."[23]

The finding of similar levels of psychiatric morbidity in other resident populations is not intended to diminish the importance of such dysfunction occurring in one-third of the resident group in the present study. It does, however, lend support to the idea that such a dysfunction is a consequence of residency, as a construct, rather than an isolated outcome for a particular group of trainees in a particular program. Indeed, the low prevalence of psychiatric morbidity found in our faculty group (8%) suggests that, beyond the training period, orthopaedic surgery may even be associated with a decreased prevalence of psychiatric dysfunction in comparison with that among physicians in other specialties[7,8]. The frequency of positive feedback from patients and their families, the relative reliability of good and excellent outcomes of orthopaedic procedures, and the current high income potential for orthopaedic surgeons may help to protect job satisfaction and reduce mood disorders. In fact, the sole factor correlating with psychiatric morbidity in our faculty group was a perception of increasing numbers of practicing orthopaedic surgeons. It is of interest that only the few faculty physicians who reported depression and anxiety also reported anxiety-provoking situations such as a hostile marketplace. This finding suggests that it is the concern about competition that may be associated with psychiatric dysfunction in some individuals.

The disparity in burnout and psychiatric morbidity between orthopaedic residents and the faculty who teach them may arise from the contrasting levels of control and autonomy experienced by the two groups. The demand-control-support model of the impact of work characteristics on psychological health is predicated on the notion that jobs with high psychological demands, minimal autonomy, and low levels of support from superiors are associated with a higher prevalence of psychological health complaints[6]. This model is supported by extensive research in industry, a few studies of health-care professionals, and one study of 166 medical residents in the Netherlands[6]. It is widely recognized that resident physicians are subject to high demands and afforded little discretion over their work content or schedules[3,6,7,13,14,21]. Although our instrument did not specifically address autonomy and control, our results revealed that difficult relationships with faculty and senior residents correlated with increased levels of emotional exhaustion and psychiatric morbidity among junior residents. Additionally, having a physician father correlated with a decreased level of burnout among residents possibly because of enhanced perceptions of support.

Inflated financial pressures on current residents may also contribute to the observed differences in quality of life and burnout between residents and faculty. Increased anticipated debt at the completion of training correlated strongly with increased depersonalization among our resident group. The faculty population is not immune to financial stressors, but they are afforded some protection by their substantially higher income level. In addition, debt load at the completion of training has dramatically increased in the recent past[1,3,12]. Furthermore, while salaries have increased over the past two decades, purchasing power (in 1967 dollars) has decreased[1-3,24]. It has been estimated that comfortably paying off a debt of $75,000 would require a salary of $140,000 per year[24]. Our resident population reported a mean debt of greater than $75,000, yet their current average salary is under $40,000 per year.

On a positive note, the majority of resident and faculty marriages and relationships appeared to be doing well. This finding suggests that, despite their current levels of stress and emotional dysfunction, these residents had in general maintained the ability to sustain an intimate, rewarding personal relationship. It is of concern, however, that the marriages or relationships of almost one in five residents and more than one in four faculty members scored within the distressed range. It is of note that this was the only negative parameter in which the faculty group scored higher than the resident group.

Our results concerning the current quality of life and psychological well-being of orthopaedic residents raised the question of appropriate intervention. Compared with other specialties, surgical residencies offer the fewest supports[3]. In a study of the anesthesia, pediatric, and psychiatry residents at Jefferson Medical College, Samuel et al. reported that 80% of the residents were interested in support groups for themselves or their spouses and that 30% to 60% of the residents were interested in individual counseling or psychotherapy[23].

The ideal intervention would improve resident quality of life and psychological well-being without detracting from the quality of the education or the level of patient care. A limit on work hours per week has been shown to improve resident quality of life, increase reading time, increase in-training examination scores, and increase the volume of surgical cases per resident in a nonorthopaedic surgical training program[11]. Whether these benefits generalize to orthopaedic programs will become evident given the recent implementation of resident work-hour restrictions.

Alternate strategies for improving quality of life among residents include increased support mechanisms provided by the residency program, the incorporation of stress management and effective emotional management training into medical school and residency curricula, and the creation of national financial assistance for medical training[1,3,5,24,25]. Support mechanisms provided by some residency programs include formal or informal support groups and individual counseling; financial counseling to address loan repayment, tax preparation, and insurance issues; professional and career counseling; legal advisors to address malpractice and contract issues; spousal support to address both emotional adjustment and practical guidance for negotiating a new city; and even child care[3]. Our study did not assess the utilization of psychiatric services or resident assistance programs offered by the medical school, although neither group reported use of counseling in general. The current mentoring program, instituted with the intention of providing professional and emotional support to residents, matches each resident with a faculty mentor and requires biannual meetings. Unfortunately, our results demonstrated little perceived benefit to either residents or faculty. Our findings indicate that current program efforts to provide support are viewed as inadequate by the residents; however, our data also revealed low expectations of benefit from additional support efforts. Furthermore, evaluation of the impact of stress management training on burnout levels has indicated that associated benefits are transitory, expiring at approximately six months unless frequent refresher training is provided[25].

In conclusion, our data revealed high levels of burnout among surveyed orthopaedic residents, yet low levels among surveyed orthopaedic faculty. One-third of our population of residents reported symptoms of psychiatric morbidity. Factors decreasing the quality of life and increasing the emotional dysfunction among residents included workload, debt load, and difficult relationships with superiors. Current support strategies employed by the training program are perceived as insufficient or ineffectual. Faculty data obtained in this study suggested the possibility that low job satisfaction and quality-of-life assessments improve after the completion of training, at least among those engaged in full-time academic practice.

The primary deficit of this study was the small study population. It is hoped that our findings of high levels of burnout and psychiatric morbidity among orthopaedic residents will stimulate additional research in this area. Expansion of the subject group to include additional residency programs, incoming residents, and graduates is planned. In addition, creation of a Web-based survey instrument and a companion instrument to be completed by the physician's spouse or significant other is under consideration. Some alteration of the survey instrument may assist in eliciting variance within and between programs. Regarding mentorship, inquiry was limited to whether the subject had a mentor and whether speaking about concerns with that mentor helped the subject to cope with stress. An expanded inquiry might provide insight into the deficiencies of the current mentorship program. Inclusion of more items specifically related to residency and orthopaedics, as well as pre-training experiences and functioning, would assist in identifying protective resident characteristics as well as risk factors for decompensation. Such an instrument might enable a program to identify residents at risk and intervene preemptively.

Readministration of the questionnaire to the original population is planned in an effort to provide for longitudinal evaluation of variations in stressors and quality of life with progression through and beyond residency. Longitudinal information may also highlight indicators of the hardiness of residents and elucidate the characteristics that allow some residents to pass through residency unscathed while others founder. One of the primary strengths of this study is its provision of a benchmark against which to evaluate the impact of residency changes such as the recently implemnted resident work-hour initiative.

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Resident Burnout

Niku K. Thomas, MD

Intense work demands, limited control, and a high degree of work-home interference abound in residency training programs and should strongly predispose resident physicians to burnout as they do other health care professionals. This article reviews studies in the medical literature that address the level of burnout and associated personal and work factors, health and performance issues, and resources and interventions in residents. MEDLINE and PubMed databases were searched for peer-reviewed, English-language studies reporting primary data on burnout or dimensions of burnout among residents, published between 1983 and 2004, using combinations of the Medical Subject Heading terms *burnout, professional, emotional exhaustion, cynicism, depersonalization* and *internship and residency, housestaff, intern, resident*, or *physicians in training* and by examining reference lists of retrieved articles for relevant studies. A total of 15 heterogeneous articles on resident burnout were thus identified. The studies suggest that burnout levels are high among residents and may be associated with depression and problematic patient care. However, currently available data are insufficient to identify causal relationships and do not support using demographic or personality characteristics to identify at-risk residents. Moreover, given the heterogeneous nature and limitations of the available studies, as well as the importance of having rigorous data to understand and prevent resident burnout, large, prospective studies are needed.

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THE WELL-BEING OF INTERNS AND resident physicians is a hotly debated topic for which the importance,[1,2] implications,[1,3] and solutions[4,5] have all been questioned. Residency is a stressful, overwhelming period during which residents work long hours and during which the lives of others depend on residents as they increase their knowledge base exponentially. Resident physicians have tremendous responsibilities in the workplace yet may feel they control very little.[6] This arrangement sets the stage for residents to develop burnout.

Debate exists about whether residents' psychosocial distress has immediate or long-term consequences for patients, or for the physicians themselves.[1] Given the goals of residency training, some stress seems inevitable,[4] even favorable,[7] yet scattered studies suggest that residents experience high rates of burnout, a severe stress reaction, and that burnout may be associated with adverse mental health and work performance.

This article reviews studies of resident burnout in the medical literature to address the following questions: (1) What is the level of clinically significant burnout among residents? (2) What factors are associated with development of burnout? (3) What are the health and performance consequences for residents with burnout and their patients? and (4) What coping resources may help residents with burnout? The article concludes by suggesting areas for further research and reform.

For editorial comment see p 2913.

BURNOUT

Burnout is a pathological syndrome in which emotional depletion and maladaptive detachment develop in response to prolonged occupational stress. The construct was originally developed through occupational psychology research to describe a pattern observed among some human service workers.[8] Through serial qualitative surveys, field observations, interviews, and confirmatory factor analysis of the primary survey instrument, researchers have characterized burnout as a psychological construct and established its construct, discriminant, and convergent validity.[9]

According to Maslach et al,[9] burnout has 3 dimensions: emotional exhaustion, in which overwhelming work demands deplete the individual's energy; depersonalization and cynicism, in which the individual detaches from

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the job; and feelings of inefficacy, in which the individual perceives a lack of personal achievement. These dimensions can coexist in different degrees, making burnout a continuous, heterogeneous construct rather than a dichotomous one.

The 22-item Maslach Burnout Inventory (MBI) measures all 3 burnout dimensions through 7-point Likert scales indicating the frequency of characteristic symptoms and is the most commonly used measure in the medical literature; the inventory was designed for and validated among human service workers,[9] including residents.[10] Each dimension receives an MBI subscore, which, relative to normative scores for the work population, is categorized as low, medium, or high. A high subscore in emotional exhaustion or depersonalization is considered indicative of clinically significant burnout.[10] The MBI has become the gold standard for identifying burnout in the medical research literature.[11]

According to the demand-control-support model, occupational stress causes burnout when job demands are high while individual autonomy is low[11,12] and when job stress interferes with home life.[6,12,13] Work-home interference may mediate the effect of personal factors on burnout.[12] Considering that residents are routinely challenged with high demands, work-home interference, and low autonomy, the appearance, correlates, and consequences of burnout among residents would almost be expected.

METHODS

The MEDLINE and PubMed databases were searched for peer-reviewed primary data studies of burnout among residents published in the English language, using combinations of the following Medical Subject Heading terms: *burnout, professional*; *emotional exhaustion*; *cynicism*; or *depersonalization*; and *internship and residency*, *housestaff*, *intern*, *resident*, or *physicians in training*. Because the construct of burnout is relatively new since the 1980s and because residency programs have evolved in the past 20 years to adapt to the issues raised in the 1984 Libby Zion case,[14] the search was limited to articles published between January 1983 and September 2004.

This search yielded a total of 67 articles. Abstracts from this list were reviewed by the author and references were selected for retrieval if they were reports of primary data collection that specifically focused on burnout or the dimensions of burnout among residents. As some known references were missing from this database search, reference lists of these articles were then examined for other relevant studies. A total of 15 articles on resident burnout were thus identified. The FIGURE summarizes the search process.

RESULTS

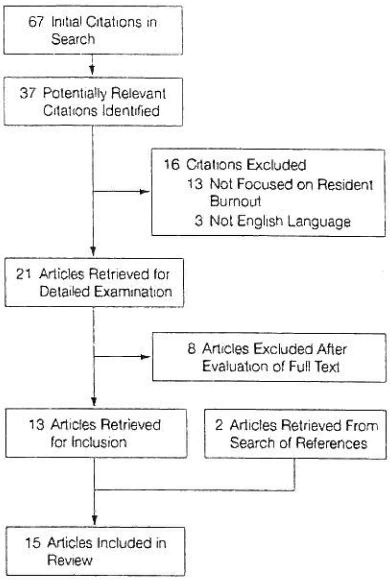
Most studies of burnout in residency were found to be small, cross-sectional surveys, designed to show numerous bivariate associations between burnout dimension scores and personal factors, work characteristics, mental health disorders, and job performance measures. Seven studies involved internal medicine residents, while the remaining studies examined burnout among residents in anesthesiology, surgery, orthopedic surgery, and family practice. Seven studies used a longitudinal design to examine the natural history of burnout or to assess the efficacy of a therapeutic intervention. TABLE 1 and TABLE 2 list the studies, their resident populations, measures of burnout, outcomes of interest, and significant findings. Because of the heterogeneous nature, methodological limitations, and overlapping information reported by these studies, these findings are reported qualitatively.

Prevalence of Resident Burnout

Eleven studies reported cross-sectional estimates of the levels of resident burnout; many have methodological issues that somewhat compromise their estimates.

Collier et al[15] conducted a national multispecialty survey in 1998, distributed to all residents by residency directors for the Resident Services Committee of the Association of Program Directors in Internal Medicine to identify personal factors associated with resident stress. Respondents indicated whether they thought they had become more or less cynical and humanistic. Although no formally validated burnout scale was administered, the study by Collier et al is included in this review in recognition that cynicism may be a precursor to emotional exhaustion or depersonalization.[8] In this sample, 61% of respondents reported having become more cynical and 23% less humanistic.[15] However, because the validity of these questions as burnout measures has not been established, these responses should be considered only hypothesis generating. Furthermore, although the study attempted to survey all US internal medicine residents, the very low response rate (18%) is well below the average response rate for physician surveys.[16] This compromises the generalizability of this study's findings because resident distress may have systematically influenced nonresponse.

Figure. Review Selection Process and Results



In a longitudinal survey of 78 multispecialty residents in Israel, Tzischin-

Table 1. Demographic and Methodological Characteristics of Studies Examining Burnout Dimensions Among Residents

Source	Original Sample Size	Period of Study	Resident Population	Study Design	Burnout Measure (Burnout Dimensions)	Covariates Measured
			Observational Studies			
Purdy et al,[19] 1987	71	1984	Ohio; 21% female; family practice	Cross-sectional questionnaires	MBI	Self-assessment item; faculty burnout ratings
Lemkau et al,[28] 1988	71	1984	Ohio; 21% female; family practice	Cross-sectional questionnaires	MBI	MCMI; MBTI; biographical questionnaire
Baldwin et al,[27] 1997	149	1986, 1993-1994	Scottish university class; 45% female; all specialties	Longitudinal interviews or questionnaires	"Feeling overwhelmed" on Attitudes to Work questionnaire (not validated for burnout)	Attitudes to Work questionnaire; recall frequency of mistakes; checklist of physical illnesses; General Health Questionnaire; attitudes to illness; alcohol consumption
Geurts et al,[6] 1999	293	NR	Netherlands academic hospital; 36% female; medicine	Cross-sectional questionnaire, stepwise regression analysis, structural equation modeling	MBI (EE, DP)	Work characteristic scale (work schedule, quantitative workload, mental workload, lack of job autonomy, dependence on superior), home characteristics scale, work-home interference scale
Tzischinsky et al,[17] 2001	78	NR	Israel; 32% women, medicine	Longitudinal questionnaire at baseline, 1 year, and 2 years; mood log and sleep actigraph monitoring at baseline, 6 mo, and 12 mo	MBI	Experience Sampling Method log of positive and negative moods and workload; Symptom Checklist-90; Job Involvement Questionnaire; Perceived Stress Scale; actigraph measures of sleep efficiency and duration
Collier et al,[15] 2002	22 933	1998	National US sample; 40% female; internal medicine	Cross-sectional questionnaire	Self-report more/less cynical and humanistic (not validated for burnout)	Any of 5 depressive symptoms, demographics, educational debt, moonlighting
Shanafelt et al,[5] 2002	151	2001	University of Washington; 53% female; medicine	Cross-sectional survey; multivariate logistic regression	MBI (EE, DP)	Self-reported frequency of suboptimal patient care practices* and attitudes†; PRIME-MD; AUDIT; demographics; stress attributions; career satisfaction
Daly and Willcock,[21] 2002	482	1998	New South Wales; all programs in region; medicine	Longitudinal survey at baseline, midyear	MBI	Primary and secondary alexithymia (coping style of emotional insensitivity, externally oriented thinking)
Michels et al,[20] 2003	350 At baseline, 203 eligible for follow-ups	June 1993-January 1996	South Carolina; 32% female; 7 family medicine programs	Longitudinal survey at baseline and every 6 mo	MBI	Beck Depression Inventory, Profile of Mood States, Hassles Survey, State-Trait anxiety and anger scales
Nyssen et al,[23] 2003	318 Faculty and residents	NR	Belgium University Network; 35% female; anesthetists	Cross-sectional questionnaire	MBI (EE)	PSSM-A; WOCCQ; problematic job situations and characteristics

(continued)

sky et al[17] noted that mean burnout scores increased from baseline to postgraduate year 1 but then decreased after 2 years, even as the perceived stress, also higher after year 1, remained high at 2 years. This characterization of the natural history of burnout is consistent with a previous finding that interns show progressively more fatigue and anger as the internship year progresses.[18]

Other studies have examined burnout among residents in a single specialty. In 1984, Purdy et al[19] measured the prevalence and recognition of significant resident burnout by administering the MBI and a single-item burnout self-assessment question to a cross-section of 67 family practice residents (response rate, 94%) at Wright State University, Dayton, Ohio. The residents' mean burnout scores were in the moderate range. In the study by Michels et al,[20] 350 family practice resi-

Table 1. Demographic and Methodological Characteristics of Studies Examining Burnout Dimensions Among Residents (cont)

Source	Original Sample Size	Period of Study	Resident Population	Study Design	Burnout Measure (Burnout Dimensions)	Covariates Measured
Observational Studies (cont)						
Biaggi et al,[22] 2003	66 residents, 26 attending physicians	December 2000 to March 2001	Spitalzentrum, Biel, and Zurich, Switzerland; medicine	Cross-sectional questionnaire; observation of work activities of 14 residents	Emotional exhaustion and aversion to clients subscales of Hacker and Reinhold's Stresses and Strains Screening in Human Services	Flanagan's Stressors questionnaire (importance of 31 aspects of work and satisfaction with those aspects); work-related stressors: estimated and measured work hours, experienced work intensity, "opportunities to have a say," autonomy (decision making and control), social support from superiors or fellow employees, "superiors interested in the well-being of employees"
Sargent et al,[24] 2004	21	NR	Single university training program; 14% female; orthopedics	Cross-sectional survey	MBI (EE, DP, PA)	Demographics, General Health Questionnaire 12 psychiatric morbidity, life and work stress questionnaire, responses to stress questionnaire, Revised Dyadic Adjustment Scale (relationship issues questionnaire)
Interventional Studies						
McCue and Sachs,[36] 1991	64	NR	Boston, Mass; medicine, pediatrics, and medicine-pediatrics residents	Experimental convenience sample, 43 in intervention group, 21 controls	MBI	Stress management workshop
Ospina-Kammerer and Figley,[37] 2003	24	NR	Southeast United States; 46% women; all years; family practice residents	Experimental convenience sample, 14 in intervention group, 10 controls	MBI (EE)	Respiratory One Method of stress reduction, 4 weekly sessions
Gelfand et al,[25] 2004	37	2003	University of California, Irvine; 11% female; all years; surgery residents	Longitudinal questionnaire and 2-wk daily work activity log; 1 wk before and 6 mo following 80-h workweek implementation	MBI (EE, DP, PA)	None

Abbreviations: AUDIT, Alcohol Use Disorders Identification Test; DP, depersonalization; EE, emotional exhaustion; MBI, Maslach Burnout Inventory; MBTI, Myers-Briggs Type Indicator; MCMI, Millon Clinical Multiaxial Inventory; NR, not reported; PA, personal accomplishment; PRIME-MD, Primary Care Evaluation of Mental Disorders; PSSM-A, Psychological State of Stress Measure; WOCCQ, Working Conditions and Control Questionnaire.

*For example, "I found myself discharging patients to make the service 'manageable' because the team was so busy."

†For example, "I paid little attention to the social or personal impact of an illness on a patient."

dents from 7 South Carolina residency programs completed the MBI during lunch conferences every 6 months between July 1993 and January 1996 and had higher mean depersonalization scores than normative samples but lower scores than the Ohio family practice residents. However, since these studies were conducted, the standard for identifying clinically significant burnout includes a score in the high range for emotional exhaustion or depersonalization.[10] For each dimension in the study by Purdy et al, the mean score was within 1 SD of the threshold for the high range, suggesting that at least 17% of residents scored within that range.

In 1998, Daly and Willcock[21] surveyed 482 first- and second-year medicine residents from all programs around New South Wales and found moderate average emotional exhaustion and high depersonalization among interns at midyear. In a study published in 1999 of 293 medicine residents in the Netherlands, Geurts et al[6] reported that these residents had mean scores in the moderate range for clinically significant burnout. In 2001, Shanafelt et al[5] mailed a survey assessing burnout and self-reported suboptimal patient care practices to 115 medicine residents (76% response rate) in a US residency program. They found that 76% of residents, regardless of postgraduate year, had high emotional exhaustion or depersonalization on the MBI. In a survey of 66 medicine residents in Zurich, Switzerland, between mid December 2000 and January 2001, Biaggi et al[22] found that 41% of residents met critical values for emotional exhaustion on the validated subscale of Hacker and Reinhold's Stresses and Strains Screening in

Table 2. Results of Studies Examining Burnout Among Residents

Source	Response Rate, %	Burnout Level	Statistically Significant Findings (*P*<.05)
		Observational Studies	
Purdy et al,[19] 1987	94	Mean EE, DP = moderate burnout	Residents had higher EE and DP than faculty Resident EE scores correlated with self-rated burnout and residency director's ratings in years 2 and 3 Excessive demands on time most often cited as cause of burnout
Lemkau et al,[28] 1988	94	Mean EE = 25 (SD, 7.3), mean DP = 12 (SD, 5.5)	Correlations: high EE with lower social support satisfaction, antisocial and paranoid personality types, positive perception-judging type, avoidant, dependent, passive-aggressive, schizotypal, borderline personalities, anxiety, somatoform, dysthymia, alcohol abuse, psychotic thinking, psychotic depression symptom disorders High DP with part-time or unemployed spouse, feeling-thinking type
Baldwin et al,[27] 1997	95	NR	Correlation between "feeling overwhelmed" and self-reported number of minor mistakes (*r* = 0.22), emergency admissions, times had to retrieve equipment, patient deaths
Geurts et al,[6] 1999	60	Mean EE = 14.2 (SD, 6.9); mean DP = 5.8 (SD, 3.2)	Work-time schedule, quantitative workload, and problematic dependency on superiors contributed to work-home interference High quantitative workload, problematic dependency on superiors, and work-home interference contributed to EE and DP Having a supportive home situation was protective against DP
Tzischinsky et al,[17] 2001	NR	Mean MBI at baseline = 2.31 (SD, 1.3); burnout increased from baseline to year 1 of residency but decreased after 2 years	Linear regression analysis: neither sleep duration nor departmental workload (derived from number of patients) predicted burnout
Collier et al,[15] 2002	18	23% Less humanistic, 61% more cynical (67% women, 56% men)	Residents with children reported increased humanism, decreased cynicism Correlation between cynicism and multiple depressive symptoms
Shanafelt et al,[5] 2002	76	76% Had high EE or DP; mean DP = 12.7, EE = 26.4, PA = 36.2	Statistically significant adjusted odds of burnout with >1 y between undergraduate and medical school, self-reported major depression, positive depression screen, negative career satisfaction, self reported suboptimal patient practices monthly/weekly (DP)
Daly and Willcock,[21] 2002	NR	Interns at midyear: moderate EE; high DP	Alexithymia at 6 mo correlated with EE (*r* = 0.2) Primary alexithymic personality style predicted high "burnout"
Michels et al,[20] 2003	(72-75)	Mean MBI scores, men: DP = 9.55, EE = 19.53; women: DP = 7.19, EE = 18.86	Men, whites, and third-year residents had higher DP than others Differences worsened over time Men had higher DP than norms
Nyssen et al,[23] 2003	48	Median burnout = 27 (moderate)	"Work organization" most problematic work characteristic Negative correlation between stress and control
Biaggi et al,[22] 2003	87	41% With "critical values" for emotional exhaustion; one third reported aversion to patients	Greatest importance/satisfaction deficits: time off, future career prospects, clear management, adequate feedback on personal performance, a right to a voice in important matters, culture of openness and tolerance, good salary, flexible work hours, time autonomy, opportunities for learning Work intensity: high in 69% of residents, "too high" in 3%; one third felt overburdened by the workload often or most of the time
Sargent et al,[24] 2004	100	Mean EE and DP high	EE: anxiety about clinical competence, increased work-home, stress in relationships with faculty and senior residents, and perceptions of work as stressful DP: increased number of hours worked, stress in relationships with nurses, anticipated postresidency financial debt
		Interventional Studies	
McCue and Sachs,[36] 1991	NR	NR	MBI scores decreased 6 wk after intervention
Ospina-Kammerer and Figley,[37] 2003	NR	NR	Mean EE decreased after intervention
Gelfand et al,[25] 2004	69	Baseline: 50% high EE, 56% high DP; 6 mo: 47% EE, 70% DP	No significant reduction in mean burnout despite significant reduction in mean weekly work hours (100.7 h to 82.6 h)

Abbreviations: DP, depersonalization; EE, emotional exhaustion; MBI, Maslach Burnout Inventory; NR, not reported; PA, personal accomplishment.

Human Services, and one third of residents reported "aversion to patients."

In 2003, Nyssen et al[23] administered the emotional exhaustion MBI subscale to 119 anesthesiology residents (response rate, 48%) at various levels of training in the Belgium University Network. Reporting their burnout distribution by age rather than training level, the authors noted that 47% of anesthetists younger than 30 years had high emotional exhaustion subscores on the MBI.

In a survey of 21 orthopedic surgery residents from a single US university identifying social and work factors associated with burnout, Sargent et al[24] found that average emotional exhaustion and depersonalization scores were within the high range. Similarly, in a recent longitudinal study of 37 general surgery residents from all years affiliated with the University of California, Irvine, who completed the MBI and kept daily diaries recording their work activities for 2 weeks (69% response rate at baseline), 50% of surgery residents had high emotional exhaustion and 56% had high depersonalization.[25]

Although it appears that burnout may be higher among surgical residents than among medicine residents, the limitations of these studies, including differences in sample size, survey instruments, and statistical reporting, make these comparisons tenuous. Additionally, the international extrapolation of these prevalence estimates is limited by cross-cultural variation in work environment.

Resident Burnout and Work Characteristics

Residents' perceptions of and reactions to the stress produced by work characteristics may vary, predisposing them differentially to burnout. The literature on burnout in other health care professions (eg, attending physicians,[12] nurses[26]) has explored prospectively the interactive roles of work intensity, work demands, and work control in triggering burnout, but data on this issue are limited for residents.

Three studies had residents name factors they found to be most stressful and 1 analyzed the association between these ratings and resident burnout status. When Purdy et al[19] asked Wright State University family practice residents what factors they believed contributed most to resident burnout, they most often cited time demands. In the report by Nyssen et al,[23] which descriptively explored stress, burnout, and residents' ratings of stressful work characteristics, anesthesia residents also reported as commonly problematic a lack of control over time management as well as work planning, work organization, inherently difficult job situations, and interpersonal relationship conflicts.

Biaggi et al[22] also specifically explored the relationship between emotional exhaustion and depersonalization, work stressors, and residents' assessment of the relative importance of work stressors and resources. One third of the medicine residents felt overburdened by the workload often or most of the time and 69% rated their work intensity as "high" ("too high" in 3%). The work characteristics rated with the greatest deficit between their importance and residents' level of satisfaction included time off, flexible working hours, autonomy with regard to managing one's own time, opportunities for learning, future career prospects, clear management, adequate feedback on personal performance, a right to a voice in important matters, a culture of openness and tolerance, and a good salary.

These 3 studies did not report differences in problematic work situations ratings stratified by burnout category, however, so it is not possible to know whether residents with high burnout rated some work situations as more influential.

Other studies have attempted to explore the relationship between work characteristics and burnout, examining factors that may be components of a causal pathway. A stratified analysis by Shanafelt et al[5] found that medicine residents with high burnout were more likely than those without burnout to rate as major stressors feeling uncertain about their future and feeling that their personal needs were inconsequential, 2 subjective perceptions that may provide targets for personal and systemic interventions. Baldwin et al[27] reported associations between work perceptions and feeling overwhelmed in interviews and a mailed survey of 142 Scottish medical students during their first undergraduate year and their senior residency year. They noted that feeling overwhelmed was correlated with number of emergency admissions, having to retrieve equipment, and the number of patient deaths. Of note, feeling overwhelmed was not significantly correlated with long hours worked over the previous week or functioning less well at work. "Feeling overwhelmed at work" during postgraduate training, a predecessor and possible proxy for emotional exhaustion and depersonalization,[8] had emerged as a significant factor during factor analysis of the Attitudes to Work questionnaire. This subjective feeling of being overwhelmed, however, is rather elusive and likely multifactorial, not simply a factor of the number of hours worked or slept, and not necessarily indicative of high burnout.

In the linear regression analysis of the longitudinal study by Tzischinsky et al,[17] in which medicine residents' sleep-wake cycles were actigraphically monitored for 5 to 7 days at a time at baseline, 6 months, and 12 months and the MBI and a workload log were completed at baseline, 1 year, and 2 years, neither sleep duration nor departmental workload (number of patients) predicted burnout. Unfortunately, the authors did not specify the sampling methods used to select the residents surveyed or the days to record workload and sleep deprivation, raising the possibility that sleep data may inadvertently have been gathered during low-intensity work periods. Whereas burnout is chronic, workload can vary considerably, warranting a generalizability measure. Presumably, using random assignments could have minimized this problem. Although this finding must be viewed cautiously, it is notable that most quantitative measures of workload were not subjectively cited as significant stressors by residents in 3 other studies either.[19,27,28]

However, 2 studies did find an association between increasing work hours and workload with burnout. Using stepwise regression methods to analyze data from their Netherlands survey, Geurts et al[6] developed structural equation modeling to characterize the relative contributing and mediating roles of work and home characteristics. Five stepwise regression analyses revealed that work schedule, quantitative workload, and problematic dependency on superiors contributed to work-home interference, that the latter 3 also independently contributed to both emotional exhaustion and depersonalization, and that having a supportive home situation was protective against depersonalization. This model is similar to the findings of Linzer et al[12] among practicing physicians. Similarly, in the cross-sectional study of orthopedic residents by Sargent et al,[24] depersonalization was significantly associated with increased number of hours worked, conflict between work and home life, and stress in relationships with nurses. Similar to medicine residents,[5,6] emotional exhaustion in these orthopedic residents was associated with residents' anxiety about their clinical competence, conflict between work and home life, stress in relationships with faculty and senior residents, and perceptions of work as stressful.

Work hours, workload, and overwork may represent similar constructs. Although cross-cultural comparisons are difficult to make, 1 interpretation of these studies is that these time constraints as well as social conflict, which are common stressors in residency,[29] contribute to work-home interference, and that these stressors, along with feeling uncertain about the future and feeling that personal needs are inconsequential, lead to emotional exhaustion and depersonalization. Why some who are exposed to these conditions do not develop burnout remains unclear.

Resident Burnout and Demographic Factors

Some demographic and personality characteristics are presumed to be stable over time and are thought to precede the onset of burnout in residency. In these studies, however, few demographic factors seem to be associated with burnout in residents. Because women have a higher lifetime risk of developing depression,[30] it is reasonable to ask whether this increased risk extends to burnout as well. Contrary to expectation, however, none of these studies has demonstrated a higher risk or differential effect of burnout for women. In fact, 1 study suggests that men are at higher risk of burnout. However, these data are limited because only 4 of the 15 studies reported burnout by sex.

Collier et al[15] found that reporting high educational debt was associated with higher cynicism, whereas having children was associated with less self-reported cynicism. Of course, with its low response rate, the sample of Collier et al may overrepresent resident financial distress as well as emotional distress. In contrast, in the article by Lemkau et al,[28] which reports personality and demographic correlates for the small survey of Wright State University family practice residents,[19] no bivariate association was found between burnout and amount of financial debt, number of children, sex, marital status, availability of a confidant, or frequency of exercise. Rather, residents with high emotional exhaustion scores were less satisfied with their broadly defined social support systems, while those with high depersonalization scores more often had spouses who were not employed or were part-time employed (information not reported by Collier et al), somewhat consistent with the finding of Geurts et al. Of note, the study by Lemkau et al may have limited power to detect sex differences because of the very small number of women surveyed. Michels et al[20] reported an association between burnout and sex, in which men, white residents, and third-year residents had significantly higher depersonalization scores than others, and these differences increased with repeated measurements. There were very few nonwhites in the sample, however, limiting the generalizability of this finding. Shanafelt et al[5] also found no association with sex or marital status; to preserve anonymity, Shanafelt et al and Collier et al collected little other demographic information.

The cross-sectional nature of these data limit their interpretability because it is not possible to determine whether burnout is a consequence or a cause of social dissatisfaction, spousal employment decisions, childlessness, or even persistently high educational debt. Furthermore, as findings become credible through replication, the fact that these findings consistently replicate negative associations may support the hypothesis that demographic factors are not reliably associated with burnout among residents.

Resident Burnout and Personality Characteristics

As with many behavioral patterns, some investigators have questioned whether certain personality types predispose residents to burnout. The family practice resident survey by Purdy et al[19] and Lemkau et al[28] included the Millon Clinical Multiaxial Inventory of personality. Although obsessive personality traits have been believed to be adaptive for physicians,[31,32] in this cross section, obsessive traits did not relate to any burnout dimension (positively or negatively). Rather, avoidant, dependent, antisocial, and passive-aggressive traits were correlated with higher emotional exhaustion scores while narcissistic, histrionic, compulsive, and schizoid personality traits were not correlated with emotional exhaustion in unadjusted analysis. Some of the correlation coefficients were rather weak (range, 0.21-0.46), however, and the clinical significance of these associations may be overstated. Furthermore, as no adjusted analysis was performed, the contribution of possible confounders like social support cannot be assessed. Given the likelihood that personality type may influence social support from superiors, this unadjusted analysis is difficult to interpret.

Daly and Willcock[21] noted that an "alexithymic" personality style (inability to recognize or describe one's emotions) predicted high burnout. However, because burnout in this study was defined as high emotional exhaustion or low personal accomplishment (rather than depersonalization), their burnout measure is inconsistent with the validated definition.[10] Thus, the contribution of personality to burnout remains obscure.

Health and Performance Consequences of Resident Burnout

Burnout can coexist with depression, but causal relationships have not been established in the literature where longitudinal data are lacking. The studies that examined them together have found an association between burnout and depression. However, although 3 studies screened residents for both burnout and depressive symptoms, none addressed the relative timing of the 2 conditions.

In the studies reported by Purdy et al[19] and by Lemkau et al,[28] higher emotional exhaustion scores correlated with higher tendencies toward psychotic depression.[28] The measure of Baldwin et al,[27] "feeling overwhelmed at work," was modestly correlated with depression score on the General Health Questionnaire ($r=0.37$). Although their study was prospective, Baldwin et al analyzed feeling overwhelmed and depressive symptoms without reporting relative times of onset.

It is possible that the experience of emotional exhaustion and poor functioning may trigger a depressive episode. In the study by Shanafelt et al,[5] 90% of residents who screened positive for depression on the Primary Care Evaluation of Mental Disorders (PRIME-MD) also had high burnout scores at that single time point, while 51% of residents with burnout reported a history of major depression during residency and 31% screened positive for depression. Alternatively, depression may influence burnout. In one study (not reviewed here), the higher their depression score, the more stressful the interns rated the feeling of being overworked,[33] suggesting that depression may sensitize individuals and predispose them to extreme stress reactions. Moreover, depression and burnout may occur independently. According to 2 prospective studies that followed up depressive symptoms through 1 year, some interns felt progressively less overwhelmed and more competent,[34] while others showed progressively more fatigue and anger,[18] yet both studies reported more depression. The nature and direction of the association between depression and burnout for residents remain unclear.

Given the fact that burnout seems to be associated with adverse patient outcomes if it affects other health care workers,[26,35] the question of how resident burnout influences patient outcomes is compelling. In the study by Baldwin et al,[27] "feeling overwhelmed at work" was positively correlated with self-reported number of minor mistakes in the past month, without a significant correlation between General Health Questionnaire 12 score and number of mistakes. In a multivariate logistic regression analysis of data from the University of Washington cross-sectional study, medicine residents with high depersonalization were 8 times more likely to self-report monthly or weekly suboptimal patient practices and 4 times more likely to report suboptimal attitudes.[5] Even though residents who had taken time off before medical school had higher emotional exhaustion scores, they were 70% less likely to report suboptimal patient care practices, suggesting some kind of protective effect of time off prior to medical school on patient care. Unfortunately, self-reported performance measures may be subject to recall bias or selection bias. An objective measure of error would be useful, as would prospective data examining whether poor patient care precedes and predisposes to burnout.

Resources and Interventions for Residents With Burnout

Although some cross-sectional data have identified common coping practices for residents, the efficacy of these practices has not been established. To manage stress, about three fourths of the residents in the study by Shanafelt et al[5] rated talking with family, a significant other, or other residents as "significant" or "essential" strategies, while residents with burnout were more likely to give such ratings to physical exercise and "a survival attitude." In directly evaluating their programs' resources, residents rated as important having at least 4 days off per month, ancillary help, and a night float. Despite reporting feeling irrelevant and uncertain, residents with burnout were less likely to rate as important presentations on stress and depression, constructive feedback, and career counseling. Without studying the efficacy of these strategies for these residents, however, it is unclear whether differential selection of these coping strategies reflects a lack of resources for the distressed, the order in which residents call on resources as they become more distressed, or which strategies fail to protect residents from burnout.

Two studies investigated the role of stress management workshops for residents. McCue and Sachs[36] describe a 4-hour stress management workshop in which they trained 43 medicine, pediatrics, and medicine-pediatric residents from a teaching hospital in personal management, relationship, outlook, and stamina skills, and observed that emotional exhaustion scores declined somewhat 6 weeks later. Depersonalization and inefficacy scores worsened, however, as they did in the nonparticipating control group, suggesting that modifying the depersonalization dimension of burnout may be particularly challenging. Ospina-Kammerer and Figley[37] also recruited 24 family practice residents who were available to participate in 4 weekly seminars to learn stress reduction techniques. Following the intervention, mean MBI scores decreased in the intervention group. Both studies were small, possibly with limited generalizability. More concerning, however, is that intervention participants may have overrepresented older and more efficient residents, as only residents with enough free time to volunteer received the intervention and residents without free time were assigned to the control group. The small sample sizes also did not allow for efficacy to be analyzed by burnout severity. More randomized efficacy studies of stress management training workshops are needed.

Based on the findings of Geurts et al[6] and Sargent et al[24] that increasing work hours are associated with higher burnout, one might expect the mandatory work-hour restrictions to result in a reduction in depersonalization scores. However, this was not found to be the case in the longitudinal study by Gelfand et al,[25] which compared surgery residents' self-reported work hours and burnout scores 1 week before and 6 months after the 2003 implementation of the Accreditation Council for Graduate Medical Education's 80-hour workweek restriction.[25] Instead, although work hours decreased significantly because of a reduction in educational activity and home call hours, mean burnout scores did not; in fact, depersonalization increased from 56% to 70%. However, in this analysis, neither burnout scores nor work hours were analyzed by residency year, so a significant but small effect within a single residency year might not be discerned. Also, because the study by Tzischinsky et al[17] suggests that the natural history of resident burnout is to resolve after 2 years independent of persistently high stress, burnout at baseline might persist despite work-hour changes, whereas lower burnout rates might be observed in residents never exposed to the previous work-hour schedule. In addition, postrestriction burnout levels were measured during the winter months, when burnout may already be higher.[21]

COMMENT

The literature on resident burnout is still in the preliminary stages of mostly probing for associations in small samples. Because specialties other than internal medicine are represented by a single study each, it is premature to conclude that different findings reflect true differences between specialties. Still, these studies, each with its methodological limitations, seem to suggest that residents from various specialties, internationally, experience burnout. These studies also suggest associations between burnout and few demographic factors, a constellation of personality types, and, as with practicing physicians, work-home interference and problematic interactions; however, these associations mostly are documented as low-magnitude correlations or bivariate associations that occur within samples with questionable generalizability. The studies suggest that burnout is also associated with depression and problematic clinical performance, as burnout and depression often co-occur, and residents with probable burnout perceive that they are less competent and that they commit more medical errors and problematic patient care practices. However, although residents with burnout seem to question their own competence and performance more, there is no objective evidence that they actually perform more poorly than other residents. The paucity of longitudinal data are the main limitation of this area of research, and many questions remain to be addressed in carefully designed studies.

Understanding of resident burnout could be enhanced by more rigorous research,[38,39] such as studying large samples of residents in carefully planned prospective studies. The work characteristics that residents face are complex and vary by specialty, program, and postgraduate year, and a study designed to characterize burnout must be sufficiently large (or deliberately specific) and prospective to control for these variables and identify risk factors. Future prospective studies also could explore the temporal relationship between the onset of burnout and depression, suicidal ideation, poor clinical performance, substance abuse, career decisions, job turnover, and patient satisfaction. Health services research could explore the costs associated with these outcomes and the personal and fiscal benefits of interventions, work-hour restriction, or other reform policies.

Preventive structural reform may prove more effective than time-intensive stress management training, but more research is needed. Although the MBI is readily available for program directors to conduct prereform and postreform burnout assessments, few data on residents are available to guide residency directors in preventing, recognizing, and managing burnout. Although resident work hours and sleep deprivation are associated with stress and medical errors,[40] in the studies examined, sleep deprivation was not found to be associated with burnout, nor was restricting work hours alone associated with a reduction in burnout. Rather, the intensity of the resident's workday and the extent to which it interfered with the resident's home life was repeatedly associated with resident burnout. These studies suggest that residency programs might begin to improve resident well-being by restoring meaning to residents' time commitments, facilitating supportive social interactions, increasing resident work control, and promoting the separation of work and home life. Translating these qualitative concepts into practical strategies will be an important challenge.

Although empirical data examining the nature and consequences of resident burnout remain scant and heterogeneous, a call to study resident well-being on behalf of funding agencies is largely absent. With sufficient funding opportunities, essential research providing information about patient safety, physician retention, and physician health could be conducted.

CONCLUSION

Young physicians who readily embraced hard work in premedical and undergraduate medical education experience high levels of professional burnout in residency training years. Aside from working long hours, something about residency seems to leave many residents feeling emotionally exhausted and cynical and leaves some depressed and critical of their own patient care performance as well. Further research is needed to determine whether, in accordance with conventional burnout models, the resident who is allowed more work control, meaningful work demands, and better self-care can have better personal outcomes and ultimately provide better patient care.

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Dear Dr. Nasca:

I am writing on behalf of the Executive Committee of the Association of Academic Departments of Otolaryngology (AADO), the organization that has a membership comprised of the chairs of departments of Otolaryngology-Head and Neck Surgery throughout the United States and Canada. We support many of the recommendations presented in the December 2008 statement from the Institute of Medicine (IOM) but we want to express some concerns. While we agree with some of the IOM recommendations, we believe that other recommendations are not appropriate, easily applicable, or realistic for implementation in otolaryngology residency programs. Therefore we are now providing the ACGME with information in this letter that we intend to be helpful in the process of deciding what changes in otolaryngology residency programs will best be able to induce simultaneous improvement in patient safety and enhancement of the resident educational experience. Our comments and suggestions follow below:

Changes recommended by the IOM that we agree are needed.

- Sponsoring institutions should provide safe transportation options. However, we are aware that implementing this recommendation could present significant logistic challenges. And, we want to let the ACGME know that many otolaryngology residents take call from home now and many of these residents live nearby the institutions where they take call so that they do not necessarily have to drive home after being on call.
- Improving handovers and safety reporting. Importantly, we believe that the limitation in duty work hours has resulted in more handovers than previously had been occurring and many of us have noticed that lapses in communication during handovers seem to be more of a cause of patient errors than resident fatigue.
- Additional resources for implementation. We agree that there is a need for institutions – and third-party payers – to commit the financial resources that will enable departments of otolaryngology and residency programs to implement the recommended changes. Without adequate resources to enable implementation, the IOM recommendations will exist merely as an unattainable set of

pronouncements that could languish in the realm of abstract proselytizing commentary instead of being the impetus for prompt and needed realistic change.

- Monitoring and evaluation. We agree that it is worthwhile to gather information and monitor the effectiveness of training programs changes.
- Moonlighting. We agree with the concepts embodied in the IOM recommendations on moonlighting but this is already a standard in the current ACGME Common Program Requirements.

Changes recommended by the IOM that we suggest be reconsidered and changed:

1. **Workload adjustment**
We agree with the recommendation that residency programs need to fulfill their core educational mission by adjusting the workload of residents to maximize the time spent acquiring knowledge and gaining hands-on experience while keeping to a minimum the time that residents spend doing things that are of limited or no educational value. However, we want to let the ACGME know that most of the learning for otolaryngology residents now takes place in the outpatient clinic and in the operating room because most otolaryngology surgery is being done on an outpatient basis; therefore, there usually is a low otolaryngology inpatient census and management of the inpatient caseload is not usually an overly time consuming burden for residents. In addition, there is beginning to be a trend toward having hospitalist physicians and licensed mid-level providers co-manage the more complicated otolaryngology inpatients so this, too, is lessening the need for stringent requirements to limit the number of patients being managed by otolaryngology residents. Otolaryngology residents spend much of their on-call time actually on call, i.e. not involved in patient care and often not even in the hospital. In many otolaryngology programs, residents take call from their homes.

2. **Duty Hours**
Otolaryngology residency program directors earnestly have strived to implement all of the current ACGME residency program requirements including those pertaining to stringent limitation of duty hours. In implementing the changes, many otolaryngology department chairs have come to realize that some of the stringent duty hour rules seem to have been written in a way that applies to issues of concern primarily for the training of residents in general surgery or internal medicine who frequently are burdened with managing the care of large number of inpatients with multiple co-morbidities. Consequently, some aspects of the ACGME duty hour requirements currently in force and those now being proposed by the IOM seem to be somewhat incongruent with the pragmatic issues that arise on a day-to-day basis in the training of residents in otolaryngology. Furthermore, we believe that some of the recommended duty hour changes could result in increased frequency of hand-offs, and more need for cross-coverage, without any significant reduction in patient care errors. In saying this, we want the ACGME to understand that chairs of departments of otolaryngology and otolaryngology residency program directors collectively feel that we can modify current duty work hour rules and some of the new IOM recommendations in ways that would culminate in an overall plan for the training of otolaryngology residents that enhances patient safety while at the same time enables residents in otolaryngology to derive maximal educational benefit from their time spent in residency training. We strongly believe that the time has come for the individual Residency Review Committees (RRC) to work with leaders in each of the medical and surgical specialties recognized by the American Board of Medical Specialties to develop specific duty hour requirements that comply with the overall thrust of the IOM recommendations while, at the same time, are tailored to fit the aspects of residency training and patient safety that are distinctive to each of the medical and surgical specialties. For example, otolaryngology residents who are in a hospital or on call for a hospital can contribute significantly to securing the airway for patients manifesting signs of life threatening airway obstruction. We believe that otolaryngology residency program directors are the ones who are best able to develop the program requirements that will keep patients safe while assuring that residents gain the experience that they need to acquire in order to become facile with the management of patients who are having acute and severe upper airway obstruction. We believe that the lives of patients in teaching hospitals can depend on the availability of a resident to assist in securing an adequate airway while the lives

of patients in community hospitals can depend on the expertise and availability of young otolaryngologists who have recently completed residency training and who must have the experience, decision-making ability, confidence, and technical expertise that will enable them to act quickly to intervene in ways that assure the best possible outcomes for patients.

I. **Enhancing supervision**

- We are not sure what the IOM intends to happen as a result of the recommendation that "the ACGME should ensure that programs provide adequate, direct, onsite supervision for residents." We believe that the Joint Commission has already required that residency program directors specify the level of supervision needed for residents to do certain procedures.
- We do not understand exactly what the IOM means in the recommendation that "*first year residents not be on duty without having immediate access to a residency-approved supervisory physician in-house*" Could the "*residency-approved supervisory physician in-house*" be a more senior level resident, or is the IOM recommending that otolaryngologists holding full medical staff privileges now begin staying overnight in the hospital when a first year resident is on call? This recommendation, as written, seems to be illogical in certain ways. First, the recommendation links the need for supervision of an in-house physician to the post graduate year (PGY) level of training rather than to the measured competence of the resident and this seems inconsistent with the increasing focus on measured competence versus accumulated experience. Some residents acquire knowledge and skills at a more rapid pace than other residents and the safety of patients could be put at risk by letting a less competent PGY-2 or PGY3 resident manage an acute problem without the assistance of an in-house physician while requiring that there be an in-house physician ready at all times to assist a PGY-1 resident who has acquired much experience and demonstrated many competencies. This seems to be an artificial and potentially inappropriate approach that inherently is wasteful of resources. Graduated responsibility is essential to otolaryngology training programs so that the first person the PGY-1 would call would not be faculty but a senior resident. For otolaryngology, we feel that the IOM recommendation for enhancing supervision is inappropriate, needs more clarification and, as written, may have unintended adverse consequences.

In summary, while the Association of Academic Departments for Otolaryngology agrees with most of the recommendations made by the IOM, we believe strongly that some of the sweeping IOM recommendations as currently written are not workable or appropriate for otolaryngology residency programs. We strongly recommend that the ACGME develop a process for modifying existing program requirements and writing new requirements that seeks suggestions and involves some level of approval from the Otolaryngology Residency Review Committee, and key leaders in academic otolaryngology who have knowledge, relevant experience, and demonstrated long-term commitment to pursuing excellence in the education of otolaryngology residents. Certainly, the AADO, the Society of University Otolaryngologists, and the new Otolaryngology Program Directors Organization (OPDO) have extensive collective expertise and all of us are eager to assist the Otolaryngology RRC in developing new and improved requirements for residency training in otolaryngology-head and neck surgery.

Submitted respectfully, on behalf of the Executive Committee of the Association of Academic Departments of Otolaryngology (AADO),

Kenneth M. Grundfast, M.D. F.A.C.S.
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cc: Jo Shapiro, MD, President, Society of University Otolaryngologists
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AMERICAN ACADEMY
OF OPHTHALMOLOGY
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March 16, 2009

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Dear Dr. Nasca,

Thank you for your inquiry about the Institute of Medicine's (IOM) recent report entitled, "Resident Duty Hours: Enhancing Sleep, Supervision, and Safety." In response to this report, we have requested feedback from all Ophthalmology Residency Program Directors throughout the United States. Below is a summary of the concerns they have expressed about the new recommendations. In brief, Ophthalmology Program Directors fear unintended consequences of the IOM duty hour recommendations would include a reduction in the quality and continuity of patient care as well as a reduction in the educational, clinical, surgical, and research experiences a trainee could achieve during a three-year program.

Ophthalmology training programs are primarily ambulatory care training programs, often with at-home call. Patient care and resident education are inherently different in this setting compared with the typical inpatient environment. Due to these factors, Ophthalmology training programs are rarely in violation of the current duty hours requirements and the field is not one in which residents traditionally have been considered overworked or chronically fatigued.

The primary concern from Program Directors was the potential impact on both at-home and in-house call systems. Although a minority of Ophthalmology programs have in-house call, it is essential to those with Eye emergency rooms, most of which are now covered by Night Float Systems designed to provide adequate rest for residents. The recommendations of a 12-hour rest period after night float and 48 hours off after 3-4 consecutive night shifts would negatively impact patient care, resident education, and resident quality of life.

A specific example may illustrate this best. In one program, in-house call was replaced with a night float system when the ACGME duty hours were established. Six or seven times a year, the Night Float Resident covers 5 nights (Sunday – Thursday) from 6 pm to 8 am (14 hours). The resident has 10 hours off between duty shifts and enjoys Friday morning to Monday morning off (almost 72 hours). The call-system was designed by residents specifically to avoid 12 hours on and off, to prevent splitting the week of call, and to increase their overall and consecutive time off.

The new recommendations would require coverage by a "third minishift" from 6 am to 8 am, result in more patient hand-offs with potential for error, and limit the ability to schedule morning educational programs. Negatively impacting resident quality of life, the rules would require another resident to share night float each week and replace the 72 hours off with 48 hours instead.

The recommendation of five hours of uninterrupted sleep between 10:00 pm and 8:00 am would have the most effect on our specialty; however, it is unclear whether the five hours of uninterrupted sleep would apply to an at-home-call resident. If it does, many programs would need to split call to give the five hour free time to each resident. This would double the number of call nights for each resident and significantly complicate the transfer of patient care. It is unclear if this would improve the already good quality of life of Ophthalmology residents who would increase call nights in order to protect sleep time which may not have been a problem in their programs.

A relevant study performed at Washington University in 2006 (Ophthalmology 2006;113:889-90) showed that, even when Ophthalmology residents took in-house call, they averaged five hours of sleep. Interestingly, on average, residents slept five hours per night on-call but only six hours a night not on-call. Perhaps the sleep deprivation in this population is not a result of being on-call. Ideally, further sleep studies could document resident sleep patterns and the impact of duty rules. If problems exist, they may be due to behavior patterns of residents during time-off, not during time-on.

Program Directors also highlighted concerns about the impact on education and patient care. Residents learn about a disease process by following a patient through an entire course of events. This rule would make it impossible to have residents follow-through on patient care from the previous night. In turn, this would decrease the educational value of the consults and increase the potential for hand-off related errors. Most importantly, it would damage the patient-physician relationship and fracture continuity of care.

Finally, at a program and institutional level, such changes may necessitate the extension or expansion of our residency training programs, requiring significant additional funding.

Each training program has its own set of personnel and financial resources, its own tempo of clinical activity, and a unique educational environment. Although guidelines such as those proposed by the IOM are exceedingly well thought out and well intended, the level of detail in the IOM guidelines makes the proposal less generalizable across disciplines and training institutions.

The second major concern was the recommendation to increase the number of days residents must have off each month from four to five, with one 48-hour period off per month. Many Ophthalmology programs allow residents to operate on Friday and see their post-operative patients on Saturday morning for approximately one to two hours. To comply with the new recommendation, a different resident would have to see the one-day post-op patients or the programs would have to cancel Friday surgical days. This would impact negatively resident education and patient care.

Occasionally, programs have invited lectures or specific meetings on Saturdays to enable local ophthalmologists to participate and accommodate speakers. This could no longer occur and would diminish the resident learning experiences by not having access to these distinguished guests.

The third major concern identified was the IOM recommendation for greater supervision of residents by "experienced" physicians. All Ophthalmology programs have faculty available at all times for supervision as needed. Requiring faculty and fellows to take in-house call or to see every after hour's patient at the time of presentation, even if the problem is not emergent, is a level of activity that is greater than is clinically necessary. If a senior resident is not considered an "experienced physician" than this creates a major scheduling challenge that would probably require float rotations to account for required post-call absences. Many programs do not have sufficient personnel or financial resources to build float rotations and doing so is likely to increase operating expenses and reduce efficient use of personnel due to the low volume of patient care that occurs at night.

Another point raised by Ophthalmology Program Directors was that these recommendations may drive faculty away from academic medical centers because the work load will fall to faculty physicians who are already overworked and underpaid. Furthermore, Program Directors expressed concern that the proposed changes do not prepare trainees for practice after training. Residency is a time to learn how to balance work and life responsibilities, to recognize personal limits and the effect of fatigue, and to work with colleagues to rearrange clinic or OR schedules after a night of caring for a patient with an unexpected emergency in the hospital or for one's own sick child at home

For example, the new recommendation for counting external moonlighting would be very easy to implement. Most programs already discourage this activity. However, it is unclear how to justify curtailing external moonlighting without curtailing other extracurricular activity which could be arguably more strenuous or involve more hours. We suggest the more desirable approach to any extracurricular activity seems to be what we currently do: monitor for evidence of adverse impact on resident performance and when identified, search for underlying causes both internal and external and make system-based modifications that are specific for the medical discipline and for the training institution.

In summary, although the IOM recommendations may be of benefit in programs well-known for long work hours, applying them to all of medicine, particularly to fields such as Ophthalmology, which is primarily an outpatient based specialty, seems counter-productive and is likely to have serious adverse effects on both resident education and patient care. A differentiation in duty hours may need to be considered for inpatient based training programs versus outpatient based training programs, for home-call versus on-site or in-hospital call, and for night float systems already designed to provide residents with adequate rest periods.

We believe all programs should adhere to the current ACGME guidelines for resident duty hours and supervision. We understand that most Ophthalmology programs are well within the current duty hour requirements and residents rarely report chronic fatigue or lack of appropriate supervision, even after hours. When problems do exist, they are identified and carefully addressed and monitored by the ACGME. Therefore, we respectfully request that any new recommendations, incorporate resident feedback, be evidence-based, and allow fine tuning on a specialty-specific basis with continued ACGME monitoring and oversight.

Sincerely,

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April 28, 2009

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Dear Dr. Nasca,

Thank you for the opportunity to comment on the *Report on Resident Duty Hours*, issued by the Institute of Medicine in December 2008. The Executive Committees of the Society of University Urologists, the Society of Urology Chairpersons and Program Directors, and the American Urological Association have carefully deliberated the recommendations of the IOM and would like to make the following observations to the ACGME leadership.

The Society of University Urologists, the Society of Urology Chairpersons and Program Directors and the American Urological Association supports, in principle, the current role of the ACGME in regulating resident work hours and the specific duty hour standards which are currently in place. While we appreciate the thoughtful, data-driven approach utilized by the IOM to assess the impact of current duty hour standards, we feel their findings may not be applicable to the working environment of the typical urology resident. Consistent with our role as academicians and teachers, we believe that more prospective studies evaluating the impact of the current duty hour standards are needed before additional changes are made. We are willing to work with the ACGME to design and participate in such trials.

While our Societies do not have independent data to inform the current discussion on the cost of implementation of the IOM recommendations, we do believe that mandating these changes would cause severe disruptions in most of our urology training programs. The average urology training program is small and usually enrolls two or three residents per year in a four year program. Most residents in urology work about twelve hours per day, five days per week and take call from home once every third or fourth night. Most of our programs do not employ a "shift" staffing system as suggested by the IOM report. Implementation of these new regulations would seriously compromise the educational experiences of most urology training programs.

Specific concerns regarding the IOM recommendations include:

Maximum hours of work per week: We support maintaining the current standard of 80 hours per week, averaged over 8 weeks.

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Maximum shift length: We are concerned about this proposed regulation. While we recognize the reasoning behind the IOM recommendations to mandate a 5-hour protected sleep period, the practical implication of this recommendation would mean creating either a separate night shift rotation or never allowing a urology resident to take night call. Unlike busy general surgical or medical services, urology emergencies such as kidney stone colic, testicular torsion or minor trauma have been successfully managed for years by urology residents taking call either from home or in-hospital. While emergencies can and do happen, they are by definition unpredictable; residents are called some nights and not on others. Some urology training programs can and do use a night float when appropriate. For many other programs the new regulations would prohibit a resident from participating in regularly scheduled daytime activities if he or she received even one telephone call during the night should that call fall in the five hour window. Urology programs simply do not have the manpower to implement this mandate. Urology program directors would have the unfortunate task of compromising resident educational experiences and depriving residents of important lessons in continuity of care if they were forced to implement this mandate.

Maximum in-hospital on-call frequency: We believe that eliminating the latitude to average the on-call frequency and comply with a strict every third night requirement is excessively restrictive. In-house on-call experiences can range from busy sleepless nights to relatively quiet nights where residents receive adequate rest. It is currently the job of the program director to design rotations that balance the educational experiences of residents with service demands that could lead to excessive time on service. The ACGME already has regulations that prevent excessive in-hospital service periods.

Minimum time off between scheduled shifts: We support maintaining the current standard of a minimum of 10 hours between duty shifts. The proposed new standards requiring 10, 12, or 14-hour rest periods after different in-hospital service periods are complex to regulate and difficult to enforce. The administrative requirements to satisfy these regulations would divert already strained resources away from the educational program. We do support the recommendation that residents should not return to work before 6 AM after they go home from a day's work.

Maximum frequency of in-hospital night shifts: We support the 4 night maximum recommendation, but believe it will be rarely applied in most urology residency programs.

Mandatory time off duty: We support increasing the number of days off to 5 per month. Residents in most urology programs already have at least two weekends off or more per month. We do not support removing the flexibility which the current

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standards provide regarding averaging the number of days off during a 4 week period. Most urology residents prefer having 2 to 3 full weekends off per month versus working portions of several weekends per month. Furthermore, partial weekend call coverage would entail more frequent "hand-offs" that can compromise patient safety and continuity of care. Weekend call in many urology residencies can be relatively light with frequent rest periods. Flexible regulations allow program directors to design optimal rotation schedules that maximize educational experiences and time off from work. The standard as proposed appears to apply to all residents, regardless of whether the call is in-house or from home.

Moonlighting: We support the principle of including both internal and external moonlighting as counting toward the 80-hour work limit.

Limit on hours for exceptions: We support the plan to retain the current policy.

Emergency room limits: We support the plan to retain the current policy.

I hope these comments assist the Accreditation Council in their deliberations over developing potential new standards for Resident Duty Hours. We appreciate the opportunity to contribute to this important discussion and would be happy to participate in a Resident Duty Hours and Learning Environment Congress if asked.

Sincerely,

Peter C. Albertsen, MD
President, Society of University Urologists

Dennis Venable MD

Dennis Venable, MD
President, Society of Urology Chairpersons and Program Directors

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April 30, 2009

Thomas J. Nasca, MD, MACP
Chief Executive Officer
Accreditation Council for Graduate Medical Education
515 North State Street, Suite 2000
Chicago, IL 60654

Dear Dr. Nasca:

The Association of Pediatric Program Directors (APPD) respectfully submits its formal position paper "APPD Response to the IOM Recommendations on Resident Duty Hours", as requested by the ACGME. This paper was prepared by the APPD Board of Directors in consultation with the membership who participated via website comments, conference calls, action teams and at our Annual Meeting. A diversity of programs participated in this process from all parts of the country from large and small programs, and from university, community, and children's hospital residency training programs.

We would like to express not only our willingness to participate in the Resident Duty Hours and the Learning Environment Congress, but our belief that it is essential that we are present at this important event. Pediatrics is different from other specialties in many ways, and we believe that no other specialty can represent our perspective adequately. We hope that we will be honored with an invitation to participate in this next step in the ACGME's process for defining its response to the IOM recommendations.

Thank you for soliciting our input. We look forward to further dialogue regarding this important topic.

Sincerely,

Susan Guralnick

Susan Guralnick, MD
President, APPD

cc:
Gail McGuinness, MD, ABP
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Association of Pediatric Program Directors (APPD) Position Statement in Response to the IOM Recommendations on Resident Duty Hours

Prepared April 2009 by the APPD Board of Directors in consultation with the membership of the APPD (an organization consisting of over 2,200 educators within accredited pediatric training programs), who participated via website comments, conference calls, and action teams, as well as at our annual meeting.

EXECUTIVE SUMMARY

The APPD leadership and members have given significant thought and study to the IOM Committee's recommendations. We support the principles of patient safety and education of residents and fellows in an environment that fosters resident well-being and development of a sense of professional responsibility. We are concerned, however, that the recommendations of the IOM Committee are intended to enhance patient safety without appropriate consideration for the educational and professional development of trainees. Furthermore, we are concerned that by neglecting these other important aspects of residency training, implementation of the IOM Committee's recommendations may ultimately risk both the safety and well-being of patients and the achievement of competencies sought in graduate medical education.

The APPD supports improved monitoring of existing duty hours requirements, enhanced supervision where that is lacking, improvement of patient handover processes, and monitoring of moonlighting activities both within and external to the training program. Furthermore (as stated by the IOM report), any implementation without appropriate system support and resources could result in unintended negative effects which could threaten patient, resident, and workforce outcomes.

Thus, the APPD strongly believes that few components of the IOM Committee's recommendations can be implemented without sufficient funding, workforce requirements, and other resources. There are some recommendations that we believe should never be implemented. We support moving forward now with improved monitoring of existing duty hours, reporting, oversight, monitoring of moonlighting and other aspects of the recommendations as below. We encourage more study and piloting of resident schedules and educational programs intended to enhance patient safety and the outcome for resident and fellow education.

CURRENT STATE

The APPD reaffirms the principles of patient safety, resident education and well-being, and support of resources for graduate medical education. We agree that the current system has room for improvement in oversight, handovers, and education as suggested by some data and reports. While data on the 2003 Duty Hours effects on Pediatrics are mixed and somewhat limited, we believe that most programs have effectively implemented and adhere to duty hours. (RRC News for Pediatrics, 2007) Programs presently have some degree of flexibility within the required duty hours to work in different shift, float, and night call systems. It is difficult to assess graduate and educational outcomes from these changes. Some educators and faculty are concerned that there may have been a reduction in attainment of educational goals and professional attitudes of trainees. Although there has not been a clear degradation in competence and other outcomes, the studies are lacking.

Since the 2003 enactment of duty hours requirements, systems of care, funding, and institutional commitment to GME have not fundamentally changed. Overall resident stress has been reduced by some reports, but there are persistent major competing demands in patient care, continuity, and education. Faculty and administrative leadership also report these challenges. There was essentially no new funding for the 2003 ACGME Duty Hours, and most programs adapted with internal institutional funding and increased demands on other providers and faculty. Testimony at the IOM hearings on resident duty hours defined the significant costs to graduate medical education training institutions. Presentations by Opas, Noah, Liekweg and Daschbach describe costs of 2.17 to 4.34 million dollars per institution. Few programs have had funding to conduct research and many unmet needs for oversight and research regarding the impact of the required changes remain. Institutional, insurer, and federal funding for GME have not significantly expanded. Thus, there are several current challenges and "gaps" which are very likely to be exacerbated by additional restrictions and limits on resident scheduling.

AREAS OF CONCERN:

SUPERVISION AND AUTONOMY

Graded supervision is a delicate balance between increasing learner responsibility for patient care and the desire by society, faculty and institutions to provide optimal care for patients. The IOM report outlines the educational principles and referenced literature with which our group of program directors agrees. It is clear that all residents are different. Some residents need less direction after certain behaviors and practices have been observed and accomplished. Other residents, even into the PL-2 and PL-3 years, may not be ready for greater independence in their care of patients. Graded responsibility and progressive autonomy are important aspects of the development of competent and safe pediatricians. Tension exists for both program directors and faculty around the issue of what level of supervision is required for a given resident. Determination of the necessary level of supervision is based on a very complex set of decisions, and on observations of the individual resident and his/her past experiences and evaluations. Rather than relying on rigidly prescribed supervision requirements, it would be more beneficial to create a set of developmental milestones to attain. Such milestones should define specific, observable and well-defined actions/behaviors expected of a resident throughout their graduate pediatric training, consistent with the goals of the Milestones project.

The APPD recommends the following Action Items regarding supervision:

a. Develop a set of standards that defines:
    i. A reasonable framework of expectations for pediatric programs to evaluate learners in a developmental manner that will inform supervisors as to how individual residents should be supervised. This would go far beyond the artificial and rudimentary PL year, thus enhancing patient safety.
    ii. Supervisory roles/levels such that program directors can develop their faculty to know and function within this supervisory framework. Faculty development in supervision is needed.

THE LEARNING ENVIRONMENT

The APPD cannot emphasize strongly enough the importance of the resident learning climate. The constraints that are inherent in overly prescriptive duty hours may encourage superficial experiences, lack of continuity with patients, and a lack of a sense of responsibility for their care. The fragmentation of care that would be imposed by the detailed work hours recommended by the IOM Committee is the most concerning aspect of the Report. The overarching importance and pressing need for time for reflective learning, interaction with supervisors and meaningful interaction with patients as a touchstone for training and professional formation cannot be ignored. There must be adequate time during residency training to allow these experiences to occur. Individual programs should be held responsible for close and available supervision that allows and encourages learners to reflect on their strengths, weaknesses, interactions, decisions, and outcomes, and enables them to form therapeutic relationships with patients. ACGME requirements should address aspects of supervision rather than further defining duty hours.

Key issues regarding the learning environment:

- Recommended duty hours are not compatible with current care models in the inpatient setting.
- Frequent nighttime shifts will negatively impact time for Continuity Clinic, an important component of pediatric residency training.
- Programs will move to shifts to avoid the "5 hour nap".
- Training to achieve competency in pediatrics may need to be extended. If length of training is not extended there may be a shift toward increased inpatient assignments to address service needs, pulling residents away from important ambulatory educational experiences.
- Extended training length may result in fewer residents entering fellowship at a time when subspecialties are facing serious workforce issues.
- Newly recommended duty hours may negatively impact resident work-life balance, since their work schedule will frequently be out of synch with their family's schedule.
- Duty hour limits will make fewer residents available to attend teaching conferences.
- Faculty willingness to provide increased clinical and teaching time to match resident schedules will be a challenge.
- A redesign of training must assure that residents have adequate educational opportunities.
    - Less direct time with patients leads to less experience.
    - Experience focused on caring for only patients with the greatest clinical need limits experience with more common, routine or preventative issues.
    - Ultimately these concerns translate into inadequate preparation for the demands of the profession after residency.

IMPACT OF WORKING IN SHIFTS

Duty hours are not a concern in the ambulatory areas of pediatrics and in the Emergency Room. However, in the inpatient arenas (Inpatient unit, PICU, NICU), there are many opportunities for improvement. The IOM recommendation of a 30 hour duty period with an incorporated 5 hour nap is not practical for implementation in any of the current models of care. Thus programs would be "forced" to move to a "shift" model as has already been done in some programs. It should be noted that Pediatric trainees spend close to 18 months in these three settings, so instead of programs having 1-3 months of night float as they do currently in some programs, night time assignments will have to increase as much as 10 fold.

A "shift to shifts" will create challenges that will have a serious impact on both education and patient safety. Shifts will not be practical if residents work only 3 or 4 nights in a row. Scheduling and staffing will be disruptive to daytime learning experiences. If residents are required to have 12 hours off after a night shift, there will be no overlap time for detailed handovers, an important patient safety concern. And when will teaching occur? Teaching at night has limited focus, addressing primarily the patient care competency. Increasing shift work will negatively impact attendance at daytime didactic conferences and workshops that have been implemented in training programs to assure that residents receive a broad education in all the competencies. In addition, a key component of pediatric education is maintaining an active Continuity Clinic with a panel of patients. The ACGME requirement is a minimum of 36 Continuity Clinic sessions per year. Residents will not be able to maintain this important part of their education when working more night shifts. Residents working shifts for 3-4 continuous nights followed by 48 hours off will significantly shorten their clinical experiences in the inpatient setting. If competencies cannot be attained, training will likely need to be extended. There is no funding for increased training at this time. Another important consideration is whether moving to shifts will have a negative impact on resident work-life balance and their sense of well being. Extended times of night work will take away from time with their spouse, significant other, and children.

Key issues regarding the impact of working in shifts:

- Recommended duty hours are not compatible with current care models in the inpatient setting.
- Frequent nighttime shifts will negatively impact time for Continuity Clinic, an important component of pediatric residency training.
- Newly recommended duty hours may negatively impact resident work-life balance, since their work schedule will frequently be out of synch with their family's schedule.
- Concern is raised about faculty willingness to provide increased clinical and teaching time to match resident schedules.
- Educational conference attendance will decrease.
- Professionalism may be negatively impacted.
- A shift work mentality may result.
- Patient safety may be impacted with increased handovers to transfer care, which may increase number of medical errors or negate any potential improvements.
- Continuity of care will be decreased.
- The patient-doctor relationship will be eroded.
- Training must assure residents have adequate educational opportunities.
  - Less direct time with patients, leads to less experience.
  - Experience focused on caring for only patients with greatest clinical need, limits experience with more common, routine or preventative issues.
  - Residents will graduate with inadequate preparation for the demands of the profession after residency.

The APPD recommends:

- Training programs should study new models of care and education that reduce work hours when possible, make optimal use of time for resident education, and provide both supervision and teaching during all phases of the resident work schedule.

- The ACGME should allow the Residency Committees, with input from Program Directors, to develop specialty-specific recommendations for:
    - Duty hours
    - Level of supervision
    - Workload
- Formalized education and use of technology to improve patient handovers
- That institutions assure that systems of care exist that decrease the risk that any provider error reaches the patient

STAFFING REQUIREMENTS TO MEET RECOMMENDATIONS

THE CINCINNATI PILOT STUDY

"At least an additional 8,247 residents would be necessary." (IOM Committee report) For individual programs, this would represent a significant increase in intern class size. The Cincinnati Children's Hospital pediatric residency program conducted a pilot study of the implementation of all of the IOM recommendations on a single hospitalist/general service for one month:

Pros:

- More "day time off" for residents
- Fewer total hours per week for each resident
- Family centered rounds unchanged
- Better supervision and communication (teams signed out with the senior, intern, and attending together)
- Improved prioritization skills and efficiency
- Increased interaction between residents and attendings- both daytime and nighttime teaching
- Increased patient contact (more patients per intern with primary responsibility vs. cross coverage)

Cons:

- Continuity of patient care with same provider was poor (affects patients and education)
- Attendance at didactic educational experiences was poor
- No reflective learning time while on duty
- Negative impact on circadian rhythm (several residents did not adjust)
- Night residents felt "isolated" from the "rest of residency"
- Attending discontinuity - residents worked with multiple attendings, affecting oversight, feedback, evaluation and competency
- Estimated resident manpower required a 25% increase, additional faculty/hospitalist requirement of 1 FTE (33% increase)

STAFFING REQUIREMENTS

Expansion of the workforce to meet IOM Committee requirements using only additional residents is not feasible due to: a limited pool of qualified applicants, GME funding caps on residency slots, and lack of institutional support for more positions. The logistics of integrating additional trainees into the current system would require programs to ensure that they were able to meet the full RRC required distribution of rotations and competency experiences. Hiring of hospitalists, nurse practitioners, and other professionals would not only require additional funding and training, but it is unlikely that such an expanded workforce is available.

Without adequate funding or workforce expansion the current faculty at teaching hospitals would be asked to add to their current duties. Increased faculty involvement would further reduce the sense of resident autonomy and responsibility for their patients. Faculty members will suffer from increased fatigue thought to be detrimental to patient safety when suffered by residents. In the interest of patient safety duty hours limitations should apply to both faculty and residents

Finally, we anticipate future workforce implications if institutions and health systems are forced participate in accredited GME training with increased costs. This will inevitably result in the closing of some residency and fellowship programs. This is an especially high risk for small training programs.

COSTS TO IMPLEMENT THE IOM RECOMMENDATIONS

The IOM estimated overall costs of $1.7 Billion. This is a significant underestimate of true costs since this estimate was based on replacing the patient care that would have been delivered only by the PL1 residents, rather than including all years of training, and did not project the annual expenses of sustaining this workforce. At the program level, Boston Combined Residency Program in Pediatrics has estimated cost to the Pediatric Department of approximately $1.7million to 2.3 million/year. Difficulties identified by the program include *"The 30 hour with a 5 hour nap was felt untenable because of replacements across the program, so we immediately went to a day team/night team model. However, it is the combination of a) limiting night shifts to no more than 4 nights in a row; b) requiring one day off per week without averaging; c) having a 48-hour period off after a string of nights; and d) trying to optimize weekend days off (for lifestyle/personal health reasons) that creates the major problems and adds to costs."*

The APPD identified the following areas, each with its own potential costs in money, time, and educational value, as important considerations. All costs should be examined from multiple perspectives: patient, resident, educational program, clinical department, institution/hospital, insurance payers, society/government and include both short-term and long-term/future cost implications (such as future workforce).

__Financial considerations__:

- Cost of increased number of providers (residents, nurse practitioners, hospitalists)
- Cost of increased monitoring by ACGME (admin. time, data systems, etc.)
- Cost of increased faculty number and time
- Cost of increased technology
- Cost of extending length of training (if require 4 yrs. vs. 3yrs. to meet equivalent)
- Cost of additional required space/rooms for increase in night personnel
- Inadequate reimbursement for GME (federal caps on resident salary, educational support)
- Increased financial burden to fellows with limited moonlighting opportunities
- Sustainability of smaller sized residency programs

APPD RECOMMENDATIONS REGARDING DUTY HOURS STANDARDS

The APPD is supportive of improved monitoring of existing duty hours requirements, oversight and monitoring of moonlighting, improved patient handover procedures, and careful attention to supervision of trainees. Our organization has concluded, however, that any revision of duty hour requirements should be undertaken with consideration for individual specialty and resident level training needs. The APPD recommends that few of the IOM Committee recommendations be implemented until funding is made available, as detailed below. We encourage study and piloting of schedules and curricula within and among residency training programs to achieve continued improvement in physician training.

The APPD Membership expressed concerns that the IOM data used as the basis for the recommendations consisted largely of studies with small sample sizes or were from non-medical fields. The greatest concern was that the recommendations would be an unfunded mandate with potential harm to patient safety and graduate medical education. Finally, we believe that the IOM recommended duty hour limits will significantly hinder the creativity and innovation which leads to improvement in resident education in all specialties, all program sizes, at every graduate medical training level.

The following table is a brief summary of the IOM recommendations and potential gaps in implementation. Some of the recommendations can be successfully implemented without major gaps in funding. However, many recommendations have major gaps in funding, workforce or resources and merit discussion of individual components - additional specifics are included in the sections that follow.

Summary table of IOM recommendations by Report Chapter	**Summary of implementation/gap**
(1) Duty Hour recommendations- additional limits in continuous hours, shift, days off, etc.	See detailed discussion, several gaps in ability to implement
(2) Moonlighting inclusion in hours- include limits, explicit requirements, programs to approve and monitor	Immediate implementation, no gaps (except financial for residents/fellows)
(3) Monitoring of hours- ACGME and programs, more monitoring	Move to implement, some administrative cost and time by residents
(4) Patient care "service" loads and balance with educational need- institutional support, caps, etc.	See detailed discussion, several gaps in ability to implement
(5) Oversight and supervision- level appropriate, graduated responsibility, on site faculty	Move to implement, although tied to gap in funding, faculty number and time
(6) Safe transportation options post-call	Move to implement, some administrative and institutional costs
(7) Development of safe hand offs, transitions, and attention to patient safety	Move to implement, some administrative and institutional costs
(8) GME sponsors should involve residents in quality, safety, duty hour monitoring	Immediate implementation, no gaps
(9) All GME funders should provide support to implement changes- also recommends meeting of funding groups	Outside of APPD, although we can provide supporting information, major gap financial
(10) ACGME to convene stakeholders to organize data, needs, resources. Also study, report, research needs.	Outside of APPD, although we can provide measurement information, major gap financial

APPD RESPONSE TO SPECIFIC ELEMENTS OF IOM PROPOSED DUTY HOURS

As indicated in the summary table above, the IOM report contains both a broad set of recommendations, in addition to specific proposals regarding duty hours. The following table is copied from the IOM Report, with the addition of our APPD recommendations for the corresponding specific items. Please see the footnotes for additional discussion of each issue.

	2003 ACGME Duty Hour Limits	**IOM Recommendation**	**APPD Recommendations**
Maximum hours of work per week	80 hours, averaged over 4 weeks	No change	No change
Maximum shift length	30 hours (admitting patients up to 24 hours then 6 additional hours for transitional and educational activities)	• 30 hours (admitting patients for up to 16 hours, plus 5-hour protected sleep period between 10 p.m. and 8 a.m. with the remaining hours for transition and educational activities) • 16 hours with no protected sleep period	24 hours patient care and educational time plus 3 hours transition time [1] (as done in NY state)
Maximum in-hospital on-call frequency	Every third night, on average	Every third night, no averaging	Every third night, with averaging [2]
Minimum time off between scheduled shifts	10 hours after shift length	• 10 hours after day shift • 12 hours after night shift • 14 hours after any extended duty period of 30 hours and not return until 6 a.m. of next day	♦ 10 hours after any shift [3] ♦ 14 hours after any extended duty period of 24 hours or more
Maximum frequency of in-hospital night shifts	Not addressed	4 night maximum; 48 hours off after 3 or 4 nights of consecutive duty	5 night maximum; 48 hours off after 5 nights of consecutive duty[4]
Mandatory time off duty	• 4 days off per month • 1 day (24 hours) off per week, averaged over 4 weeks	• 5 days off per month • 1 day (24 hours) off per week, no averaging • One 48-hour period off per Month	♦ 5 days off per month, averaged over 6 months [5] ♦ 1 day off per week, with averaging [6] ♦ One 48-hour period off per month
Moonlighting	Internal moonlighting is counted against 80-hour weekly limit	• Internal and external moonlighting is counted against 80-hour weekly limit • All other duty hour	♦ Internal and external moonlighting is counted against 80-hour-weekly limit ♦ All other duty hour

		limits apply to moonlighting in combination with scheduled work	limits apply to moonlighting in combination with scheduled work [7]
Limit on hours for exceptions	88 hours for select programs with a sound educational rationale	No change	No change
Emergency room limits	12-hour shift limit, at least an equivalent period of time off between shifts; 60-hour workweek with additional 12 hours for education	No change	No change

1. Maximum Shift Length

The IOM Report recommends maximum shift length of no more than 16 hours. Limiting shifts to 16 hours is concerning to the APPD for several reasons. Changing to a shift schedule would double the number of handovers on the rotations that typically have 24 hour call schedules, increasing the likelihood for patient care errors. The significant discontinuity of care associated with this fragmentation is not only a patient safety risk, but could jeopardize resident education associated with longitudinal care. Pediatric residents will lose the opportunity to follow the evolution of disease processes, as the average length of stay for most inpatient services is 2.5 days. It is likely that the disruption in continuity of care will also decrease patient care satisfaction, due to fragmentation in the patient-physician relationship.

These changes have the potential to significantly impact resident education. Anticipated areas of impact include: decreased reflective time, shifting from educational activities such as conferences, educational rounds and small group teaching sessions to patient care tasks and increased clerical/administrative tasks. Key educational elements of residency such as Continuity Care Clinic would be dramatically reduced since residents on night float could not attend clinic when working nights. Moving to a schedule that is designed using only shifts requires approximately 25% more residents. Since there are not sufficient residents available, implementing this schedule would require residents be assigned to additional patient care activities preferentially over educational activities.

These recommendations could disrupt the balance of educational experiences to shift the focus to inpatient and subspecialty training at the expense of ambulatory, community, and other aspects of pediatrics.

The data on sleep deprivation that was provided in the report does not directly apply to pediatrics. The literature cited supporting limited shift length is based on work that focuses on a single task activity throughout each duty shift. Residency differs in that it is a dynamic mix of clinical, reflective and other educational activities and not simply continuous repetitive tasks. Each patient case is unique, requiring different skills and activities, each with varying intensity and complexity. Resident patient care activities include supervisory experiences, communication with patients and families, communication with faculty and other educators, as well as the transfer of care to another physician.

As written, the IOM recommendations on shift length, series of shift length and required days off following shift work would lead to a negative impact on resident quality of life. Residents would have more time spent cross covering on patient care services and less time spent home at night. Increased resident burn-out has been reported with decreased satisfaction at work.

2. Maximum in-hospital on-call frequency

Although we support, in principle, the concept of every third night call with no averaging, the APPD feels it is important to allow residents flexibility in their schedule in order to ensure resident quality of life. There are similar concerns about the prescriptive recommendations for the number and timing of days off and weekends off without averaging. There must be oversight by the program director to ensure that this flexibility is not over-used and that the work schedule of the residents is constructed to provide adequate rest and continuity of experiences.

3. Minimum time off between scheduled shifts

The IOM Report recommends that the time required off between shifts should remain at 10 hours between any two shifts. This allows adequate time for transfer of information, and still allows the resident to return to work after the 10 hour break to provide continuity of care to the patients.

4. Maximum frequency of in-hospital night shifts

The IOM Report recommends that the number of consecutive night float shifts not exceed 4 days. To conform to a 3 or 4 day maximum is quite complex and disruptive to a program. The APPD strongly recommends a schedule of 5 consecutive night shifts. This schedule allows residents to maintain a reverse circadian rhythm throughout the week, instead of switching back and forth between days and nights. A 5 consecutive night schedule also reduces the disruption in education of residents from other services that would need to cover the gaps in the night float schedule. Residents cross-covering will not know the patients as well as residents who have cared for those same patients over time, placing patient safety at greater risk.

5. Mandatory time off duty

The IOM Report recommends 5 days off per month, without averaging. The APPD recommends that up to 5 days off per month should be averaged over 6 months, just as actual post-training practice has such variability.

6. Mandatory time off duty

The IOM Report recommends that each resident has one day off per week without averaging. The APPD recommends that residents have the flexibility to choose to group days off. Thus, averaging of one day off per week should be allowed to continue.

7. Moonlighting

The APPD recommends that all moonlighting hours should be under the direct supervision of the program director.

REQUEST FOR FUTURE PARTICIPATION

The Association of Pediatric Program Directors would like to express not only our willingness to participate in the Resident Duty Hours and the Learning Environment Congress, but our belief that it is essential that we are present at this important event. Pediatrics is different from other specialties in many ways, and we believe that no other specialty can represent our perspective adequately. We hope that we will be honored with an invitation to participate in this next step in the ACGME's process for defining its response to the IOM recommendations.

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April 27, 2009

Thomas J. Nasca, MD, MACP
Chief Executive Officer
Accreditation Council for Graduate Medical Education
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Chicago, IL 60654

RE: CoPS Response to the Institute of Medicine Report on Resident Duty Hours

Dear Dr. Nasca:

We thank you for the opportunity to provide the ACGME with a formal position paper in response to the Institute of Medicine (IOM) Report on Resident Duty Hours that was issued in December of 2008. This position paper reflects the consensus opinion of the Council of Pediatric Specialties (CoPS). CoPS represents more than 14,000 pediatric subspecialists in the United States, including Program Directors and Division Directors who supervise the training of subspecialty fellows.

We support the basic principles of the IOM report regarding patient safety, resident supervision, resident safety, and the importance of effective “hand-offs”. We believe that the ACGME must view this as a unique opportunity to carefully examine the policies that guide postgraduate medical education in the United States. The following material summarizes the main points of our position regarding the IOM report. In the attached document we respond point-by-point to key IOM recommendations.

Position Statement

1. *Restricting resident duty hours further will have a significant impact on the preparation of residents for pediatric fellowships and on the competency of fellows.* Training program directors, especially those in pediatric critical care specialties (Neonatology and Critical Care), indicate that beginning fellows currently lack sufficient clinical and technical skills to perform at expected levels. Reductions in resident and fellow duty hours will adversely impact the competence of fellows in training and will likely lengthen the duration of training required to achieve the clinical competence necessary to care for children with complex medical conditions.

2. *Restricting duty hours further will be costly to implement, especially for small programs.* There is insufficient GME support currently to recruit the trainees necessary to support an increased duration of training or to fill the clinical needs created by additional reductions in duty hours. Current estimates indicate that at least 25% more trainees will be needed if the IOM recommendations for resident duty hours are implemented. If resident duty hours are restricted, more aspects of the care of subspecialty patients will be shifted from pediatric residencies to subspecialty services. There are currently insufficient numbers of fellows or subspecialists to assume all of the anticipated teaching and clinical responsibilities. Based on data from the American Board of Pediatrics, indicating that there are more than 3400 fellows in training in pediatric specialties, we estimate that up to 1000 more fellow trainees will be needed if the IOM recommendations, especially the revised 30 hour day, are implemented. Given that the *direct* costs of training one fellow for three years are currently $200,000, *at least* an additional $200 million in GME support will be needed to provide an adequate fellow workforce if the IOM recommendations are implemented. This cost is *in addition to* the $1.7 billion estimated in IOM report. There are insufficient numbers of applicants, especially US medical graduates, to fill current fellowship positions, let alone the numbers necessary if the IOM recommendations are implemented as written.

3. *There is a workforce shortage in pediatric subspecialties.* It will be extremely difficult for pediatric subspecialists to assume additional clinical duties should fellow and resident duty hours be reduced further. The average age of pediatric subspecialists ranges from 48.4 years (emergency medicine) to 55.7 years (nephrology) (*data from The American Board of Pediatrics, 2008-2009*). The costs of hiring additional subspecialists for training environments are prohibitive and the supplemental workforce, whether aging subspecialists or mid-level providers, is not currently available to provide adequate access to subspecialty care in US children's hospitals, let alone in community hospitals.

4. *Fellows must be viewed differently than residents.* The "one size fits all" approach to the policies and regulations for residencies and fellows does not fit the current educational needs of fellowship training. Fellows, especially in their final years of training, function like junior faculty members. They require autonomy and must engage in scholarly activities, especially if they anticipate academic careers.

5. *Changes in the educational and duty hour requirements for fellows must be data-driven.* We encourage the ACGME to propose studies that will be initiated now and continued through the implementation of any changes in the structure of postgraduate training. We must have high quality data to guide the future directions of fellow education. At the present time, data supporting substantial changes from the current duty hour structure are modest, at best.

We applaud the ACGME's desire to receive opinions from its constituents. We sincerely hope that the responses and the recommendations provided by organizations such as CoPS will be considered carefully by the ACGME and used to create policies that will ensure training excellence and safe, effective patient care. We look forward to the opportunity for representatives of CoPS to participate in the Duty Hour Congress scheduled for June and to represent the opinions of the Program Directors and Division Directors of pediatric subspecialties.

Sincerely,

The Executive Committee of the Council of Pediatric Specialties
Victoria Norwood, MD, Chair
James Bale, Jr., MD, Vice-Chair
Daniel Coury, MD
Paul Darden, MD
Richard Mink, MD
Christopher Kennedy, MD

Summary of Council of Pediatric Specialties Opinions Regarding the Key IOM Recommendations

IOM Recommendations	**CoPS Opinion**
80 hour rule	*CoPS believes that non-patient care related activities of fellows, e.g., research time, manuscript preparation, etc., should be exempt from the 80 hour rule.*
30 hour shift but rest after 16 hours of work; 5 hours of rest; no new patients after 16 hours	*CoPS opposes this recommendation.* It is costly to implement (at least 25% more trainees will be needed) and will be extremely difficult for programs to implement without changing to an all shift, day-float, night-float system. Fellows must function like faculty physicians, especially in their senior years. More data are needed to determine the optimum length of continuous duty hours to achieve this goal, especially in critical care specialties.
Maximum 4 nights of work in succession	*CoPS opposes this recommendation, if it will be applied to call from home.* Fellowship programs, especially small programs, have insufficient fellow or faculty workforce to implement this currently.
Mandatory 5 days off per month	*CoPS agrees with this recommendation.*
External moonlighting should count toward the 80 hour rule	*CoPS agrees with this recommendation, but the IOM and ACGME must recognize that educational debt is a major burden for graduating medical students and a major factor influencing career choices.* As many as one-half of the fellows in many programs moonlight to pay their debts. Educational loan repayment programs should be available to all fellows, including those entering clinical careers. Any reduction in resident or fellow duty hours must be linked to mechanisms to reduce the burden of educational debt.

Enhanced night time supervision	*CoPS agrees with this recommendation.* However, CoPS also recognizes that fellows require sufficient opportunities for autonomy, especially in their senior years, when they function like junior attendings. Recommendations for increased supervision by faculty, especially if "in-house" must take into account the *severe* workforce shortages that current affect virtually all pediatric subspecialties.
Defined elements in the effective transfer of care	*CoPS agrees with this recommendation.* We will work with our partnering organizations to implement analysis of "hand-offs" or "sign-outs" to understand the necessary and sufficient elements of this critical aspect of patient care. Patient safety and medical error are influenced by several factors, including physician fatigue and sleep deprivation. It is unknown, however, if the errors avoided by providing opportunities for rest will be off-set by the errors that are perceived to be inherent in the more frequent hand-offs necessitated by shortened duty hours or shift work. The ACGME must encourage the performance of well-designed studies to critically examine these issues.

American Academy of Pediatrics
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March 24, 2009

Michael M. E. Johns, MD
Chairperson
Committee on Optimizing Graduate Medical Trainee (Resident)
Duty Hours and Work Schedules to Improve Patient Safety
Institute of Medicine
500 Fifth Street NW
Washington, DC 20001

Dear Dr. Johns:

On behalf of the American Academy of Pediatrics (AAP), I am sending you the enclosed comments in response to the Institute of Medicine's recent report, "Resident Duty Hours: Enhancing Sleep, Supervision, and Safety." These comments reflect the diverse perspectives and opinions of the physician leaders that provide clinical, policy, research, and other expertise on our committees, councils, and sections. We have solicited their comments in an attempt to garner thoughtful and constructive feedback on the myriad issues addressed in the report's recommendations.

The American Academy of Pediatrics is an organization of 60,000 primary care pediatricians, pediatric medical subspecialists, and pediatric surgical specialists dedicated to the health, safety, and well being of infants, children, adolescents, and young adults. To this end, we support efforts of the Institute of Medicine and others to prepare resident physicians to deliver high-quality care to America's patients.

As the following pages will demonstrate, the input received from our members, while varied, did focus on several key issues. Among these were the effect of resident duty hours on the work hours and fatigue of attending physicians, concerns about the absence of data and evidence to support new duty hour regulations, fragmentation of patient care, and the costs and resources required to implement the IOM duty hour recommendations in residency programs.

The Academy commends the IOM for its thoughtful work in the preparation of this report, and hopes that the comments provided above will prove helpful in its future deliberations on the important issue of resident duty hours and the impact of the recommendations to patient care and safety.

Thank you.

Sincerely,

David T. Tayloe. Jr.

David T. Tayloe, Jr, MD, FAAP
President

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COMMITTEE ON BIOETHICS

General Comments:

The Committee on Bioethics appreciates the opportunity to comment on the draft IOM report on resident duty hours. The committee offers some general comments, along with specific points regarding the scope and recommendations in the report. In general, the committee notes that it is hard to disagree with what lies behind these new recommendations, and it is hard to disagree with making resident worklife reasonable and amenable to good education.

However, there is a real danger in isolating resident hours from the rest of the system. It is doubtful that there will be additional resources available to the system to hire additional providers, and there is no question that older physicians (i.e. attendings) are for the most part being asked to absorb the consequences of duty hour changes. The data are pretty clear that sleep deprivation and long hours are tolerated much less well by older individuals than by younger ones, so that shift can hardly be justified on the basis of "patient safety." Furthermore, in practice the work hour restrictions seem to lead to more "baton passes" and diffusion of responsibility, with attending physicians providing most of the continuity of care. The point is not that these changes are bad, but that focusing solely on residents really just shifts the problem; it does not fix it.

Specific Comments:

- If the report's primary focus is on sleep loss, fatigue, and patient safety, its scope is too narrow—it fails to address sleep loss and fatigue in other health care workers, such as attending physicians. The recommendations regarding enhancing supervision will potentially, unintentionally exacerbate this issue.

- If the report's secondary concern is the quality of resident education, it provides inadequate, prospective attention to the absence of competency-based evaluation mechanisms and the potential need to extend residency training.

- The report provides inadequate attention to sleep loss and fatigue on night float rotations, the likely replacement for extended duty periods if the report's recommendations are accepted.

- The focus on moonlighting is another inappropriately narrow framing. One might focus on moonlighting in terms of the effect on patients cared for during the moonlighting itself. The focus rather appears to be on the effect of moonlighting on sleep loss and fatigue and its secondary effect on patients cared for during residency training. In this regard, there are many things residents might do that promote sleep loss and fatigue unrelated to the structure of the residency program. What are the resident's responsibilities in this regard? The limits of residency programs' efficacy are suggested by the recommendation that they "ensure that residents take the required sleep during extended duty periods."

- The report appropriately emphasizes the resources required to implement the report's recommendations.

- The recommendation permitting documentation of exceptions to work hours is a step forward from the prior position that work hours could never be violated.

DISTRICT CATCH FACILITATORS

General Comments:

First, I think that recognition of tasks that do not need to be perfomed by residents and are not of educational value that can performed by others under the "Workload Adjustment" section is essential to aid in resident education.

Second, I think that while the "Duty Hours Adjustments" recommendations might enhance patient safety in theory, those recommendations are often not feasible, especially in the setting of small residency programs that still rely on the 30-hour work shift to balance the number of patients and residents for maximum safety. By decreasing the number of hours a resident can work, it will only increase the number of patients each resident can carry, which will not enhance patient safety or resident learning.

EXECUTIVE COUNCIL ON COMMUNITY PEDIATRICS STEERING COMMITTEE

General Comments:

- In general it looks OK, and nothing to add.
- No question that residents are sleep deprived, which affects their medial decision-making, but with the time restrictions placed by this policy, it makes the hours of residency much better than the hours of our pediatricians. Typical pediatricians may get more sleep, but we start at 8am and finish at 6pm the following evening, and we have no "protected time" without a pager.
- It seems that the guidelines have been well thought out, and the recommendations are very detailed.
- I agree with the guidelines regarding patient load, but wonder if the new generation of pediatricians will be ready for community pediatrics.

Specific Comments:

- I do have a problem with including "service" credit for 5 hours of uninterrupted, protected, safe sleep while on call.
- Many areas of the country have no pediatric hospitals. Our patients call at all hours, and if they need admission, we come to admit them.

- Hours are also long for the pediatric subspecialists who take sequential nights on call, none of which are guaranteed to be quiet.

Working closely with a University training program and safety-net hospital, I have only a few questions/recommendations:

- I would like to see suggestions on how this program can best work—meaning, how many more residents will have to be funded and how should the shifts work?
- Where will the funds come from to have in-house supervising physicians?
- What is the guideline for a supervising physician? Same specialty?
- I think it is important for patient safety to help ensure residents get adequate sleep and breaks, but we also need to note if residents are frequently out of the hospital, because they will see less continuity of care.
- Night shifts can help decrease this loss of continuity. I agree with many of the recommendations, but without increased funding from the government, I do not see this as feasible.
- What methods for lobbying the government will be taking place?

COMMITTEE ON CONTINUING MEDICAL EDUCATION

General Comments:

- The new recommendations have a potential for posing major financial problems for many residency training programs at a time when operational costs of health care is a critical issue.
- Rapidly rising health care costs must be a consideration when organizations force increasing financially burdensome rules on hospitals. How are the financially strapped hospitals expected to pay for additional in-house supervision of residents? The IOM may be addressing an "ideal health care system," but this is not the time to force new major costs on an already crumbling health care system.
- The "rigidity" of the work limits is counter to teaching professionalism and responsibility for care of individual patients.
- It is not evidence based that these changes will favorably impact safety. It is quite possible that the more frequent turnover of patient care to less-prepared residents may actually create new safety issues.
- There is a stratification of responsibility from internship to the various levels of residency and specialty fellowship, with a gradual transition to full responsibility of patient care, critical decision making, and teaching of junior trainees. The same rules cannot apply to

interns and to third-year fellows. Many in-house specialty fellows and senior residents get significant sleep during coverage, but their continuity of care for individual patients may be compromised when they must leave for artificially forced rest periods.

- Medicine is a profession. We sometimes work hard and put in long hours to maintain professional responsibility to our patients. We do not punch time clocks.

SECTION ON COMPLEMENTARY AND INTEGRATIVE MEDICINE

General Comments:

- Overall, the report is excellent and clear. However, there needs more context and data behind specific recommendations. Why 5 hours of rest? Why "ever" work 30 hours straight, because it seems too easy to game the system on this and violate this rule.

- Some additional context would be helpful. What rules are used by airlines, flight controllers, pilots, long distance truck drivers, nurse, and others who engage in high-risk duties in which others' lives are at risk?

- Why not learn from nurses? They provide great continuity of care, and they seldom work more than 12 hour shifts. They have learned how to hand over patients at the end of shifts.

- Of course, we should make sure that any resident who is impaired due to fatigue or a broken ankle or a sudden viral illness should make it home safely, but why are we letting them work so long and become so fatigued that we need to drive them home? Would it not be better to transfer shifts before this becomes necessary? Of course, they will want to say they can do it, just as we did in the bad old days. This rule just strikes me as a very, very sad commentary on where training is.

SECTION ON ENDOCRINOLOGY

General Comment:

I think that in general the IOM report is well thought out, and most of the recommendations seem reasonable, though some will be challenging to implement.

Specific Comment:

The one recommendation which seems to me to be the most troublesome is in the section on Duty Regulations where it is suggested that residents be allowed 5 hours of uninterrupted sleep during extended call. While this would clearly help with preventing sleep deficit, it would cause major problems with transfer of responsibility for patient care during those 5 hours. If the intern can get some sleep, while the senior resident covers for the patients of multiple interns he or she knows a little about, that might not be so bad, except that the senior resident needs sleep, too. So one would need to rely on night floats to an even greater extent than programs do now, and this might work out alright on units where patients are stable and not much happens between 10 pm and 6 am, but it would not work on a service with a lot of sick kids, such as the NICU or PICU.

COMMITTEE ON FETUS AND NEWBORN

General Comments:

- While I agree with the goal to reduce fatigue in trainees, I am bothered by the arbitrary nature of these recommendations. I could be wrong, but they do not seem to be evidence-based. The current restrictions on work hours are already disruptive to education and clinical care. Our pediatric housestaff generally spend one day in continuity clinic and leave by 8:00 AM following a night on call. That means they are spending 3 or 4 days out of 7 working in the NICU.

- Although both resident/fellow and patient safety are realistic expectations and were sorely abused in the past, these current recommendations only further shift the workload burden to the attendings or neonatal nurse practitioners (NNPs) (that is, if you are lucky enough to have this manpower available to staff the unit 24/7). This degree of "coddling" not only limits their educational/clinical exposures, but they are poorly prepared to enter the world as an attending where there does not appear to be any work hour restrictions clinically, let alone the surplus of administrative duties we also face in the academic, clinical, and/or research arenas.

  With the decline in the resident's clinical responsibilities as well as the mandate by the ACGME that they participate in a QI project, community activity, scholarly activity, among other experiences, we may need to make the residency a minimum of four years. However, I doubt economically that a proposal for such an extension of training would be favorably received.

- Given the economic climate, I am doubtful that hospitals or other agencies will provide funds to hire additional care providers (hospitalists or NNPs).

Specific Comments:

- The requirement for 5 hours uninterrupted sleep if taking a 24 hour call: In addition to requiring more handoffs (with increased risk for errors), we do not have the manpower (other than faculty) to fill in the gaps during those sleep periods. Besides, there is no guarantee that residents or fellows will sleep during the required rest periods. Moreover, if followed, this is the end of the "on call" system of medical practice (whether one thinks that is a good or a bad thing, it should be recognized as a game-changer). Our fellows will only be able to take night call when they are not on service, since we must have someone available at all times of the night. This in turn has major implications for their "dedicated" research time, if they have to do their night call when they are supposed to be doing research.

- Night shifts limited to 4 nights in a row: This one simply makes no sense. What about all the people who work the night shift their entire lives? I can understand the need for a two day/night period between taking night shifts and returning to days, but not the limitation on the number of nights in a row to 4.

- Just a personal experience note: With the institution of the 80 hour limitation, I changed the residents' schedules, so that our interns do all day shifts (12 hours/day for 6 days/week, with two "out early" days and one afternoon gone to clinic). The second-year resident does the same day schedule for 2 weeks, then switches to nights (12 hours/night, 5 nights/week). The third-year resident does the same, only in reverse. This has been generally well-received by the residents, has helped with continuity especially at night, and improved teaching opportunities for interns. This will not continue to be possible if the nights are limited.

- Some of the past restrictions were made with the assumption that residents would read while off duty. I do not believe this has happened, and I do not believe that it has been formally studied. In addition, I believe that a great deal of learning in medicine needs to be experiential, and even the current hours have restricted the number and kinds of patients that a resident sees. Our residents leave their training not having seen a number of conditions that we were very familiar with. Private pediatricians and fellowship directors all seem to agree that the current expertise of the graduates is less than it used to be. I already believe that the residency ought to be extended at least another year as a result of the past reforms in hours. Further restrictions only mean that the residents will see fewer cases and have less experience. The implications of this need to be examined. There needs to be some recognition that residents need to not only pass a written test of general knowledge, but to know how to respond in a crisis and to recognize a disease, its complications and course.

- The few studies I have seen have looked at residency sleep and alertness. This is commendable, but I wonder if anyone has looked at the effect of resident fatigue on actual patients. The more a patient's care is passed off between physicians, the more likely it is that important history is lost and that mistakes will be made. Even worse, it is my opinion that the current reforms have been as workable as they are is because the faculty has picked up the slack. No one has looked at the hours that the faculty are working and what effect that has on patient care. Further reforms mean to me that I and my colleagues will have to work harder once again. I believe it is ironic that the fuss is strictly about the work hours of the younger doctors. Sleep deprivation becomes worse, not better, as one ages.

- I agree that there has been far too little work done to look at the effect of the previous reforms to know whether further reforms are needed or even safe. It seems that evidenced-based medicine only applies to the giving of actual care, not to the social aspects.

- I am very worried that these reforms are being carried out in the current economic climate. There is no way that more residents will be hired to pick up the slack, and I doubt that the attendings can pick up much more slack. To me that means that there may be a further increase in errors or that wait times may dramatically increase. This could be quite dangerous. Finally, the rigidity of the restrictions does not allow training centers much creativity to respond to increased demands.
- Lastly, many residents have told me that they do not have the sleep deprivation that we had, but that they feel a great deal of stress about how efficiently they work and whether or not

they can get all their work done before they sign off on a patient. Is it not possible that further "reforms" may increase the stress of the resident, make illness more likely, and make mistakes more common?

- Recommendations for sleep do not address location of sleep: Is safety better with enhanced sleep at home versus in-hospital sleep (dingy call rooms) vs. no sleep (but "off "time).
- No recommendations made to provide and improve supervision.
- Safety: limitation for external moon-lighting is a positive recommendation.
- A 12-hour shift limit for the emergency room should also apply to intensive-care specialties. These services usually run 24/7 and now necessitate at least 2 formal rounds in the morning and evening (both of which can also be teaching rounds) and a third late night "walkabout".

COMMITTEE ON GASTROENTEROLOGY, HEPATOLOGY & NUTRITION AND THE SECTION ON NUTRITION

Specific Comments:

- I would like to know how these work hour limitations will apply to post-residency trainees (fellows).
- If a fellow is "on service" for five week days, and then covers weekends, will that be out of compliance, since this means they will be covering 7 days with no 24-hour off-duty period? Our fellows typically cover 5 days per week plus every fifth weekend. Weekdays typically begin about 7:30-8 am and end between 5 and rarely as late as 9 pm, depending on how busy the inpatient service is on any particular day. Would all fellowships have to file a waiver to allow fellows to cover every 3-5 weekends in turn with other fellows?
- Does writing notes electronically from home count towards the service hours?
- Additionally, how do we weigh "moonlighting," which cannot be in a subspecialty field, and the remainder of a fellow's training? If this counts towards the 80 hours, and a fellow does a 24-hour rotation in a nursery or an ER during a weekend off to help financially make ends meet, are they then restricted that week from doing more than 56 hours total?
- The implications of cutting the resident hours further on the hours that we as attendings provide service for patients and resident/fellow education are not yet defined. Will we eventually be subject to same restrictions for patient safety?

SECTION ON HEMATOLOGY/ONCOLOGY EXECUTIVE COMMITTEE

General Comments:

The AAP Section on Hematology/Oncology supports the intent of the IOM report to improve patient safety through the goals cited in the statement. However, these goals will only be met if there are adequate safeguards against the potential adverse effects of such changes. It is important that consideration be given to how such changes will impact the immediate issue and also those within the circle of influence to prevent unanticipated consequences. This includes both the time and resources to implement any changes and defined methods to evaluate their impact.

Specific Comments:

Duty Hour Adjustments

- In order for the changes in resident duty hours to positively impact those in training and the patients, it must be combined with an increase in the number of physicians-in-training. Such increases will address the lost man hours both for those in training, as well as for the future physician workforce that will incorporate the hour limits in their professional careers.

- The economic issues are mentioned but not really addressed. If children's hospitals, which are particularly at risk for decreased resident funding, have to pay for additional resident/fellow slots and increase support staff, they may elect instead to limit or eliminate residencies, an unintended adverse effect. There must be a funded increase in the numbers of and compensation for physicians-in-training.

- Another result of decreasing resident duty hours is the impact this has on the workload of the attending physician, whose hours have expanded as residents/fellows' hours have contracted. Since attending physicians are the individuals ultimately responsible for the patients, there needs to be some way of alleviating their work hours. How changes in resident/fellow work hours affects fatigue in attending physicians needs to be addressed.

- In order to maintain the quality of pediatric training in view of the proposed duty hour changes, serious consideration should be given to expanding residency to 4 years, especially if there is the expectation to make residents participate in quality assurance and other projects, as suggested in the report. A reduction in resident duty hours should not eliminate/negatively impact some of the most important parts of the training experience.

  As an example: Diagnostic talks for a patient with a newly diagnosed cancer often happen in the late afternoon, when everybody is else is "tucked in," and you have a reasonable expectation that you have an undisturbed hour to devote to that family. Even now, it is extremely hard to make residents part of this experience, either because they are post call, in continuity clinic, or have already reached their hour limitations. The same would be true of fellows, as well.

- If residencies and fellowships are prolonged, the related cost implications may not make this education feasible for many individuals. Consequently, initiatives that focus on reducing the cost of education (larger grants and scholarships - not more loans) and increasing the compensation during post-doctoral training should be part of the overall plan. Increasing the length of residency and fellowship may decrease the number of fellowship-trained physicians. In the adult medical field, where there are inadequate numbers of primary care providers, many would consider this a good thing. In the pediatric hematology/oncology field, where the salary is not much different between pediatric hematology/oncology practitioners and general pediatricians, extending the training period for cash-strapped residents would likely quickly lead to a workforce shortage.

Improving the Safety of Residents and the Public:

- Regarding the specific issue of " . . . provide safe transportation options for any resident who for any reason is too fatigued to drive home safely." Who will decide when it is no longer safe to drive?

- The provision of subsidized housing near campus would allow lowered expenses, decreased risk of driving while sleep deprived, and the option to live with their families while off duty.

Workload Adjustment:

- What is of "limited or no educational value?" An example for the oncology discipline: being able to read a protocol and to write chemo orders according to the protocol is a necessary and vital part of training. However, doing it over and over again lacks educational value (and is less safe than using preprinted or electronic order forms).

Improving Handovers and Safety Reporting:

- The risks of increased hand-offs are also mentioned, but it is not clear whether the effect on patient safety attributed to decreasing resident work hours would be more than offset by the greater risk from increasing transfers of care. There should be a call for funded research into optimal ways to transfer patient responsibility safely.

SECTION ON MEDICAL STUDENTS, RESIDENTS, AND FELLOWSHIP TRAINEES

General Comments:

- The financial implications and resource allocation issues raised by the IOM recommendations are a big issue. While I think that the IOM recommendations on resident work hours are good in theory, I have some serious concerns about their practicality and feasibility, especially considering the fact that the country is in an economic downturn, and the IOM proposals would require an enormous amount of additional resources in order to implement the requirements, including funding for extra coverage. Moreover, many programs, especially small ones, would not have the flexibility or numbers necessary to make these proposals a reality without a significant amount of help.

- The Section still has concerns that there is poor compliance with the 80-hour ACGME restrictions; therefore it is hard to believe that further restrictions would be followed. I believe many programs, especially surgery and medicine residencies, are not anywhere close to complying with the 80-hour ACGME restrictions. I have no hard data, but I would imagine that a large percentage of existing programs (of all specialties, not just pediatrics) are not complying with the current work hour restrictions. Enforcement of current restrictions should be a priority before any additional restrictions, also difficult to enforce, are in place.

- There still is much to be learned from the consequences of the 80-hour ACGME restrictions. In a systematic review by JAMA on the effect of reduction of resident work hours (Fletcher, KE; Underwood, W; Davis, SQ; et al. Effects of work hour reduction on residents' lives: a systematic review. *JAMA*. 2005;294(9):1088-1100), a number of conclusions were reached. Most of the 54 studies that were reviewed concluded that resident quality of life was improved. However, most of the studies had limitations of study design and non-validated instruments. They were not able to determine the effects of improved quality of life on education and if it translated into better patient care. Further studies are needed in these regards.

- Working long hours during residency may help to "prepare" young physicians for the need to work long hours in the future. Many practicing pediatricians must work many consecutive hours when they are on call, and the point could be made that working long shifts during residency prepares one for professional life.

- Parents probably would not want post-call residents taking care of their children, given the studies that show effects of heavy call on driving and standardized tests. We need to show parents that we are wanting to give them the best care possible, and that should include an alert, rested physician, who is able to spend time with them, because he/she is alert enough to care for them.

- Many residents feel they are able to give better care when well rested. I feel that in our hospitals, our pediatric residents and patients have benefitted from cross-coverage and float systems. Residents are just better able to recognize problems and make good decisions, as well as to learn and teach students, when they are not exhausted.

Specific Comments:

- The 5-hour "nap" is not realistic, due to logistic and financial reasons. I think, as many others have probably already noted, that the 5-hour sleep requirement is unrealistic within a program that is based on overnight call. I know that some programs have tried to accomplish this with a hospitalist or other person that admits after midnight, but you are still responsible for care of the patients on your own service. Frankly, if this is the goal, I think the only way to accomplish it is to move towards a night float system across the board (which I personally support). Maybe that should be the way to frame it in the report ; I am worried that, as it stands, most programs would simply dismiss this recommendation outright as impossible.

- The 4-day limit of night shifts seems excessive. I do not think it is necessary for there to be a 4-day limit on night shifts – 5 days in a row is common to many programs and works nicely (most programs I know of still offer night-float residents weekend days off, a 48-hour period.) If it is limited to 4 days, then that weekend is in jeopardy and you start having random days off during the week, which is less desirable. A 5-day limit would be more appropriate.

- There might be special circumstances where averaging maximum in-hospital on call frequency of every third night should be considered. I do not know if people have thought about it, but if we are not able to average calls, it will have large implications for the ability of most programs to allow residents to spend holidays with their families. Most programs I know of tend to allow residents to have call every other night for a period of one week, so that every resident can have the week of either Christmas or New Year's to spend with their families. While this call stretch is grueling, it is much appreciated to be able to have that vacation time during the holidays.

COMMITTEE ON MEDICAL LIABILITY AND RISK MANAGEMENT

General Comments:

Continued cutbacks in resident hours will erode the learning experience and create a generation of pediatricians who are ill-equipped to manage sick infants and children. Continuity of care has already suffered greatly. In neonatology, the complexity of care continues to escalate, while the resident experience and expertise diminishes, leaving a huge gap to be filled by mid- and upper-level care providers. Unless the total length of training is increased to make up for this difference, short-term gains from less fatigue will be far outweighed by long-term disasters.

SECTION ON NEPHROLOGY EXECUTIVE COMMITTEE

Specific Comments

- The IOM/ACGME report is not balanced and further research, and better evidence is needed to support their recommendations.

- The recommendations regarding a maximum shift length of no more than 30 consecutive hours (with 5 hours sleep) is reasonable, but not being able to admit after 16 consecutive hours is not appropriate. The current state of the pediatric workforce and its financial capability is not able to support the second portion of the recommendation.

- Greater consideration to and implementation of a night float system should be addressed.

- The IOM recommendations do not address how non-direct patient work such as conferences and other teaching rounds factor into the 80-hour work week. In many cases, these rules are not applied and enforced consistently. These rules need to be clarified since teaching time has already been minimized, and that has limited educational opportunities.

- Many of the new recommendations by the IOM/ACGME are very vague and not individualized. Specific guidelines need to be made for different training levels and would suggest the following levels:
    - intern
    - 2-3 year resident
    - 1st year fellow
    - 3rd year fellow

- The issue and emphasis of improving overlap/communication cannot be overstated. The IOM/ACGME is appropriate in recommending the development of specific guidelines regarding this issue. They would be beneficial from a practice perspective and set a precedent that proper handover care/communication is a vital component of the care process.

- Consideration must be given to the effect of any rule implementation on faculty. The IOM/ACGME needs to consider the effect of their actions on the (shrinking and aging) faculty.

- The statement about obtaining additional resources to finance the recommended changes is alluded to, but should be directly supported within the document.

- The moonlighting recommendation is one that is likely to be accepted rapidly.

COMMITTEE ON PEDIATRIC EDUCATION

General Comments:

- The committee proposes several recommendations that should be considered as a package and implemented in concert. The recommended parameters concerning the reduction in duty hours and fatigue mitigation are particularly intertwined. Not only would the benefits of these duty hour parameters be less likely to materialize if they are implemented piecemeal and in a disjointed fashion, but also unintended and potentially harmful consequences could result without the accompanying committee recommendations on workload and funding.

  For example, if duty hours are reduced again but workload remains at current levels, residents will be under greater stress as they rush to complete work, which increases the likelihood of making errors and could further reduce the amount of time they have for educational activities. This could negatively impact the safety of both current and future patients. The potential benefits to society of well-trained physicians and fewer people suffering from preventable adverse events argue for all funders of graduate medical education to contribute appropriately to support these graduate medical education reforms.

- Issues of improved oversight, compliance measures, and handoff safety are very important and should continue to be better developed, described, and disseminated. We cannot minimize these principles while we look at some of the harder specific recommendations.

- This IOM report is a bit curious in that some elements are very proscriptive and potentially restrictive to creative solutions in GME training and scheduling (specifics like the 5-hour night nap, limit on days of float, etc.).

- Overall the report speaks to necessary changes to ensure patient safety and reasonable working conditions for residents.

- Other than comments below, strong support for the report's overall and specific recommendations.

Specific Comments:

- Several elements have some relative weak basis in data/evidence that may not be applicable (from other industry, etc.) and in implementation have potential consequences to education and safety as they are generalized to hundreds of different institutions and programs. They will also be a challenge to implement, oversee, and administer.

- There is not a present or near-future workforce available or funding in place to meet these needs in what would equate to a 25% reduction in resident available time/workforce. We cannot examine GME in a vacuum, and if these hours are important for trainees, then faculty, NPs, and others should also be held to these standards. Thus, while well-intentioned, the AAP must question if these potential gains will be realized while implemented (as a example of the IOM prescription for GME like a new medication: how do we go from an ideal research setting out into the field, from efficacy to effectiveness, and how do we do Phase 4 and post-marketing surveillance?)

- There should also be some concern about preparedness for practice, length of training, and potential need for funding if this created trainees who, by our own competency standards, could not be ready for graduation in 3 years of pediatrics. The timing is interesting in an era in which the ACGME is asking for more documentation, more oversight, and more faculty time. Yet the residents will be present less, and the faculty will be picking up slack and potentially not be present or invested in teaching or advancing important competencies the AAP, ACGME, and others have tried to implement.

- If more duty hours restrictions occur before the financial piece is worked out then there might be hospital pressure to discontinue residencies. The tracking that will be needed and money to finance these changes might cause administrators to use the same money and find solutions that do not include residents especially places that are above the cap already. Even in the new IM RC requirements for July 2009, the caps are lower for residents, and therefore teaching teams are smaller with the same resident complement.

- The recommendation on the 16-hour limit may pose considerable problems for some programs; while the principle is fully justifiable, discussion should include the need to consider how patient care can be maintained with a 16-hour limit.

- I agree with the concept encompassed in the night float requirement, but the variations that occur with night float versus the other duty hour requirements are all different. Four nights per week versus 5 nights per week do not seem evidence based. There is also less evidence for 5 days off per month versus 4.

COMMITTEE ON PEDIATRIC EMERGENCY MEDICINE COMMENTS

General Comments:

- We share the concern of many that these recommendations are primarily concerned with fatigue and its effect on patient safety, and do not address the concern of the increase in hand-offs that will occur that are also detrimental to patient safety. Supervision of residents is important and not stressed to the same degree as shift length and fatigue.

- As Osler said, "Medicine is learned by the bedside and not in the classroom . . . See, and then reason and compare and control. But see first." The recommendations continue to decrease the amount of clinical exposure that our trainees receive in their residencies. Will duty hours necessitate an extension of the residency training period?

- The cost of introducing these recommendations is great. Other sources of staffing and funding must be found and developed in a short period of time.

- Continuity of care and observation of the natural history of disease will suffer. Not all learning can be done in short shifts.

Specific Comments:

- The recommendations should have little or no impact on emergency medicine training as shift work is the norm, and 60-hour work weeks are the maximum allowed; in fact, if fatigue is the major concern, we should be advocating for shorter shifts in this high-acuity area.

- We await interpretation of the need for 48 hours off after 3 or 4 nights of consecutive in-hospital night duty. Does this apply to consecutive 8 or 12 hour overnight ED shifts?

- The major concern for emergency medicine training is the possibility of having fewer trainees as they are shifted to staff inpatient services to adhere to these new guidelines; "resource allocation" may be detrimental to emergency medicine training and staffing.

- Another concern is that we count on the residents learning about the natural progression of acutely evolving disease processes during their inpatient rotations; these new recommendations may not allow for continuity of care.

- A specific recommendation is to provide public transportation vouchers or taxi transportation at the end of a shift. An alternative would be to provide a place for residents to sleep without interruption.

COMMITTEE ON PEDIATRIC RESEARCH

General Comments:

- It is not clear from the report what the evidence base is that the proposed changes will improve safety. Is it possible the disruption in continuity of care will prove to be more of a safety risk?

- The report recognizes the need to monitor the implementation of the changes, but fails to discuss the need to also monitor the outcomes of the changes. COPR feels the changes should be implemented on a trial basis and that the outcomes should be systematically monitored to see if the changes are having their desired effect.

- More attention needs to be paid to carryover impact of the changes on attending physicians and mid-level providers.

- COPR is concerned about the impact of the changes on resident education related to research. The changes will make it more difficult for residents to be exposed to meaningful research seminars, classes, and mentorship experiences. Reduced contact with research mentors and leaders may add to the growing problems of not enough residents receiving meaningful research experiences and not enough residents interested in academic careers.

COMMITTEE ON PRACTICE AND AMBULATORY MEDICINE

General Comments:

- COPAM wonders if there is evidence that these measures will actually improve the educational experience of the resident and improve patient care enough to balance the cost to training programs and administrative headaches.

- COPAM questions whether training programs have the tools to accomplish what is intended by restricting duty hours. For example, how will programs assess whether a resident is too sleepy to drive, how much time is adequate for patient workups, how much resident supervision is required, etc. And while additional time for sleep is granted, there is no guarantee that residents will actually sleep, rather than spend time with family or friends.

- Another concern is how the added cost to hospitals and training programs for these new recommendations will be met within the 24-month implementation time period. Many hospitals are adding extra hospitalists and allied health practitioners to their staff to provide 24/7 coverage of their inpatient units in the absence of housestaff. Other programs are slowly increasing the size of their residency training programs, within the guidelines of the ACGME, in order to make up for the shortfalls in resident coverage. Attending faculty are also being called upon to spend additional overnight and weekend time in the hospital, another potential added cost to these programs. The extent to which these added costs are then passed along as increased charges, ultimately burdens individuals, insurance companies and the government, thereby requiring much longer than 24 months to implement these changes in their systems.

- COPAM's final concern is the impact of these guidelines on the residents' training time spent in direct patient care. Residents who come out of programs with these new guidelines may have less experience and overall knowledge. Trainees in surgery are likely to require additional proctoring and on-the-job training. While this document attempts to address some of these issues, the primary way to gain experience is through direct care of patients. COPAM wonders if residency training duration will have to be increased to account for the decreased time in patient care resulting from duty hour restriction. Certainly, the ACGME and other relevant agencies will be responsible for tracking the outcomes of these changes in training and their impact on quality of care, within training programs, and following their completion.

COUNCIL ON SPORTS MEDICINE AND FITNESS

General Comments:

The Council on Sports Medicine and Fitness Executive Committee feel that these recommendations are overly ambitious, will require a significant increase in cost to the programs through need for increased administrative staff, as well as housestaff. In addition, our group is concerned that by severely limiting the number of extended hours housestaff can work, we are not adequately preparing them to work under conditions of fatigue when it is necessary as an attending physician. Finally, one member was concerned that the statement that duty hours must not exceed 80 per week, should not be averaged over 4 weeks.

The IOM report's recommendations would be nice in an ideal world. Two overall problems as I see it are:

- There will need to be a large influx of funding for more resident coverage.

- There will be a decrease in the educational value of the current 3-year residency. Programs would need to go to a 4-year term to achieve the educational goals (it is hard enough now with the current limits).

Specific Comments:

- Who is going to fund the taxis to take residents home (especially in large cities or rural areas)?

- If you include moonlighting into the 80-hour work limit, then in most cases, moonlighting will become extinct, which some programs and residents alike count on for support and extra income.

- It is unrealistic to think a resident can drop everything and go lie down for 5 hours in the middle of an extended shift. This time would be cut down to ~3 hours in most cases.

- The night float should be limited to 5 nights (not 4) to allow for a 5-day work week. The residents will have 12 hours off in between shifts which is more than their counterparts.

Response to the Institute of Medicine *Resident Duty Hours: Enhancing Sleep, Supervision and Safety.*

BY THE COUNCIL ON RESIDENT EDUCATION IN OBSTETRICS AND GYNECOLOGY (CREOG)

FROM THE AMERICAN COLLEGE OF OBSTETRICIANS AND GYNECOLOGISTS (ACOG)
FEBRUARY, 2009

I. Impact of implementation of the recommendations on OB/GYN residency training—

Background:

The primary purpose of an OB-GYN residency training program is to prepare physicians in training to be independent practitioners of obstetrics and gynecology. To do so, residency training must mimic the practice of obstetrics and gynecology. To be competent and safe physician, an OB-GYN must acquire a wide variety of knowledge and skills. Perhaps more than any other discipline, obstetrics requires a physician to be prepared to deliver care on a twenty four hour basis. To deliver safe care, an obstetrician must be prepared to follow a woman in labor at any time of the day or night. An obstetrician must be prepared and able to make decisions rapidly at any time.

To deliver safe care, an obstetrician must be able to balance his or her own physical needs, including the need for sleep, with the needs of patients in labor. Resident physicians must learn when they can and can not deliver safe care. They should not be required to work beyond the time that they can deliver safe care. Recognizing this dilemma, OB/Gyn residency programs have led the way in reducing work hours and sleep deprivation. The first description of a method to reduce sleep deprivation and work hours in residency was in an OB/Gyn residency and published in an OB/Gyn journal.

The CREOG Committee on Education strongly agrees that residents must have adequate rest and supervision in order to learn effectively and give safe care. However, we must consider the impact of work hour restrictions on resident learning, on preparation for independent practice and on patient safety. The Institute of Medicine has conducted a thoughtful, thorough investigation of resident's work hours and has made specific recommendations for changes in resident work hours. We believe that implementation of these recommendations may have unintended consequences on resident education, patient safety, and preparation for independent practice in obstetrics and gynecology.

All OB/GYN programs provide coverage for Labor and Delivery on a continuous basis. To provide adequate experience in complicated obstetrics and emergency gynecology, residents must have access to cases on a 24 hour basis. OB/GYN residencies predominately use either a "night float" system or an "extended duty" (call) system, or a combination of the two. Many residencies use a "night float" system during weekdays and an extended duty system on weekends. OB/GYN residencies often have complex schedules built around Labor and Delivery, clinic, and OR schedules; as well as scheduled didactic time. Many of these schedules are fixed by the day of the week. Operating room days are usually fixed by day of the week, and clinic schedules are built around a Monday-Friday schedule. Scheduled didactic time is usually tied to the weekly calendar. Current work hour requirements are tied to a weekly calendar. A schedule must be adaptable to a weekly calendar to be implemented in an OB/GYN residency.

There are currently 249 accredited residency programs in obstetrics and gynecology with 4,911 filled slots, an average of approximately 20 residents per program, or 5 per year. Many OB/GYN residencies have four or five residents per year. In most residencies, time is equally divided between obstetrics and gynecology, with time further divided between office practice and hospital time. It is typical for a program to have three residents assigned to Labor and Delivery at a time, with handoffs occurring twice per day. Schedules must be arranged so that there is continuous coverage for admissions to Labor and Delivery for residents to obtain adequate experience in obstetrics. In most OB/GYN residencies, the vast majority of hospital admissions are of laboring women. Unlike some other training programs, the majority of work and experience in Labor and Delivery does not come from admissions of laboring patients, but from following laboring women and performing deliveries and cesarean sections.

II. Impact of implementation of specific IOM recommendations on education in OB/GYN residency programs--

We wish to examine the impact of specific recommendations of the IOM that are changes from 2003 ACGME and OB/GYN RRC policies. These are summarized as follows:

- **Scheduled continuous duty periods must not exceed 16 hours unless a 5-hour uninterrupted continuous sleep period is provided between 10 p.m. and 8 a.m. This period must be free from all work and call, and used by the resident for sleep in a safe and sleep-conducive environment. The 5-hour period for sleep must count toward total weekly duty hour limits. Following the protected sleep period, a resident may continue the extended duty period up to a total of 30 hours, including any previous work time and the sleep period.**
- **Residents should not admit new patients after 16 hours during an extended duty period.**
- **Extended duty periods (e.g., 30 hours that include a protected 5-hour sleep period) must not be more frequent than every third night with no averaging.**
- **After completing duty periods, residents must be allowed a continuous off-duty interval of**
    - **A minimum of 10 hours following a daytime duty period that is not part of an extended duty period,**
    - **A minimum of 12 hours following a night float or night shift work that is not part of an extended duty period, and**
    - **A minimum of 14 hours following an extended duty period; and residents should not return to service earlier than 6 a.m. the next day.**
- **Night float or night shift duty must not exceed four consecutive nights and must be followed by a minimum of 48 continuous hours off duty after three or four consecutive nights.**
- **At least one 24-hour off-duty period must be provided per 7-day period without averaging; one additional (consecutive) 24-hour period off duty must be provided to ensure at least one continuous 48-hour period off duty per month.**

III. OB/GYN residencies use either a "night float" system or and "extended duty" system. We will examine the impact of the recommendations on these two systems--

Extended duty:

In an extended duty system, a resident could not work longer than 16 hours without a 5 hour rest period and could not admit new patients after 16 hours. Laboring patients are admitted on a 24 hour basis. Implementation of this recommendation in Labor and Delivery would require that two residents cover a call slot each night – one could admit patients for 16 hours (0700 -2300), then sleep for 5 hours (2300 – 0400) and then could care for laboring patients again until 1300. It is not clear if the resident could accept care of laboring patients admitted by someone else, or if the resident would then need to perform other duties (such as clinic) the next morning.

At 2300, another resident or other non-resident provider would have to accept responsibility for admissions and care of laboring patients. If it is another resident, that person would have to begin their shift in the evening in order to be able to admit patients for at least 16 hours. If a resident is to be able to admit patients until 0800 and cannot admit patients for longer than 16 hours, that person would have to begin work no earlier than 1600. That person would then be on a "night" shift.

Functionally, implementation of this requirement would mean that a resident could not be primarily responsible for Labor and Delivery for longer than 16 hours. It would eliminate the use of extended duty shifts to cover Labor and Delivery, and functionally force programs to adopt a "night float" system.

Night float systems:

To implement the IOM recommendations in a night float system, residents would have to work no more than 4 nights followed by 48 hours off duty. Residents would have to have 12 hours off duty after a night float shift. This would mean that "handoffs" in Labor and Delivery would have to occur every 12 hours. In order to give adequate time for hand-offs and meet the requirements for 12 hours off duty, the "handoffs" would have to occur during the "day" shifts hours. Thus the day shift would have to be a

For example, this means that if the night float resident works from 1900 – 0700, then hand-offs (or board rounds) would have to be scheduled at 0630 and 1900 to allow 30 minutes for the handoff. This means that the "day" shift would be from 0630 to 1930, a total of 13 hours. The day shift would then have 11 hours off (meeting the required 10 hours off).

However, after 4 days the "night float" residents would have a 48 hour period in which they did not work. This means that other residents would have to cover the two nights not covered by the night floats. These would be a different two nights every week. As shown above, these could not be covered by an extended shift in Labor and Delivery.

IV. Mechanisms required to meet the recommendations--

1. Assign two residents to each night float rotation.

By assigning two residents to each night float rotation for Labor and Delivery, one resident could work for 4 nights and another work for 3 nights. The resident who worked the 4 nights would then have 48 hours off, and could then be available for a "short shift" one day before repeating the week. The other resident would work 3 nights, be off 48 hours, and then be available for 2 "short shifts" the next week. The schedule is shown below:

Resident	Mon	Tues	Wed	Thurs	Fri	Sat	Sun
A	12 hr NF	12 hr NF	12 hr NF	12 hr NF	off	off	13 hr day
B	off	off	13 hr day	13 hr day	12 hr NF	12 hr NF	12 hr NF
C	13 hr day	13 hr day	Other duty	Other duty	13 hr day	13 hr day	

Resident A would work 61 hours and have 48 hours off. Resident B would work 62 hours and have 48 hours off. Both residents would have the required 12 hours off after a night shift and 10 hours off after a day shift. Resident C would work less than 80 hours per week if the other duty was less than 14 hours, have one day off per week and be available for other duty (clinic, operating room) two days per week.

Compared to a traditional night float schedule with extended calls on the weekend, such a system requires that one additional resident be assigned to cover labor and delivery each week. (See below)

Resident	Sun	Mon	Tues	Wed	Thurs	Fri	Sat
A	14 hour night float	14 hour night float	14 hour night float	14 hour night float	14 hour night float	off	off
B	11 hour day	11 hour day	11 hour day	11 hour day	11 hour day	24 hour	off
C	off	Other duty	Other duty	Other duty	Other duty	Other duty	24 hour

The net result of implementing that system will be that residents will be assigned to obstetrics for more rotations, and time on office practice and gynecology will be decreased. Residents will not get more experience in obstetrics.

2. Use extended shifts with no admissions after 16 hours.

This requires that a resident could spend no more than 16 hours primarily responsible for Labor and Delivery. After 16 hours, another resident would have to be available to admit patients. If a resident is to be available for admissions 24 hours a day, and the length of time an individual resident can admit patients is limited to 16 hours from the beginning of the shift, and a resident on an extended shift must have five hours of sleep between 2200 and 0800, then some resident will have to be responsible for admissions beginning at 2200. If that resident then must have sleep from 0300 – 0800, then another resident must be available for admissions beginning at 0300.

For a resident (A) to have 16 hours available to admit patients and have 5 hours off beginning at 2200, that resident's shift would have to begin at 0600. That resident would then have to have 5 hours to sleep between 2200 and 0300. They then could work until 1200 but could not admit patients. They could then have 14 hours off and be required to return to work as early as 0200 the next day. That resident could conceivably then cover admissions from 0300 – 1100.

Another resident (B) would then have to be available for admissions at 2200. If that resident covers admissions until 0300 and then must sleep from 0300-0800, then a third resident (C) would have to be available from 0300 – 0800 for admissions. For a resident (C) to have 16 hours available to admit patients and have 5 hours off beginning at 0300, that resident's shift would have to begin at 1100. That resident could then work from 0800 until 1700 (nine hours), have 14 hours off and could return to work at 0700. If a resident covers admissions from 0300 - 0800, and they can sleep from 2200 until 0300, they will have to begin their shift no earlier than 1600 in order to stop being responsible for admissions at 0800 (16 hours). They then could work until 1700.

For a resident to be available to cover admissions beginning at 0300, that resident would either have to begin a "short shift" at 0300 (with time for checkout), meaning that the resident could work until 1500; or an "extended duty" shift. That resident could then cover admissions until 1900 (16 hours) but would then have to have 5 hours to sleep. However those five hours would not be between the recommended 2200-0800 time period. Alternatively, that resident could begin work no earlier than 1600 and cover admissions until 0800, sleep for five hours (until 1300), and then complete nine hours (until 2200). Again, the required five hours of sleep would not occur between 2200 and 0800.

To cover with an extended shift system, there would have to be a minimum of two or three residents on call each night to cover admissions. If only two residents are used, one would have to begin a shift at 1600 in order to be able to admit until 0800. Since a resident could not take an extended shift more often that every three days, it would require nine residents to be available in a "call pool" to cover admissions on a 24 hour basis.

Resident	Mon	Tues	Wed	Thurs	Fri	Sat	Sun
A	Admit 0600 – 2200, sleep 5 hrs (2200-0300	Other 0300-1200	10 hr	10 hr	Admit 0600 – 2200, sleep 5 hrs (2200-0300	Other 0300-1200	Off
B	Admit 1100 – 0300,	sleep 0300-0800, other duty 0800-1700	Off	Admit 0300 – 0800, other duty 0800-1300	10	30 (16+5 hr sleep)	
C		Admit 0300 – 0800, other duty 0800-1300					
D		Admit 0600 – 2200, sleep 5 hrs (2200-0300	Other 0300-1200	10 hr	10 hr	Admit 0600 – 2200, sleep 5 hrs (2200-0300	10

As can be seen, it is virtually impossible to design a call system to cover admissions on a 24 hour basis using an "extended duty" system. It is only possible to do so by having residents assume duty at odd times – such as 1400 or 0300, or by using "swing shifts" where residents work some night shifts and some day shifts every week.

3. "Hybrid" systems".

It would be possible to assign a "night float" resident to be responsible for admissions between 2200 and 0800, with one or more other residents assigned to "extended duty" calls who did not admit patients between 2200 and 0800. Those residents could then care for laboring patients when they were not sleeping, and could presumably assume care of patients when their sleep time was over. This would require that the care of laboring patients be transferred at 2200, 0300, and 0800 (and presumably in the evening), thus increasing the number of handoffs and the potential for error.

V. Impact of the above systems on resident education--

The net result of implementing the recommendations of the IOM will be to force residencies into a "night float" system AND to increase the number of residents assigned to night call. As a result, residents will spend more time on night duty and less time on day duty. Of necessity, daytime rotations will be decreased. The net result on resident education will be to increase service over education.

It can be argued that admissions between 2200 and 0800 should be covered by non-resident providers, such as attending physicians or allied health care providers. To do so in teaching hospitals would require hiring additional providers and require shifting duty of attending physicians from teaching to service. Given the current economic realities facing teaching hospitals, it is highly unlikely that there will be funds available to hire these people. Even if such funds were available and such people assumed these duties, it would increase the number of handoffs required. In addition, it would decrease the experience of resident physicians.

VI. Alternative suggestions for reducing work hours and sleep deprivation in OB/GYN residencies--

The CREOG Education Committee agrees that it is important to increase patient safety and to decrease resident sleep deprivation. The committee would like to suggest alternatives to the IOM recommendations as follows:

1. Work hours should be strictly limited to 80 hours per week.

2. Extended duty shifts should be limited to 25 hours without exception, with 23 hours off after an extended duty shift.

3. Extended duty shifts must occur no more often than every 3 nights without averaging.

4. Night shifts should be limited to 13 hours, with 11 hours off duty between shifts.

5. No more than 5 night shifts may be taken in a row, with at least 46 hours off after 5 night shifts.

6. A minimum of 10 hours off must occur after any other duty period.

Submitted to CMSS by:

J. Chris Carey, MD
CREOG Education Committee,

Jessica Bienstock, MD,
Chair- CREOG Education Committee

Sterling B. Williams, MD, MS
ACOG Vice President for Education
Director of CREOG

CORD
Council of
Emergency Medicine
Residency Directors

May 1, 2009

Thomas J. Nasca, MD, MACP
Chief Executive Officer
Accreditation Council for Graduate Medical Education
515 North State Street, Suite 2000
Chicago, IL 60654

Dear Dr. Nasca:

Thank you for inviting the Council of Emergency Medicine Residency Directors (CORD) to participate in the review of the Accreditation Council for Graduate Medical Education's (ACGME) standards for resident duty hours and key dimensions of the learning environment.

CORD joined with seven other emergency medicine professional organizations to produce a consensus paper regarding these issues, and strongly supports and endorses the attached collaborative consensus paper on behalf of emergency department patients and emergency medicine chairs, program directors, faculty, and residents.

If invited, CORD would be pleased to participate in the ACGME Resident Duty Hours and Learning Environment Congress in June 2009, in Chicago, Illinois.

Sincerely,

Mary Jo Wagner, MD
President

MJW:bam

Enclosure

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UNIVERSITY OF
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Medical Center

DEPARTMENT OF EMERGENCY MEDICINE

NEBRASKA'S HEALTH SCIENCE CENTER

May 1, 2009

Thomas J. Nasca, MD, MACP
Chief Executive Officer
Accreditation Council for Graduate Medical Education
515 North State Street, Suite 2000
Chicago, IL 60654

Dr. Nasca:

Thank you for inviting the Emergency Medicine-RRC to participate in the review of the Accreditation Council for Graduate Medical Education's (ACGME) standards for resident duty hours and key dimensions of the learning environment.

The EM-RRC joined with seven other emergency medicine professional organizations to produce a consensus paper regarding these issues, and strongly supports and endorses the attached collaborative consensus paper on behalf of emergency department patients and emergency medicine chairs, program directors, faculty, and residents.

Sincerely,

Robert L Muelleman

Robert L Muelleman
Chair, EM-RRC
Professor and Chairman
Department of Emergency Medicine
University of Nebraska Medical Center
Medical Director
Emergency Medical Services
The Nebraska Medical Center

S
A
E
M

Society for Academic Emergency Medicine

May 1, 2009

Thomas J. Nasca, MD, MACP
Chief Executive Officer
Accreditation Council for Graduate Medical Education
515 North State Street, Suite 2000
Chicago, IL 60654

Dear Dr. Nasca:

Thank you for inviting the Society for Academic Emergency Medicine (SAEM) to participate in the review of the Accreditation Council for Graduate Medical Education's (ACGME) standards for resident duty hours and key dimensions of the learning environment.

SAEM joined with seven other emergency medicine professional organizations to produce a consensus paper regarding these issues, and strongly supports and endorses the attached collaborative consensus paper on behalf of emergency department patients and emergency medicine chairs, program directors, faculty, and residents.

If invited, SAEM would be pleased to participate in a Resident Duty Hours and Learning Environment Congress in June 2009, in Chicago, Illinois.

Sincerely,

Katherine L. Heilpern, MD
President

901 N. Washington Ave • Lansing, MI 48906 • (517) 485-5484 • Fax (517) 485-0801
2009 Annual Meeting, May 14 - May 17, New Orleans, LA

American College of Emergency Physicians®
ADVANCING EMERGENCY CARE

May 1, 2009

Thomas J. Nasca, MD, MACP
Chief Executive Officer
Accreditation Council for Graduate Medical Education
515 North State Street, Suite 2000
Chicago, IL 60654

Dear Dr. Nasca:

Thank you for inviting the American College of Emergency Physicians (ACEP) to participate in the review of the Accreditation Council for Graduate Medical Education's (ACGME) standards for resident duty hours and key dimensions of the learning environment.

ACEP joined with seven other emergency medicine professional organizations to produce a consensus paper regarding these issues, and strongly supports and endorses the attached collaborative consensus paper on behalf of emergency department patients and emergency medicine chairs, program directors, faculty, and residents.

If invited, ACEP would be pleased to participate in a Resident Duty Hours and Learning Environment Congress in June 2009, in Chicago, Illinois.

Sincerely,

Sincerely,

Nick

Nicholas J. Jouriles, MD, FACEP
President

Copy Dean Wilkerson, JD, MBA, CAE

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May 1, 2009

Thomas J. Nasca, MD, MACP
Chief Executive Officer
Accreditation Council for Graduate Medical Education
515 North State Street, Suite 2000
Chicago, IL 60654

Dear Dr. Nasca:

Thank you for inviting the American Academy of Emergency to participate in the review of the Accreditation Council for Graduate Medical Education's (ACGME) standards for resident duty hours and key dimensions of the learning environment.

The American Academy of Emergency Medicine joined seven other emergency medicine professional organizations to produce a consensus paper regarding these issues, and strongly supports and endorses the attached collaborative consensus paper on behalf of emergency department patients and emergency medicine physicians and residents.

If invited, the American Academy of Emergency Medicine would be pleased to participate in a Resident Duty Hours and Learning Environment Congress in June 2009, in Chicago, Illinois.

Sincerely,

Larry D Weiss

Larry D. Weiss, MD JD FAAEM
President

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Emergency Medicine Training, Patient Safety and the Effect of Duty Hours Regulations

The emergency medicine (EM) community is pleased to have been invited by the Accreditation Council for Graduate Medical Education (ACGME) to provide a review of the standards for resident duty hours and key dimensions of the learning environment.

This request is in response to both a planned five year review of the 2003 resident duty hours standards and the Institute of Medicine's (IOM) 2008 report, "Resident Duty Hours: Enhancing Sleep, Supervision and Safety." (1)

Representatives from the following emergency medicine organizations developed this consensus document on these important aspects of our educational programs. These organizations represent a total of 187 allopathic and osteopathic emergency medicine residency programs training approximately 5,700 residents annually.

American Academy of Emergency Medicine (AAEM)
Association of Academic Chairs of Emergency Medicine (AACEM)
American College of Emergency Physicians (ACEP)
American College of Osteopathic Emergency Physicians (ACOEP)
Council of Emergency Medicine Residency Directors (CORD)
Emergency Medicine Residents Association (EMRA)
Residency Review Committee of Emergency Medicine (RRC-EM)
Society for Academic Emergency Medicine (SAEM)

Background:

As one of the youngest medical specialties in the ACGME, emergency medicine has been a progressive leader in providing innovative graduate medical education (GME). Emergency medicine recognized early on that GME is a balance among **patient safety**, **resident wellness** and resident **training experience**. Within this balance EM established that resident duty hours and supervision are integral aspects affecting all three of these elements.

For more than twenty years, EM has taken steps to improve patient safety through faculty supervision and resident duty hour requirements via the ACGME/ RRC-EM's special program requirements. In the early years of EM training it was common to have resident-only coverage of emergency departments (ED) on weekends and nights. While this was an improvement from years prior when there were no physicians with any EM training, many patients in the ED were still seen and discharged without any faculty supervision. Difficulties with diagnosis, emergency procedures, and resuscitation during these 'off-hours' often had no faculty input or involvement.

In the late 1980s, in an effort to improve patient safety and residency training experience, the RRC-EM became the first specialty to modify the program requirements to require full-time in-hospital faculty supervision. Today all residents in the ED are supervised by board certified (or working toward achieving their board certification) emergency physicians twenty-four hours a day, seven days a week. It is rare for a patient to not be physically examined by an attending physician in a contemporaneous fashion, and all but minor procedures are actively supervised. More recently, guidelines were developed to require a minimum ratio of faculty staffing hours per patient volume to assure an adequate number of faculty for supervision and teaching in the ED.

Emergency medicine residency programs accredited by the ACGME also have almost twenty years of experience utilizing more stringent duty hour regulations for EM rotations. In 1990, the RRC-EM mandated that residents rotating in the ED must have an average of one day in seven free of all clinical and educational requirements. Noting that ED shifts are often eight to twelve hours long, frequently require constant, non-stop care, and recognizing that adequate sleep and resident wellness is critical, the RRC-EM further defined acceptable EM duty hours. Based on a consensus of EM educational leaders, the concept of equivalent time off between shifts was determined a reasonable expectation. At the same time, the length of ED shifts was limited to no more than twelve continuous scheduled hours with an equivalent period of continuous time off between scheduled work periods. Currently, the RRC-EM understands there needs to be a modest amount of time for residents to sign out at the end of each shift, so a limited time after the twelve hour shift is allowed for the safe transfer of patient care.

In 1995, additional EM specific duty hour requirements were implemented to further balance patient safety, resident wellness, and the residents' training experience. Assuming five consecutive twelve-hour shifts, a tacit agreement existed at that time that sixty hours was a reasonable maximum clinical load. These hourly requirements were formalized by the RRC-EM and were not to be averaged over multiple weeks. As didactic sessions are considered critical for resident education and with the understanding that didactic time is not as stressful as clinical duty, an exception was made for didactics time. Since then, the RRC-EM has limited EM residents to sixty hours per week working clinically in the ED with a maximum of seventy-two hours per week duty hours including all didactics and other educational activities. In January 2005, additional refinements were made to the EM program requirements to formalize these tacit agreements with respect to duty hours in the ED.

Finally, the specialty of emergency medicine and EM training programs recognized that off- service rotations require different intensity, have different expectations and requirements and that the ideal situation was to have EM residents treated the same as residents in other specialties. Emergency medicine does not expect that requirements appropriate in the ED are necessarily appropriate for other specialties. Because of these considerations, the RRC-EM has stated that duty hours and supervision requirements for EM residents on non-EM rotations were subject to the requirements of the RRCs in those other specialties.

With this history as a backdrop, as representatives of the specialty of EM and EM graduate medical education, we have provided the ACGME with the requested position paper on resident duty hours, including the recent 2008 IOM recommendations. We intend to address these recommendations with respect to patient safety, resident wellness and the resident training experience through the lens of emergency medicine. Finally, we included a brief discussion on the perceived financial impact of the 2008 IOM duty hour recommendations.

Patient Safety

Resident Supervision: The IOM made the following recommendation regarding resident supervision.

> **IOM Recommendation:** To increase patient safety and enhance education for residents, the ACGME should ensure that programs provide adequate, direct, onsite supervision for residents. The ACGME should require the Residency Review Committees, in conjunction with teaching institutions and program directors, to establish measurable standards of supervision for each level of doctor in training, as appropriate to their specialty; and first-year residents not to be on duty without having immediate access to a residency program-approved supervisory physician in-house.

For twenty years, the RRC-EM has mandated that residents be directly supervised twenty-four hours a day in the ED by the physical presence of attending physicians. While the degree of supervision decreases as a resident assumes progressive responsibility commensurate with their increasing competence, attending physicians are always immediately available in the ED to ensure that safe, appropriate, high quality emergency care is provided to all patients. This level of supervision also ensures that attending physicians are able to provide resident teaching twenty-four hours a day. Research has suggested that this increased supervision may improve patient safety. One study showed that direct supervision of residents in the ED is "significantly associated with better compliance with guidelines, regardless of level of training."(2) However, this study did not find that direct supervision improved patients' satisfaction with their experience. Patient safety was also improved by direct supervision of non-emergency medicine residents rotating in the ED. (3) Attending input into patient care by these residents "resulted in frequent and clinically important changes in patient care."

EM residency programs meet this IOM recommendation of resident supervision and have done so for many years. The specialty of emergency medicine believes that supervision of EM residents should be adequate, direct and on-site, regardless if the EM resident is working in the ED or training on another hospital service; supervision is especially important in clinical areas where the patient acuity is high and immediate supervision is often mandated for complex medical decision making. Other specialties should seek ways to meet the spirit of the IOM recommendation regarding resident supervision.

There are other IOM recommendations that may instead have negative effects on EDs and EM training programs. Instituted to improve patient safety, there is limited data to support the concept that duty hour restrictions do in fact have a significant impact on improving patient safety. To the best of our knowledge, there is no EM specific data that demonstrates improved patient safety as a result of duty hour restrictions.

Improving Handovers and Safety Reporting: The emergency medicine community agrees with the IOM in their concerns for patient safety and continuity of care with increased restrictions on resident duty hours.

> **IOM Recommendation:** Teaching hospitals should design, implement, and institutionalize structured handover processes to ensure continuity of care and patient safety. Programs should train residents and teams in how to hand over their patients using effective communications. Programs should schedule an overlap in time when teams transition on and off duty to allow for handovers. The process should include a system that quickly provides staff and patients with the name of the resident currently responsible in addition to the name of the attending physician.

Duty hour restrictions initiated in 2003 have raised concerns that the educational and patient care milieu may be more fragmented now. At both the student and resident level, multiple studies demonstrate there are more hand-offs of patient care resulting in less continuity of care. (4) We know that hand-offs in care represent a particularly dangerous time, placing patients at particular risk for medical error. In fact, a cohort of internal medicine residents report that failure to report important information during sign-out is one of the top five suboptimal patient care practices. (5) The high-risk nature of patient care transfers is well recognized and the Joint Commission has reported that nearly 70% of sentinel events arise from communication errors. Among these communication errors 50% occurred during hand-off of patient care (6), prompting the Joint Commission to provide specific recommendations to address the sign-out process. These recommendations have been published as part of the 2008 "National Patient Safety Goals" as a standard for improvement and prevention of medical error. (7)

Effects on Emergency Department Patients: Emergency medicine has concerns about the IOM recommendation that there be a sleep period for on-call residents.

> **IOM Recommendation:**
> Programs should design resident schedules using the following parameters: Scheduled continuous duty periods must not exceed 16 hours unless a 5-hour uninterrupted continuous sleep period is provided between 10 p.m. and 8 a.m. This period must be free from all work and call, and used by the resident for sleep in a safe and sleep-conducive environment. The 5-hour period for sleep must count toward total weekly duty hour limits. Following the protected sleep period, a resident may continue the extended duty period up to a total of 30 hours, including any previous work time and the sleep period. Residents should not admit new patients after 16 hours during an extended duty period.

If implemented on other services, emergency medicine is concerned that this recommendation will adversely and significantly impact patient safety and flow of admitted ED patients awaiting an inpatient bed.

Most academic teaching hospitals are configured in such a way that inpatient resident teams (e.g. internal medicine, general surgery, pediatrics, and OB/GYN) present in the ED to perform examinations and write admission orders. Unless additional personnel are added, a mandated five-hour sleep period will create a significant shortfall of resident workforce to complete the admission process. In many large tertiary academic centers, a dozen or more internal medicine or surgical residents may be working nights. The five-hour mandated sleep period would remove upwards of 50-60 resident physician work hours per night from the available complement of inpatient staff. Emergency departments already experiencing significant delays in the admission process and high levels of inpatients boarding in the ED would suffer greatest from this workload deficit resulting in a greater risk to patient safety. In June 2006, the IOM issued a report on the nation's emergency medical services and discussed ED crowding. From the June 2006, IOM report "Future of Emergency Care in the United States" (8):

> "…[When] patients cannot be transferred from the ED to inpatient units, this can lead to the practice of "boarding" patients—holding them in the ED, often in beds in hallways, until an inpatient bed becomes available. It is not uncommon for patients in some busy EDs to be boarded for 48 hours or more. These patients have limited privacy, receive less timely services, and do not have the benefit of expertise and equipment specific to their condition that they would get within the inpatient department.
>
> Another consequence of overcrowding has been a striking increase in the number of ambulance diversions. Once considered a safety valve to be used only in the most extreme circumstances, such diversions are now commonplace. Half a million times each year— an average of once every minute—an ambulance carrying an emergency patient is diverted from an ED that is full and sent to one that is farther away. In 2004, according to the American Hospital Association (AHA), nearly half of all hospitals—and close to 70 percent of urban hospitals—diverted patients at some point during the year. Each diversion adds precious minutes to the time before a patient can be wheeled into an ED and be seen by a doctor, and these delays may in fact mean the difference between life and death for some patients. Moreover, the delays increase the time that ambulances are unavailable for other patients."

Paradoxically, the current IOM recommendation on duty hours may exacerbate the very problems cited in the IOM report. Even when inpatients beds are available, if the admission process is delayed because some admitting teams are protected from service and are not available, the effect on patient flow is the same; ED crowding will worsen and contribute to the issues discussed in the June 2006 IOM report. ED crowding contributes to increased hospital length of stay, more frequent admission to extended care facilities by boarded patients and is associated with worsening patient outcomes. (9)

Critically ill patients requiring admission and specialty care present to the ED twenty-four hours a day. While the absolute gap in coverage may be less for some services such as orthopedics, neurosurgery or pediatrics, these services are critical to safe and timely patient care in the ED. Emergency medicine is very concerned that patient care in the ED may be compromised significantly if resident and fellow consultants are delayed because they have assumed additional patient care responsibilities from physicians who are in the protected five-hour period or cannot respond if they themselves are in a protected period. Consultations to the ED are almost always immediately required because of critical patient care issues. Patient care cannot always wait for a consultant from a specialty service to complete the recommended five-hour protected period.

In March 2009, there was a discussion at the CORD *Academic Assembly* regarding the IOM report and the impact the recommendations would have on EM programs. An informal poll of program directors indicated that many directors believed there would be a significant impact on patient care, in particular, boarding admitted patients in the ED, if further duty hour restrictions were implemented. The discussion led to the development of an informal on-line survey of EM residency directors on the subject of duty hour restrictions. Eighty-seven people responded to the survey representing over 50% of the emergency medicine residency programs. (10) Twenty-four percent of respondents noted that their EDs were already boarding admitted patients due to restrictions placed upon admitting residents. The program directors anticipated that boarding in the ED would only get worse and negatively affect patient safety.

Effect of ACGME 2003 Common Duty Hours Requirements on the ED: Because of the previously described efforts by the RRC-EM at improving resident supervision and patient safety through self-imposed duty hour restrictions, the 2003 ACGME common duty hour requirements seemed to have a minimum effect on ED rotations. However, they did result in considerable changes on off-service rotations as they struggled to meet the new requirements. One of the changes was that other specialties decreased the time their residents spent rotating in and learning emergency medicine. The loss of this emergency care education was chosen since these services needed to reallocate their workforce to cover their own inpatient care needs. Another ongoing impact of the 2003 duty hour restrictions is an increased difficulty in identifying the proper consulting resident physician due to the greater turnover of on-call specialty residents. Lastly, some surgical specialties that used to take night in-house call changed to at-home call. As a result these consultants often rely heavily on telephone assessments, placing patients at risk for diagnostic and management errors, as admissions too often either get shifted to other less appropriate services or just occur with telephone orders without a contemporaneous direct patient assessment. Anecdotal stories exist across all specialties about this type of impaired patient care but no published studies or cases are known regarding these changes.

Workload Adjustment: Another unintended consequence of the 2003 common duty hour requirements was an increase in ED crowding from the adjustment of resident workload; there is concern that the new IOM recommendations will lead to further crowding and compromise patient safety.

> **IOM Recommendation:** To ensure that residency programs fulfill their core educational mission, ACGME should require that institutions sponsoring residency programs appropriately adjust resident workload by providing support services and redesigning healthcare delivery systems to minimize the current level of residents' work that is of limited or no educational value, is extraneous to their graduate medical education program's educational goals and objectives, and can be done well by others; and providing residents

> with adequate time to conduct thorough evaluations of patients and for reflective learning based on their clinical experiences.
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> ACGME should require each Residency Review Committee to define and then require appropriate limits on the caseload (for example, patient census, number of admissions, number of surgical cases to assist per day, cross-coverage) that can be assigned to a resident at a given time, taking into consideration the severity and complexity of patient illness and the level of residents' competency.

The reduction in duty hours along with established caps on workloads has increased pressure on EDs and increased patient risk. As noted previously, much of crowding in the ED is due to holding inpatients for hours or days, while waiting for an available bed (a practice called boarding). Multiple scientific studies confirm that boarding inpatients is perhaps the greatest patient safety issue in the ED. (11-18) It has been shown to increase patient morbidity and mortality. The Joint Commission has documented that ED boarding is the cause of more than 15% of all hospital sentinel adverse events (31% of those occurring in the ED). (19) Despite the serious adverse events associated with boarding inpatients in the ED, the practice is common. In the recent survey of EM program directors, 76% said they boarded patients on a daily basis. (10) Of greater concern, 60% of all programs boarded patients when in-patient beds were available. Pertinent to this discussion, 24% of all programs boarded because house staff from the admitting service had reached their cap and the patient had to be held and cared for in the ED until the next day

Resident Wellness

The Merriam-Webster dictionary defines wellness as "the quality or state of being in good health, especially as an actively sought goal." This admittedly vague concept is difficult to quantify, leaving several authors to further define wellness into seven separate dimensions, including physical, intellectual, spiritual, emotional, environmental, vocational and social senses of satisfaction and health.

Globally, it seems intuitive that physician well-being is linked to professional performance and in turn to patient safety. Additionally, it seems logical that adequate rest and time for outside, restorative activities provide medical professionals with balance and therefore wellness. Unfortunately to date, these intuitions with respect to residency training have been poorly explored. Specifically, there are no clear definitions of physician balance or wellness, and research is lacking to support that their achievement and maintenance promote better care.

Assuming a link between wellness, performance, and patient safety does exist, the profession must also assume it exists in a balance, and that this balance is one society should strive to preserve in both the short-term setting of a resident's training and, more importantly, in the long-term setting of a physician's career since it impacts professional performance throughout a physician's working lifetime.

Short-term resident wellness is in part related to the quality of the work environment, length of duty hours, avoidance of fatigue and sleep deprivation through appropriate sleep cycles and adequate time for relaxation. The current ACGME requirements focus heavily on these components, with the belief that improving resident wellness ultimately leads to improved physician performance and patient safety. While this is surely true on one level, great concern exists among many medical educators that over-emphasis on duty hours and short-term wellness marginalizes GME programs' long-term responsibility to both trainees and society. These responsibilities include, but are not limited to, assuring over-all quality of training, total comfort and competence in clinical skills, minimal career stress, maximal career happiness, professionalism, and vocational ownership.

Effect of the IOM Recommendations on EM Rotations: As noted previously, almost all of the IOM proposed changes for duty hour restrictions would not change the scheduling of resident shifts in the ED. The RRC-EM requirements currently meet or exceed the limitations described by the IOM for maximum hours per week, maximum shift length, minimum time off between scheduled shifts, and mandatory time off duty.

Duty Hour Adjustments: The IOM recommendation suggesting that residents must be scheduled off for a continuous forty-eight hour period after working three or four consecutive night shifts would, however, have negative consequences for scheduling EM clinical shifts at many training programs.

> **IOM Recommendation:** Programs should design resident schedules using the following parameters: Night float or night shift duty must not exceed four consecutive nights and must be followed by a minimum of 48 continuous hours off duty after three or four consecutive nights.

Some EM programs schedule residents for a month or block of nights to limit circadian disturbances, while other programs have residents work a week or string of nights at a time. Limiting nights to just three or four in a row does not seem to be supported by EM sleep studies and will cause scheduling problems.

Much has been studied about work hours and circadian rhythms. It is generally agreed that it is healthiest for a person to have a routine diurnal circadian rhythm. In medicine, however, this regular schedule is not possible given healthcare needs are present 24/7. Night work requires the reversal of the diurnal sleep/wake schedule. The IOM recommendation that limits the night shifts to four consecutive nights is not beneficial for physicians working in an ED. It is known from the literature that night shift work is associated with health and safety risks. (20-21) Phase-shifting the circadian clock such that it is more aligned with night work and day sleep is one way to lessen these risks. However, it generally takes two weeks to change one's circadian rhythms to a nocturnal existence. Circadian entrainment to night shift work can be done more quickly with the strategic use of bright light, scheduled dark environments, sunglasses and melatonin. (22-23) This means that the benefit of the phase advancement is only available if a person works for longer blocks of night shifts. Limiting the shifts to four will force individuals to start shifting their circadian rhythms and then force them to shift back to a daytime circadian phase. Blocks of night shifts have been shown to be beneficial in EM. (24) Placing a cap on the number of night shifts is not beneficial in emergency medicine because it does not allow individuals to phase delay their sleep in a gradual manner or take advantage of the reversal of their diurnal sleep/wake schedule once they have achieved it.

Whatever the specific determinants of both short and long-term wellness may be, clearly they vary on an individual basis. And although a few may be universally defined (i.e. the requirement for some sleep), most determinants likely cannot be mandated in a dogmatic fashion. For instance, while some physicians might require more sleep to function well, others derive greater benefit from exercise or leisure activities. Likewise, one resident may find that shorter daily shifts allow for more family time than do longer shifts with blocks of time off. However, if another resident derives a greater sense of well-being by being with family for some portion of every day, it is unreasonable to expect that this resident's well being and by association, his/her patient care performance, will be enhanced by longer shifts with block free time.

Clearly, additional research is necessary. Provider wellness is important as a goal of its own, but it takes on additional significance when physician well being is linked to clinical performance, patient safety and clinical outcomes. ACGME and all medical educators must remain cognizant that the ultimate goal is safe patient care provided by physicians who enjoy a sufficient degree of life-long wellness. Furthermore, those responsible for the training of physicians must bear in mind that the attainment of wellness is more complex than sufficient sleep alone. Finally, balance and wellness will be defined by the individual and is likely not static over time. More research using validated tests of well-being and linking well-being to clinical performance is needed.

<u>Moonlighting:</u> One of the aspects of wellness defined by some residents is their participation in moonlighting. Emergency medicine residents choose to moonlight as emergency practitioners for a variety of reasons including to help allay their financial debt and further their clinical experience. Though EM organizations agree with controlling the residents' duty hours associated with residency, monitoring activities outside the purview of a residency program as recommended by the IOM is fraught with difficulties.

> **IOM Recommendation:** The ACGME should immediately amend its current requirements on moonlighting by requiring that any internal and external moonlighting for patient care adhere to the duty hour limits listed above (80 hours and all other limits), even if the program has received an exception to schedule longer hours; and requiring that sponsoring institutions, if they choose to permit moonlighting, include provisions in resident contracts that (1) a resident must request prospective, written permission from the program director for moonlighting, and (2) resident performance will be monitored to ensure that there is no adverse effect of moonlighting on resident performance.

Moonlighting currently is given a broad definition by the ACGME and IOM as "patient care activities external to the educational program that residents/fellows engage in…."

Emergency medicine organizations generally agree that residents should practice clinical care in an ED only under appropriate supervision. As with all employment, activities outside the residency program are not and should not be controlled by the program if they do not affect the professional behavior or clinical performance of the resident at work. Residents should have some autonomy during their non-work hours. Attempts to monitor outside moonlighting would not only be difficult but would infringe on residents' personal freedom. Examples include the resident who wishes to volunteer at a homeless shelter, or those with an EMT license who wish to staff an ambulance shift. These are not just financial opportunities but often wellness issues. We believe that program directors should be permitted to use their judgment in monitoring this situation. Because a program director already has the responsibility and flexibility to monitor resident fatigue and the capability regarding the resident with outside concerns (family issues, medical illness, etc.), a program director should continue to have the responsibility and flexibility to monitor outside work activities for a resident including any patient care activities.

Resident Training

As medical education is the combination of patient safety, resident wellness and resident training, emergency medicine understands that any act that affects one component will affect all. Resident duty hours have a clear impact on all of these aspects, and the balance among them must be remembered when focusing so ardently on just one aspect,

Duty Hour Adjustments: One of the recommendations by the IOM is to allow a five-hour rest or "nap" break when a night shift is required:

> **IOM Recommendation:** Scheduled continuous duty periods must not exceed 16 hours unless a 5-hour uninterrupted continuous sleep period is provided between 10 p.m. and 8 a.m. This period must be free from all work and call, and used by the resident for sleep in a safe and sleep-conducive environment.

Though this would not relate directly to an ED shift, encouraging naps in emergency medicine has been shown to be beneficial. Current research does suggest naps improve performance and mood of workers. (25-29) However, these are generally short naps to prevent sleep inertia, which is the grogginess that one experiences when awakening. In one study specific to emergency medicine, a forty minute midnight shift napping opportunity at 3 am resulted in maintenance of performance measures and mood ratings in a group of residents and nurses working twelve-hour shifts in the ED. (30) Introducing short napping opportunities may be the solution for resident well-being on inpatient teams too. This would avoid the negative effect of a five-hour 'nap gap' contributing to ED overcrowding while still improving the struggle with sleep inertia.

Resident Length of Training: In other disciplines such as surgery there is a growing but still limited set of data that demonstrates an improvement in patient outcomes after duty hours decreased. However, there is also concern that significant reduction in case volume may lead to inadequate operative experience. Surgical educators speculate that although outcomes are improved in teaching centers where there is 1:1 attending physician oversight, this improvement may not be sustained in independent practice. (31-32)

Similarly, EM residency directors were asked at a recent national meeting if they thought they would have to extend their training if the IOM recommendations were implemented due to a decrease in experience from duty hours and workload limitations. Approximately 40% of the participants believed they might have to extend their residents' training. (10)

Emergency medicine residency training programs are designed to produce competent clinicians for clinical practice in the specialty of emergency medicine. These programs must meet training goals of the prescribed regulatory accrediting body sanctioned by the American Board of Medical Specialties or the Bureau of Professional Education of the American Osteopathic Association (AOA) in order to gain admittance to formal board examinations. (33-34) Currently there are two accepted processes for training in residency programs, namely the allopathic and osteopathic pathway. Both systems adhere to strict national regulatory standards. There are some differences in the provision in administering a residency program. Allopathic programs offer either a three or four year training design depending on the institution. (34) Osteopathic programs uniformly require a four-year post-professional school training standard to be eligible for board certification. (35)

Regulatory bodies offer core competency measures as well as procedural and resuscitation guidelines as standards for residency programs to meet as part of the residency program approval process. (36-37) However, current guidelines may fall short in some areas as in the case of attaining the recommended minimal number of procedures in surgical cricothyrotomy or cardiac pacing. Although core competency measures have recently been introduced as a bench mark for proficiency and ultimately board eligibility, the process of determining milestone attainment is largely predicated on a time unit of measure, either three or four years.

Most practitioners accept the concept that performance improves as a direct function of improved knowledge through training and experience. There is a point at which further work fails to predict superior performance. (38) As a comparison guideline, there has been quantification of attainment of acceptable performance in the music industry as well as other disciplines outside of the medical profession. The level described as 'serious amateur' required 2,000 hours of *deliberate practice* to achieve. The least accomplished expert required 5,000 hours and the accomplished expert required 10,000 hours. (39) Residency training is designed to graduate experts who demonstrate acquired learning objectives and develop scientific reasoning skills so that future practice remains innovative.

In comparing the length of training applied in the United States (US) with other countries there is a fair degree of variability. For the sake of comparison, in the United Kingdom medical schools are five years in length followed by two years of Foundation Programme, three years of Acute Care Common Stem, and five years of Higher Training. Work duty hours are limited to 56 hours per week. The student is exposed to approximately 12,000 patient encounters during the course of training. (40) However, this model has been criticized as being inefficient and non-pragmatic because it requires training not pertinent to the specialty. Similarly, when one looks at the Canadian as well as other European models, the trend supports lower weekly duty hour requirements combined with a longer overall training period. (41-42)

The current education process in the US matriculates students into a four-year medical school program followed by a residency program. Emergency medicine residents enter a three or four year program that is institution specific. (35) The resident in a three-year program can expect to have approximately 4,300 patient encounters, 500 procedures and 143 resuscitations at the end of the educational program. (43-45) A four-year EM resident can expect to see 5,900 patient encounters and acquire further skills contributing to a more professionally mature graduate product. There is no consistent data suggesting one curriculum model is an improvement over another for the cohort of EM residents.

Monitoring and Evaluation: The change in resident experience with a three year or four year program and with the possible changes from any current or further duty hour restrictions must be evaluated in a scientific manner. All EM organizations agree with the IOM recommendation to put resources towards further study of resident education.

> **IOM Recommendation:** To gather the data necessary to monitor implementation of these recommendations and to prepare for future adjustments as needed to achieve the desired objectives, ACGME should convene a meeting of stakeholders and potential funders to set priorities for research and evaluation projects.

As we have identified, emergency medicine has both a three- and a four-year residency model. Further work duty hours restrictions, especially on off-service rotations, may lead to substantial decreases in case volume and academic instruction, resulting in the need to re-evaluate the current curriculum. This may include the possibility of adding another year of training to the programs, and/or making curriculum adjustments to obtain the necessary expected outcome that is currently attained.

If the restrictions on duty hours lead to the lengthening of the EM training program by another year, GME cost would be dramatically increased. Calculating just the direct salary and benefit costs to pay residents for this extra year in some or all of the 187 residency programs would equal 8-11 million dollars. It is unclear whether this cost would be reimbursed through the usual Medicare direct graduate medical education (DGME) payments or borne by the institutions that train these residents.

In summary, further work duty hours restrictions on resident training such as those proposed by the IOM will greatly pressure US emergency medicine training programs to consider increasing their length of training to achieve the similar competencies society currently expects. This in turn would significantly increase the cost of resident education.

Financial Analysis:

Additional Resources for Implementation: The community of emergency medicine is strongly supportive of the IOM recommendation suggesting an understanding of all stakeholders, including the American public and our patients, that these recommendations will require a significant financial investment in the already under-funded health care system.

> **IOM Recommendation:** All financial stakeholders in graduate medical education, such as the Centers for Medicare and Medicaid Services, Department of Veterans Affairs, Department of Defense, Health Resources and Services Administration, states and local governments, private insurers, and sponsoring institutions, should financially support the changes necessitated by the committee's recommendations to promote patient safety and resident safety and education, with special attention to safety net hospitals. An independent convening body should bring together all the major funders of graduate medical education to examine current financing methodologies and develop a coordinated approach to generate needed resources.

Improving the Safety of Residents and the Public: An example of the non-medical costs that will be added to the health care system is the recommendation for providing safe transportation for residents.

> **IOM Recommendation:** The committee recommends that sponsoring institutions immediately begin to provide safe transportation options (for example, taxi or public transportation vouchers) for any resident who for any reason is too fatigued to drive home safely.

Emergency physicians see the results of driver fatigue daily and are strongly in support of assuring safe transportation for our residents. The only solution proposed by the IOM may not be appropriate or cost effective and flexibility should prevail for a solution to this issue. The cost and availability of taxicabs or public transportation to transport fatigued residents home is quite variable in different settings. In one location, the cost to provide this may be prohibitive; in another rural training site the lack of availability of cabs or public transportation may be a limiting factor. Having a sleep room available for the fatigued resident may be the most effective solution in a community. The current stance of the ACGME to allow each institution to ensure the safety of their residents within the constraints of the community and with the available resources should be continued.

Improving Adherence to Duty Hours: The IOM report includes many other recommendations that will increase the cost of medical education. Society must address the cost/benefit ratio of these suggestions before any organization mandates further change.

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> **IOM Recommendation:** ACGME and residency programs should ensure adherence to the current limits now, and to any new limits when implemented, by strengthening their current monitoring practices. To provide additional support, the Centers for Medicare and Medicaid Services and the Joint Commission should take an active oversight role.

> Sponsoring institutions should provide for confidential, protected reporting of duty hour violations by residents through their compliance office or by an entity above the program level that does not have direct responsibility over the residency programs.

Program administrative costs include duty hours monitoring systems, the recommended compliance officer required to provide confidential protected reporting of duty hours' violations and the repeated unannounced visits by ACGME for monitoring. Other unanticipated costs might include information technology hardware, software and technician support to allow for more asynchronous learning due to increased restrictions from duty hours on conference attendance by the residents.

If the unintended consequences of the IOM's suggestions for duty hours occur, the cost to the health care system from the emergency medicine view point will be significant. As explained above, it is very difficult to separate the educational costs from the health care costs due to the intertwined nature of EDs and EM residency programs.

The last change in duty hours resulted in less resident staffing of teaching hospital EDs when other residency programs abandoned their EM experience to increase their own specialty staffing needs. This effect will likely recur with further duty hours restrictions, resulting in a need for an increase in the number of EM residents, board certified emergency physicians, or mid-level providers to cover the increasing patient volumes of the ED.

Though the costs to society would be high to replace the work done by residents with new, more restrictive duty hours, the ability to fill the need with appropriately trained clinicians is a concern. Workforce studies with data from 1999, 2005, and a current unpublished study all found that a significant gap in the supply of emergency physicians being trained compared to the staffing needs to provide residency-trained emergency physicians in all US emergency departments. (46-47) With the possible increased length of training and increased need for staffing in teaching hospitals, the supply of emergency physicians will not meet the anticipated demand for more than the ten to thirty years currently estimated.

One critical aspect needed for an increase in the length of training for EM residency training and to ensure adequate staffing for EDs is funding. With the current regulations for residency funding by the Centers for Medicare and Medicaid Services (CMS), residency programs are not funded above a specified number of spots. With institutions 'capped' or limited to the current number of resident months, the cost of increasing the number of residents or the length of training for residents will fall to the academic medical centers.

Conclusion:

In the field of emergency medicine, residents are supervised at all times by certified "masters" that are at the bedside and immediately available for consultation at all times.

This strategy is the best method to prevent medical mistakes of any cause, including from resident fatigue. We believe that continuous supervision by engaged faculty should be the first line of defense for patient safety.

The way in which emergency physicians staff the ED is fundamentally different than the way many other specialties cover their clinical obligations. Emergency physicians work shift work and when working nights, usually have no obligations during the day. Therefore limiting night shifts to three or four followed by two days off will mean very frequent resetting of the circadian rhythm. This will lead to resident fatigue and threaten patient safety.

Enacting the IOM recommendations will have several negative effects on EDs and emergency medical education. The most obvious effect of decreasing the amount of time that residents work in a clinical environment will be to limit the absolute number of patients they see. This will unquestionably result in a decline of the clinical skills and preparation of our graduates for unsupervised practice. This will lead to a fundamental patient safety problem after these residents graduate and move onto independent clinical practice. Residency is an apprenticeship, and much like any other skilled trade, a decrease in the quality of that apprenticeship will lead to a decrease in the skills of the eventual master of the trade.

Enacting the IOM recommendations within other specialties will also have severe effects on the ED. These recommendations will lead to slower throughput times in the ED. Slower throughput times will lead to overcrowding and decrease in patient safety in the ED. Residents on admitting services will not be admitting patients during the required "rest time." This will slow patient flow and lead to many more transfers of patient care. It is well documented that the most dangerous period for patient safety is patient care transfers. As studies have shown, requiring these patient care transfers each night with the resultant decrease in patient flow will have disastrous effects on patient safety on the inpatient wards and in the ED. The IOM recommendations will mandate night float teams taking admissions of patients they will not eventually be caring for and daily patient care transfers to the teams that will be responsible for eventual patient care.

Another unintended but critical effect of the IOM recommendations will be to decrease the number of residents working at any given time. In the very challenging financial climate of today's health care marketplace, decreasing resident work hours will force hospitals to either cut services or threaten patient safety by increasing the workload on the residents and faculty. Both of these options put the patients and the public at risk. We as a profession and as a public cannot allow further strain on already over-burdened EDs and teaching hospitals.

To guarantee competent graduates under such significant financial and time restrictions we would need to seriously consider increasing the length of residency training and increasing the number of residents in training. This would allow trainees to see a critical number of patients in order to obtain the clinical skills and cognitive abilities to practice in a safe manner. Without addressing these important issues, enacting the IOM recommendations amounts to an unfunded mandate. This unfunded mandate would burden on already tenuous system and lead to failure and disastrous outcomes for patient safety and medical education.

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Institute of Medicine
Work Hour Recommendations

Response to Accreditation Council for Graduate Medical Education
April 16, 2009

It is a pleasure to have the opportunity to respond to the Accreditation Council for Graduate Medical Education (ACGME) with our comments concerning the new recommendations by the Institute of Medicine (IOM) related to resident duty hours. This position paper is a combined response from many of the major national radiology organizations. These organizations are absolutely committed to the concepts of patient safety, management of resident fatigue, and excellence in education.

We applaud the intent of the IOM and consider their goals to be aligned with our core values of excellence in patient care and resident education. We offer suggestions to further improve upon their recommendations by enhancing their practical application to the field of radiology to better ensure compliance. Organizations that participated in preparing this response included:

American College of Radiology
American Roentgen Ray Society
Radiological Society of North America
Association of University Radiologists
Association of Program Directors in Radiology
Society of Chairs of Academic Radiology Departments
American Association of Academic Chief Residents in Radiology

The current ACGME duty hour rules only became effective in 2003 and we embrace them fully. However, we do not feel that there has been sufficient time to see the true effect of those rules and feel that we should consider any such effects before ACGME implements any major changes to the rules. Furthermore, there is continued concern regarding compliance with the current rules which should be addressed before there are significant changes to the rules. An improvement in compliance could be addressed by stricter monitoring and oversight by the residency programs, local institutions, and the ACGME.

We feel that a "one-size fits-all" approach to all residency programs is not optimal. While resident fatigue is an important issue for all training programs to address, the educational and work hour issues in radiology are very different from those in internal medicine or surgery for example. We strongly feel that any changes in the duty hour requirements should be Residency Review Committee (RRC) specific or jointly apply to RRCs with similar training needs (i.e. radiology, pathology etc). It should also be noted that radiology residency training programs range from large to small, urban to rural, state to private, and single hospital to large multi-hospital medical center. There needs to be some flexibility in the rules to enable all programs to comply.

Specific issues we wish to address:

Maximum frequency of in-house night shifts (night float). The IOM recommendations allow a maximum of only four consecutive night float shifts with 48 hours off after these shifts. Currently, most radiology programs that use a night float system have six consecutive 12 hour night float shifts followed by one day off. The radiology RRC in fact allows up to nine consecutive night float shifts with the caveat that there must be an average of one day off in seven.

While we appreciate the fatigue issue related to night shift work, the IOM report does not seem to present convincing evidence for a significant difference in resident fatigue when comparing four consecutive night float shifts versus five or six. Also, in order to have the same number of night float shifts, the residents would be away from the important day time educational activities of the department more often (estimated at about 50 percent more often than the current system).

Compliance with this recommendation would therefore have a significant negative impact on training. We also believe that the establishment of diurnal rhythms allowing restful sleep may be difficult to establish if night float shifts are limited to only three to four consecutive shifts. We recommend that the maximum become five or six consecutive shifts to be followed by 48 hours off.

Supervision. The IOM recommendation is that programs provide adequate direct on-site supervision for residents. We are in full agreement that there needs to be adequate supervision of resident clinical activity while keeping in mind that they do need to have some independence in order to expand their clinical confidence. Off-hours resident supervision in radiology is very different from supervision in surgery or obstetrics. The digital environment in radiology lends itself more readily to off-site resident supervision through PACS and teleradiology. This has become standard procedure in the field of radiology.

The IOM also recommends that first-year residents not be on duty without having immediate access to a residency program- approved supervisory physician in-house. PGY1s are most commonly not a part of a radiology residency program as they are doing their preliminary year of training. First-year radiology residents (R1s/PGY2s) are currently not allowed to take independent call as per current radiology RRC rules and are on call only with a more senior resident working together in house. They cannot render an independent preliminary interpretation during the entire R1/PGY2 year.

It is unclear from the wording of the IOM recommendation if a more senior resident could be an approved supervisory in-house physician. However, we presume that is the case. These two issues cited above are examples where radiology is different from other specialty programs and where radiology's unique attributes merit thoughtful independent consideration rather than broad generalized requirements. We strongly feel that requirements such as these be made by the individual RRCs.

Mandatory time off duty. The IOM recommendations are one day off per week with no averaging and one 48 hour period off per month. The current ACGME requirement is one day off per week averaged over four weeks. We feel that the current ACGME requirement should be maintained because of flexibility of scheduling both for the department and for the individual resident. At times the residents want to change the call schedule so they can have a full week off for personal reasons. Also there are times when there is an unexpected illness of the on-call resident that might require another resident to occasionally have to work seven days in a row. This should be strictly monitored by the program to ensure that this is a rare event. The IOM report does not seem to provide convincing evidence that having one mandated 48 hour period off duty per month would have a significant effect on resident fatigue except after several night float shifts. This seems to be purely a life style issue for the resident but we think that is important and support this recommendation.

Maximum shift length. The IOM recommendations are 16 hours with no protected sleep followed by five hours of protected sleep with the remaining hours for transition and educational activities for a total of 30 hours. Currently the ACGME requirement is 24 hours with up to six hours for transition and educational activities. Interrupting patient care activities at 16 hours and mandating that the resident stop these activities at this time will cause problems with continuity of care. Although this is less of a problem in radiology than in some of the other clinical services, these issues still exist. This is a common occurrence with emergency department patients who may be having multiple different imaging examinations to diagnose a critical problem. The flow of information about such patients would be disrupted if the resident was abruptly taken off service. Also it is felt to be impossible to monitor that the resident will actually be sleeping during this mandated five hours of protected time. If a resident is keyed up after a busy first 16 hours of call he/she won't be able to fall asleep right away for the mandatory five hours. The resident will unwind by taking care of personal issues, surfing the Internet, watching TV etc. This issue is acknowledged in the IOM report.

Resident fatigue and transportation. The IOM recommendation is that the sponsors immediately begin to provide transportation options for fatigued residents. We certainly understand the concern about fatigued residents driving home and their increased risk for accidents. However we would strongly recommend that institutions be given some options. One option might be to have the resident once off duty stay in the hospital dedicated on-call area to nap before he/she drives home. This would be most important in rural areas where public transportation is not readily available. If a fatigued resident is transported home, the issue of how he/she will return to work and/or retrieve a personal automobile needs to be addressed.

Moonlighting The IOM recommendation is that all internal and external moonlighting counts against the 80 hour limit. We absolutely agree. However, as a practical matter, it will not always be possible to get accurate information on external moonlighting from all residents, and the programs and institutions have no control over this. If this recommendation is adopted, we feel there must be some level of resident responsibility for accurate reporting.

Monitoring of duty hour compliance. The IOM recommendation is to strengthen the monitoring practices to include oversight by the Centers for Medicare & Medicaid Services and the Joint Commission. We strongly believe that monitoring of resident work hours should be more rigorous. However we feel that the residency programs, the institutions and the ACGME should do the monitoring. This could be done by quarterly work hour surveys at the institutional level and more frequent ACGME Web surveys of every resident specifically related to duty hours.

We are fully supportive of the current ACGME duty hour regulations. The Institute of Medicine report itself points out that there has been inadequate study of the outcomes of the current duty hour regulations. The issues identified with compliance further complicate adequate evaluation of the effect of the current rules. While we respect and support the aims of the Institute of Medicine report, we feel compliance and outcomes assessment should be addressed before additional regulations are imposed because of the profound impact these changes will have.

Thank you very much for giving us the opportunity to share our views on resident duty hours. We would welcome the opportunity to participate in a Resident Duty Hours and Learning Environment Congress if we are invited to participate.

Lawrence P. Davis MD

Lawrence P. Davis, MD FACR
Chair, ACR Commission on Education

Harvey L. Neiman, MD

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American Society *of*
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April 7, 2009

Thomas J. Nasca, M.D., MACP
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Re: Resident Duty Hours

Dear Dr. Nasca:

The American Society of Anesthesiologists (ASA) appreciates having an opportunity to respond to your request for formal feedback regarding resident duty hours, the recent Institute of Medicine (IOM) Report on Resident Duty Hours and the deliberations under way by ACGME on this important aspect of graduate medical education.

As you know, anesthesiology residency programs have been responsive to the 2003 ACGME resident duty hour restrictions. They have revised the educational curriculum and modified both the didactic and clinical experiences to ensure that residents receive appropriate clinical skills and training and are prepared for their careers in anesthesiology. These changes have been possible based on reengineering of clinical care delivery, considerable effort on the part of the faculty and other major changes in the educational environment. The recommendations made in the recent IOM Report will, if implemented, have considerable additional impact on the future training and experience of anesthesiology residents, might mandate a lengthening of their residency training and could have the unintended effect of compromising the quality of patient care.

On behalf of the American Society of Anesthesiologists, let me provide some specific comments in response to your request:

- *Your organization's formal position on the recommendations contained in the Institute of Medicine Report, including impact analysis, from your organization's perspective, on costs and impact of implementation*

  Let me begin by noting that ASA supports the recommendation by the IOM and the requirements of ACGME and the Residency Review Committees for improved resident supervision. The anesthesia educational programs have consistently provided close supervision of residents during all clinical rotations, often providing one-on-one coverage during surgical procedures and on other clinical settings. Anesthesiology residency programs require in-hospital faculty supervision in all clinical situations, both elective and emergency. Anesthesiology faculty are available in the hospital to provide direct supervision of residents and to deliver personal care when residents are not able to do so either as a result of the complexity of the clinical situation or limitations on duty hours. Anesthesiology programs recognize and support the educational needs of the residents and that education supersedes clinical service.

In discussions with the educational programs and after reviewing the impact of the current duty hour restrictions on clinical training, the ASA has concerns about the potential unintended consequences of the proposed IOM restrictions on resident duty hours.

Impact on the Patient Safety

Anesthesiologists have a unique relationship with other providers, most often surgeons as well as patients. Because the practice of anesthesia occurs in the most complex settings in the operating rooms, procedure rooms and intensive care units, continuity of care is essential both to patient care and to resident education. The 2003 mandated reductions in duty hours had impact on resident sleep and reduced the likelihood that sleep deprivation compromised clinical decision-making. They increased the likelihood of complications in patient care due to transfers of care (handoffs). The IOM recommendations further limiting duty hours will require even more frequent transfers of care, often in situations that are not amenable to safe transitions without jeopardizing patient safety.

In adapting to the current duty hour limitations, anesthesiology, like other specialties has implemented clinical care algorithms and protocols to optimize care during transitions and under care team models. Practicing anesthesiologists frequently utilize the anesthesia care team model in which attending anesthesiologists direct trainees and non-physician providers. In such a model, these protocols are essential to ensure that members of the care team have the information necessary to provide good clinical care. However, even under these controlled conditions, every transfer of care creates an additional opportunity for loss of vital information and possible error. In contrast to the recent systematic approaches to reducing errors, the additional restrictions on duty hours could have the opposite effect and actually increase errors as a result of transitions of care, sometimes at critical periods in the patient's course during a procedure or while receiving care in the intensive care unit.

Further limits on resident duty hours may have another potentially harmful effect on patient care. When these transitions are mandated for a resident, the resident is required to leave the clinical setting and transfer care to another provider – and, in most cases, the attending faculty physician assumes responsibility for the transition of care. Once in practice, however, the resident who has not had to make a decision about the appropriate timing for such a transition or the method for communicating with the provider who is taking over the care may not have the experience upon which to make the right judgment. Since every physician confronts these situations as part of routine clinical care, residents must learn when patient needs take precedence and transitions of care are not acceptable. If they are not allowed to learn how to handle these decision points and determine the most appropriate time to transition care, patient care may be compromised. While academic departments have attempted to teach residents about these important transitions in care, further mandates to remove a resident from the clinical setting arbitrarily will make it difficult to provide the appropriate education and role modeling.

Impact on Resident Education

The additional limitations on duty hours proposed by the IOM are much more restrictive and will have major impact on resident education. Under these new requirements, residents will have less time to participate in clinical care and didactic educational programs, including simulation. The Anesthesiology RRC requires not only demonstration of competence in a number of areas, but also defines a minimum number of procedures that must be performed as part of anesthesia training. The requirements are reinforced by the performance on both written and oral examinations that correlate directly with clinical experience and exposure to didactic educational sessions. Further limitations on duty hours will not allow residents to complete the requirements in the time frame currently available to do so. As importantly, some programs are having difficulty meeting the requirements under the current duty hour restrictions. In addition to the impact on the clinical experiences of the residents, further limitations on duty hours or the ability to average duty hours over two to four weeks will compromise resident opportunities to participate in didactic educational programs, grand rounds, morbidity and mortality conferences and other sessions. For example, pre-call and post-call residents will probably not be able to attend some educational conferences due to their clinical obligations. These didactic experiences are an essential component of residency training for anesthesiologists and all other specialties and must be maintained. As a result, if the IOM recommendations are adopted by ACGME, the duration of anesthesia residency programs may have to be extended and the educational programs will have to undergo major reorganization. The cost associated with the lengthening of the programs and modifying the curriculum will be considerable at a time when the resources to cover the costs have not been identified.

Impact on Work Force Costs

The cost of replacing residents in response to further limitations in duty hours will be staggering. As an example, in response to a request from the IOM to quantify the labor costs associated with further reductions in resident duty hours, Northwestern Memorial Hospital (NMH) estimated that it would cost an additional $15 and 24 million for that hospital alone depending on the type of providers employed. If additional resident positions were added rather than other providers, the costs would also be excessive. At the present time, no one has identified a source of funding for these additional positions. Since there are no data to document that additional restrictions in duty hours will improve patient safety or resident welfare, these additional health care expenses do not seem justifiable at this time.

Impact on Professionalism

Further limitations to resident duty hours will have significant impact on the attitudes of anesthesiology residents and all specialties with respect to their commitment to patients and professionalism. The restrictions will create an even greater impression that physicians are shift workers whose primary motivation is their own welfare rather than the welfare of their patients. The current limitations to work hours has been disruptive, but with a great deal of effort on the part of the training programs and the RRCs, the duty hours have been implemented in a way that ensures that residents are not abused, that they have reasonable periods of time without clinical responsibilities and, at the same time, that patient care is paramount. The training programs have allowed residents to retain their professionalism and commitment to patients by completing long surgical cases to ensure safe patient care without compromising on overall duty hour limitations. This flexibility is critical to the residency programs, but also to the profession as a whole. Physicians can and will make the right decisions about their commitment to patients and themselves and not compromise either. The duty hour restrictions must take this professional attitude and commitment into account.

Impact on Quality of Anesthesia Care

ASA is committed to maintaining the highest standard of medical practice of anesthesiology and to improving patient care. The society was concerned about the impact of the current duty hour limitations on the education and quality of care provided by the next generation of anesthesiologists. In response to the 2003 ACGME requirement to limit duty hours, the residency programs reengineered the curriculum and clinical experiences to ensure that the residents were well-trained and able to provide the highest standard of care. As a result, although current residents work fewer hours than most anesthesiologists in private practice, the residents understand the needs of their patients and have been able to enter the workforce and fulfill their obligations. Further reductions in duty hours will not prepare the residents for their future careers in anesthesiology.

Residents have uniformly demanded high quality education and training. They seek residency programs that provide them with the appropriate depth and breadth of clinical experience that will prepare them to become capable anesthesiologists. A recent informal survey indicated that residents feel that further limitations in duty hours without sufficient flexibility to allow them to maintain continuity of care and participate in all educational opportunities will not improve, but will compromise their training.

- *Your organization's formal position on the current ACGME Resident Duty Hours Standards including impact analysis, from your organization's perspective, on costs and impact of implementation*

The American Society of Anesthesiologists is supportive of the current duty hour standards. In discussions with program directors and department chairs, ASA has learned that the programs have adapted to these requirements and made modifications in the educational experiences for residents and fellows to comply with them. In most cases the experience of the residents is satisfactory and the requirements allow residents to participate in the elective and emergency care and develop the expertise to provide continuity of care as needed and transition care to other providers when appropriate. Residents recently recruited to community practices are well-trained and have the skills and experience necessary to fulfill their obligations and provide appropriate clinical care to their patients. These changes have come at significant cost to the academic departments for a number of reasons. The duty hour limitations have reinforced the notion that resident education takes precedence over clinical service. As a result, all departments have had to increase the faculty-resident ratios; in most programs for all complex surgical cases and for anesthesia provided in remote locations (radiology, cardiac cath laboratories, GI suites, etc.) the faculty-resident ratio is 1:1. In addition to ensure that residents are able to participate in all didactic educational sessions, most departments have increased the number of faculty and utilize faculty to provide a larger percentage of the clinical service. It is difficult to quantify these additional costs, but, for many departments the faculty numbers have increased by 15-25% without any increase in clinical volume or income to cover these costs. Further faculty, CRNA or resident recruitment will be difficult due to the current workforce and the limited sources of funds to cover the additional associated costs.

- *Your organization's formal recommendations regarding dimensions of Resident Duty Hours standards, and justification (wherever possible) for this position with evidence*

The current limitations on duty hours that was mandated by ACGME have been satisfactorily adopted by anesthesiology residency programs. In those cases in which a violation of the duty hour limitations was identified, the problems were rapidly addressed and resolved. We are not aware of any ongoing concerns identified by the Anesthesiology RRC or ACGME. ASA and its members believe that the proposed IOM duty hours will be much too prescriptive and are both unrealistic and unnecessary. The current standards have been working and we are not aware of any problems in patient care or resident welfare as a result of the current requirements.

For anesthesiology residencies, clinical training must incorporate night call and off hour responsibilities, since many emergency cases that occur during these hours have invaluable educational value. Anesthesia residents and subspecialty fellows must have exposure to emergency clinical situations, including trauma care, urgent and emergent surgical services, such as transplantation, emergency obstetric care and intensive care medicine in order to become competent anesthesiologists and deal with the increasingly complex needs of the patients. ACGME has been sensitive to these requirements, while also mandating compliance with the overall duty hour limitations. The current flexibility in accounting for the duty hours has allowed the residents to have appropriately broad and comprehensive educational experiences without undue burden.

ASA supports ongoing supervision of the residents and endorses the care team model to facilitate transitions of care and to address fatigue, should it occur during a complex clinical case. Unless problems are identified that relate specifically to duty hours, we do not endorse further restrictions. If ACGME or others propose further limitations on duty hours, resources must be identified to allow adoption of more restrictive standards, including additional funds to cover the cost of lengthening the training of residents and to allow recruitment of additional residents into the specialty.

- *Your organization's formal recommendations regarding standards governing key aspects of the Learning Environment, and justification (wherever possible) for this position with evidence*

With the implementation of the 2003 duty hour limitations, ACGME has worked closely with the RRCs and with programs to enforce the requirements and ensure that resident education is maintained. ASA enthusiastically supports ongoing monitoring of duty hours by ACGME, the Residency Review Committees and the sponsoring organizations. Additional mandatory enforcement by other agencies is neither necessary nor appropriate. The training oversight must be maintained by ACGME; The Joint Commission (TJC) and payor organizations do not have a role in the oversight of educational programs, nor the expertise to do so in a way that will ensure resident acquisition of competencies.

- *Your organization's willingness to participate, if invited, in a Resident Duty Hours and the Learning Environment Congress, to be held in June 2009 in Chicago, Illinois. This Congress will be configured to provide the ACGME leadership will the breadth of perspectives of the medical community as they embark on review and revision of the Resident Duty Hours and Learning Environment Standards*

Representatives of the American Society of Anesthesiologists will be pleased to participate in the Congress to be sponsored by ACGME. Anesthesiology training programs have many requirements that are consistent with those of other specialties, but also some unique aspects of training that must be taken into account as further refinements are made in the resident duty hours. Input from members of our specialty will be critical in the deliberations and discussions. We look forward to participating in the Congress.

I hope that these comments are helpful to you and ACGME as you consider how to incorporate the recommendations of the IOM into future duty hour requirements. The goals established by ACGME for resident work hours and education are based on current data on resident performance, adequacy of supervision and clinical competence. Unless additional data that support the need for further restrictions are provided, we see no need for further limitations that will compromise education and, in the end undermine delivery of high quality patient care.

Sincerely,

Roger A Moore M.D

Roger A. Moore, M.D., President

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April 29, 2009

Via Electronic Mail (tnasca@acgme.org)
Thomas J. Nasca, MD, MACP
Chief Executive Officer
Accreditation Council for Graduate Medical Education
515 North State Street
Suite 2000
Chicago, IL 60654-4322

Dear Dr. Nasca:

Thank you for the opportunity to provide the views of the American Board of Anesthesiology (ABA) on the current ACGME Resident Duty Hour Standards and the recommendations of the IOM Report on Resident Duty Hours issued in December 2008.

Enclosed is the ABA Position Paper on the IOM Report on Resident Duty Hours.

Sincerely yours,

Mark A. Rockoff MD

Mark A. Rockoff, MD
Secretary

MAR: mep

The American Board of Anesthesiology (ABA)
Position Paper on the
Institute of Medicine (IOM) Report on Resident Duty Hours

Outline

I. Your organization's formal position on the recommendations contained in the Institute of Medicine (IOM) Report, including impact analysis, from your organization's perspective, on costs and impact of implementation.

   A. Introduction

   B. Compliance with IOM Recommendations

      1. Impact on Quality of Patient Care and Patient Safety
      2. Impact on Quality of Resident Education
      3. Impact on Resident Professionalism and Integrity
      4. Impact on Quality of Graduating Residents
      5. Impact on Clinical Service

II. Your organization's formal position on the current ACGME Resident Duty Hours Standards including impact analysis, from your organization's perspective, on costs and impact of implementation.

III. Your organization's formal recommendations regarding dimensions of Resident Duty Hours standards, and justification (wherever possible) for this position with evidence.

IV. Your organization's formal recommendations regarding standards governing key aspects of the Learning Environment, and justification (wherever possible for this position with evidence.

V. Your organization's willingness to participate, if invited, in a Resident Duty Hours and the Learning Environment Congress, to be held in June 2009 in Chicago, Illinois. This Congress will be configured to provide the ACGME leadership with the breadth of perspectives of the medical community as they embark on review and revision of the Resident Duty Hours and Learning Environment Standards.

The American Board of Anesthesiology (ABA)
Position Paper on the
Institute of Medicine (IOM)
Report on Resident Duty Hours

I. Your organization's formal position on the recommendations contained in the Institute of Medicine (IOM) Report, including impact analysis, from your organization's perspective, on costs and impact of implementation.

A. Introduction

Preliminary analysis of existing data and current practice indicates that compliance with the Institute of Medicine (IOM) report on resident duty hours could cause unintended consequences in anesthesiology including dilution of resident training, decreased clinical exposure to essential teaching cases, and even adverse patient outcomes. Adoption of the IOM recommendations could cause substantial downstream negative effects impacting (1) the quality of patient care and patient safety, (2) the quality of resident education, (3) resident professionalism and integrity, (4) the quality of graduating anesthesiology residents, and (5) clinical service.

The recommendation of the IOM for **improved resident supervision** is strongly supported by the ABA. For many years, Anesthesiology has required in-hospital faculty supervision of all resident-provided care 24 x 7, and this level of faculty supervision contributes to the high quality and safety of anesthesiology care provided in teaching centers.

1. Impact on the Quality of Patient Care and Patient Safety

Anesthesiology is a unique profession because of the acute nature of patient interactions experienced within our specialty. Many anesthesiologists practice in high acuity settings such as operating rooms and intensive care units (ICUs). Continuity of care is important in such settings to promote patient safety. The IOM duty hours proposal will add transfers of care of either extremely ill patients or those who face unique physiologic challenges while in acute settings. These additional transfers of care could jeopardize patient safety because there is strong evidence that transfers of care in acute clinical settings increase the frequency of complications and death.

Even with carefully developed protocols, each transfer of care is an additional opportunity for error or loss of vital information. To meet the new IOM recommendations, trainees in the operating room would have to transfer the care of their patients to other anesthesia care providers at the end of their shift rather than staying for short periods of time to complete their cases. Vital information can be overlooked during transfers, and patients may have an increased risk of adverse outcomes. Proposed duty hours could affect continuity of care in intensive care settings even more than in operating rooms. Patients admitted to ICU's are generally the sickest in the hospital, and more frequent transfers of care for these patients than necessary can be even more problematic for patient safety.

2. Impact on Quality of Resident Education

The IOM duty hour recommendations are both stringent and restrictive. Under these guidelines, residents will have reduced clinical and didactic time. In anesthesiology training programs, the quality of a resident commonly correlates with duration of clinical experience and exposure to quality didactics. The IOM recommendations will dilute both clinical and didactic experience. We know, for example, that performance on the written and oral anesthesiology board certification examinations correlates with both clinical and didactic experience. The ACGME's Review Committee (RC) for Anesthesiology recommends a minimum number of anesthesia procedures / techniques that each resident must perform. Even currently, some residency programs are having difficulty meeting the minimum requirements. With implementation of the new IOM requirements, many residents would not fulfill the minimum requirements. Thus, the duration of the residency may have to be extended to meet the RC requirements. Extended training, would of course, require additional financial resources.

Perhaps more importantly, the ABA has a minimum passing standard for both the written (Part I) and oral (Part 2) examinations. Residents trained under the proposed IOM guidelines may not have obtained the knowledge necessary to pass the exams after their training. One potential solution to this shortfall would be to "lower the bar" by accepting lower scores as evidence of adequate knowledge acquisition. The ABA, however, has no intention of taking this approach because of its fiduciary responsibility to the public and patient safety. Thus, some residents may need additional time in their training programs to be able to pass their subsequent board certification exams. This additional time would require financial support, none of which has been identified to date, despite the commentary on this issue within the IOM report.

There is already an indication of a correlation between reduced duty hours and board certification rates. In one neurosurgery program in Florida, the program director noted a progressive diminution of the mean board scores of residents when taken for credit in the 5-year period since July 1, 2003 as compared to the 5-year period leading up to the July 1, 2003 implementation of the current ACGME resident duty hours standards. Though it is not at all clear that duty hour limitations are responsible for this, it is concerning. The specialty of pediatrics appears to be experiencing a similar downward trend in their board performance at the national level. This trend occurred earlier for programs in New York after the state implemented limits on resident hours prior to 2003. (source: ACGME Bulletin, January 2009, J. Richard Lister, MD, MBA, and William Friedman, MD). These data would suggest than any additional decrease in work hours might further reduce the residents' clinical abilities as measured by the assessment of their knowledge.

The proposed IOM duty hours could negatively impact didactics and conference attendance by residents. Pre-call and post-call residents may not be available to attend scheduled conferences because of the requirement for them to adhere to work hour requirements.

3. Impact on Resident Professionalism and Integrity

The ABA worries that adoption of the IOM proposed duty hours will foster and promote "shift worker mentality" among residents. An important goal of professionalism training is to instill a sense of responsibility. Delegation of shifts when providing patient care for patients does not necessarily support patient responsibility. While the ABA believes that processes can be designed and implemented that improve patient safety in shift environments, unique patients and situations require flexible approaches. The ABA believes that training program directors who are closest to interactions between trainees and patients should facilitate opportunities to provide this flexibility within the overall 80-hour work limitations already in place.

With the unrealistic duty hour proposal of the IOM, there is increased pressure on resident to under-report duty hours. This problem arises not because residents wish to break rules but because they encounter patient care episodes in which they reasonably believe it is in their patients' best interests for the care to be continuous. The proposed additional restrictions on the use of duty hours may conflict with the goal of teaching and instilling professionalism.

4. Impact on Quality of Graduating Residents

Current residents are already working less than fully-trained anesthesiologists in private practice. A further reduction in duty hours would leave them ill-prepared for the real world. For example, most private practitioners in anesthesiology work longer hours than current residents. With the proposed truncation of duty hours, dilution of residency training, and decreased exposure to didactics, graduates may not be ready for clinical practice. Imagine what would happen to our soldiers if they were "coddled" during their training only to be thrown into combat situations for which they had no practical training.

Anesthesiology residents overwhelmingly oppose duty hour changes that would compromise their training. They do not want diluted learning experiences. Residents demand quality education and training with adequate depth and breadth of clinical experiences that will prepare them to be consultant-level, board-certified anesthesiologists who can safely care for any patient encounter in situations they are likely to face once they complete their training.

5. Impact on Clinical Service

For the specialty of anesthesiology at teaching hospitals, preliminary analysis of the data indicates that compliance with the proposed IOM guidelines will result in an immediate reduction in the anesthesia resident workforce by at least 10 – 15%. The resulting resource gap would have to be filled with additional residents, anesthesiologists, or mid-level providers. The cost associated with these additional anesthesia care providers would be substantial.

II. Your organization's formal position on the current ACGME Resident Duty Hours Standards including impact analysis, from your organization's perspective, on costs and impact of implementation.

The ABA supports the current duty hours standards. We believe it balances the need for resident education and training with protection of trainees and patients.

III. Your organization's formal recommendations regarding dimensions of Resident Duty Hours standards, and justification (wherever possible) for this position with evidence.

The proposed IOM duty hours are much too prescriptive and unrealistic, and were presented without evidence of adverse, unintended consequences or identification of viable funding sources for the additional personnel that will be required to provide patient care. The current standards work well for the specialty of anesthesiology in that they reasonably limit work hours.

IV. Your organization's formal recommendations regarding standards governing key aspects of the Learning Environment, and justification (wherever possible) for this position with evidence.

The ACGME, RRC, sponsoring institutions, and residency programs should ensure adherence to the current limits now, and to any new limits when implemented. Neither Medicare nor the Joint Commission should be involved. Professionalism should be regulated by medical organizations, not government agencies.

V. **Your organization's willingness to participate, if invited, in a Resident Duty Hours and the Learning Environment Congress, to be held in June 2009 in Chicago, Illinois. This Congress will be configured to provide the ACGME leadership with the breadth of perspectives of the medical community as they embark on review and revision of the Resident Duty Hours and Learning Environment Standards.**

The ABA would be pleased to participate in the Congress.

In response to your much appreciated letter inviting comment on Resident Duty Hours, the Association of Pathology Chairs submits the following.

The specific quantitative impact of the Accreditation Council on Graduate Medical Education (ACGME) Resident Duty Hours rules has been much less on pathology than on many specialties, but all the more frustrating because of the fundamentally poor applicability of these rules to the actual modes of training in our specialty. This provides us, however, with a conveniently different perspective from which to "triangulate" and comment on system issues underlying both the ACGME's current and the Institute of Medicine's (IOM's) proposed rules.

Briefly to illustrate how different our modes of training actually are from the "one size fits all" model around which both these "general purpose" duty hour rules (and learning environment expectations) have been designed, let us point out that the rules are explicitly aimed at ensuring recovery from chronic sleep restriction, which is considered to be driven by frequent (every-third-night rule) extended (thirty-hour rule) in-house call, leading to extended (eighty-hour rule) weekly work hours, which ultimately necessitate at least one full day per week (one-day-in-seven rules) free of any work responsibilities to allow for recovery (Resident Duty Hours: Enhancing Sleep, Supervision, and Safety, http://www.nap.edu/catalog/12508.html (IOM Report) 7-18, *"Recent studies of recovery from chronic sleep restriction indicate that at least 1 full recovery day (24 hours) for ad libitum sleep time is needed to ensure that performance deficits do not become excessive and pose a risk to performance when work schedules that induce sleep restriction exceed a 6-day period. This can only be accomplished in residents if the 1 day a week is guaranteed in duty hour limits."*).

Essentially all pathology training, as well as variable but often large parts of the training in virtually all specialties, is quite unlike this. In pathology, the incidence of violations of the above rules is as follows (from the on-line 2007 and 2008 ACGME Resident Survey Data for Pathology, 2,101 Residents Surveyed):

ACGME rule	Every-third-night	Thirty-hours	Eighty-hours	One-day-in-seven
Violation rate	0.2%	0.5%	1.5%	1.4%

Direct application of the same calculations used by the IOM (IOM Report 9-15, http://www.iom.edu/Object.File/Master/60/498/Commissioned%20Paper_Cost%20Analysis.pdf) to estimate economic impact of duty hour compliance would indicate need for a grand total of four (4) additional resident or substitute mid-level practitioner FTEs for the whole (2,101) population of surveyed residents. Conclusion: the single-common-mode-of-training model fails to generalize meaningfully to the practical circumstances of pathology training programs.

Let us consider the practical impact on pathology Graduate Medical Education (GME) of the ACGME's present expectations for learning environment and duty hours, and the IOM's proposed expectations. **We commonly encounter three learning environment/duty hour problems in pathology**, none of which is unique or even specific to pathology, but rather relates to our typical mode of resident and fellow training, which is also found in rotations of many other specialties and subspecialties.

Our typical mode of training may best be represented to you as that of a consultative service. To illustrate this and draw out its significance for appropriate learning environment and duty hour expectations requires us first to set forth our major conceptual issue, both with the ACGME's present and the IOM's proposed learning environment and duty hour expectations.

This conceptual issue is the lack of a taxonomy of modes of GME. This deficiency becomes readily apparent when one considers **pathology's most-often-violated duty hour rule, which is the ten-hours off between shifts rule** (frequency 5.8% in the 2007-2008 ACGME Survey Data). For all practical purposes, GME in pathology does not have shifts, and this is because the unstated underlying assumption behind this rule is false, i.e., that, in general, GME is provided in the context of continuous shifts of care for a patient population, with in-house on-call coverage. Such a simplistic assumption is far from either necessary or desirable, and to rectify this situation, we propose a taxonomy for GME that, with very necessary input from other specialties and subspecialties, can and should form the basis for a more specifically applicable set of expectations, more optimally conducive to the simultaneous achievement of effective physician training and safe and efficient patient care.

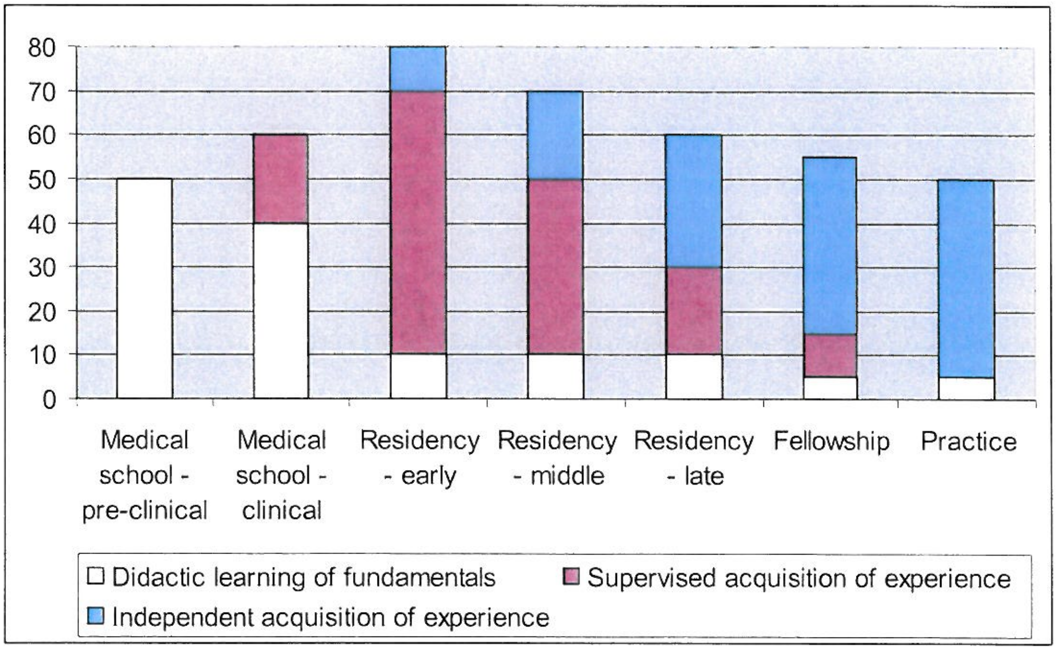
Any clinical learning environment for GME may be characterized by three parameters: how it is organized (with logically associated ways in which the clinically relevant on-call coverage is provided), the mode of supervision provided for each level of training, and the nature of the work in terms of trainee-patient interactions. (A tabular itemization of the elements of this parametric taxonomy is on pages 10 and 11.)

The typical pathology consultation service is case-based in its work assignment (as opposed to time-based, with either shifts for continuous (ward) care or sessions for periodic (clinic) care). Consultation services have a varied mix of trainee-patient interactions: real-time, generally in the mode of an evaluation and management service, and off-line, in the mode of processing and preparing clinical information and/or images, slides or other materials, on which to base a report containing diagnostic impressions and/or therapeutic recommendations.

Such services, neither being time-based nor providing continuous management of the patient population, do not have shifts, and are in their essence episodic rather than schedule-driven: one day may have several cases of exceptional clinical importance and/or teaching value, while the next day may have few or none. Thus, a single daily number for hours off cannot achieve an optimal balance between the trainees' desire both to learn when opportunity presents and to provide good clinical care when it is needed, and their need to be well-rested. To achieve this, it would be best to set a daily minimum time off (for example eight hours, based on the IOM recommendation for maximum shift length without protected sleep period of sixteen hours in Table S-1 of the IOM Report) and a higher number of hours off on average (for example the ten set by ACGME precedent) over the course of a week (which would effectively be achieved by a non-averaged, seventy-hour, five-day weekly limit for such a service, or a non-averaged, eighty hours, seven-day weekly limit).

The benefit of the first parameter of our taxonomy for modes of GME activity (how the learning environment of clinical care on the teaching service is organized) becomes evident when it is recognized that it frees up such a case-based, "non-shift" service from inappropriate restrictions, without restricting the choice of a potentially very different set of expectations for time-based, "shift" services.

The learning environment in a well-organized training program closely approximates the work environment. Ensuring there is educational value to as much of the trainees' work as possible is a prime responsibility of any training program director. Extending, however, beyond the practical purview of any one training program, this environment should sustain and encourage a continuum of learning and work that smoothly transitions its trainees between the primarily didactic environment of medical school and the primarily experiential environment of practice. Attempts abruptly to differentiate one part of this continuum from another are intrinsically artificial and potentially deleterious. This has bearing on the issue of supervision versus independence, as well as on workload and duty hours. Clearly, in the later years of training, an expectation of continuity with subsequent practice should mean an increase in independent responsibility, but this qualitative increase ought to be combined with a commensurate decrease in quantitative workload. A conceptual graphic depiction of this is as follows:



The assumption here is that the *didactic learning of fundamentals* of medical care and the *independent acquisition of experience* are both very demanding of the individual and high-stakes for society; these must therefore be regarded as relatively inflexible in terms of the time that can usefully be spent on them in any day or week (in the conceptual graphic, a maximum of 50 hours per week between them). In contradistinction, *supervised acquisition of experience* can by its nature be of net benefit (perhaps diminished but still substantial) even over significantly (though not indefinitely) expanded amounts of time (in the conceptual graphic, two times the number of hours that the sum of the didactic learning and the independent acquisition of experience is less than the 50 hour maximum). Proving whether this is a correct assumption would be a nontrivial exercise, but we posit that this assumption underlies the actual structure of most medical education as it presently takes place. One conclusion that may unarguably be drawn from this, however, is that it clearly presumes the supervision is appropriate and meaningful. Assessment and validation of progressive supervisory capability is thus an essential element not only of a prospective competency-based residency, but of our present time-based residency as well. The IOM report cites reports of two categories of stressors in training (IOM Report 6-21): work stress factors of fatigue, excessive workload, inadequate time, distractions, and stress; and intellectual stress factors of inadequate knowledge and inadequate supervision. While duty hour rules and workload limits may address the work stress factors, only a systematic process of progressive, validated competency, and, in particular, of supervisory competency will address the intellectual stress factors.

In this context, we must state our reservations about a wish expressed at one point (though elsewhere qualified) in the IOM report, that GME can reliably be so thoroughly supervised as to pose no (zero) net risk to the current patient population (IOM Report 4-1, "*The inherent inexperience of residents as they train need not affect patient safety if they are adequately supervised by more experienced physicians guiding them toward gradual independence.*"), without adverse impact on the future competency of the current trainees to provide future care for patients (IOM Report 1-9, "*The quality of the educational experience of residents today is a "determinant of patient safety and health care quality for decades to come". Educators asked the committee to consider the long-term goal of ensuring patient safety by producing competently trained physicians versus the potential risks to patients that they treat during residency training.*" and IOM Report 4-2, "*An intrinsic challenge of GME has been to find a balance between the educational needs of residents, who require increasing independence as they learn, and the safety needs of patients, who may benefit from being cared for by more experienced physicians. The tension between these two aspects has become more obvious over the past few decades along with a growing attention to safety in medical care.*" and "Accepting the Risks in Creating Confident Doctors", The New York Times, March 17, 2009, http://www.nytimes.com/2009/03/17/health/17mind.html).

On a more positive note, we also take exception to the statement in the report that supervision of trainees by attending physicians would always be optimal (IOM Report 4-8, "*While an attending level supervisor is the ideal for all residents to be taught and guided under, for practical purposes and to avoid exacerbating the limited supply of supervising staff, the committee concluded that a senior resident (equivalent to a PGY-3) is an acceptable minimal level of experience to serve a supervisory role to more junior residents (PGY-1 and PGY-2 residents).*"). Any training program director will quickly come up with circumstances where an appropriately qualified trainee of one or two years more seniority would be the ideal teacher and supervisor for a junior resident, circumstances in which an attending might not understand a junior resident's confusion nearly as intuitively as the junior's just-slightly-more-senior resident colleague would.

A learning environment issue closely-related to the above is **the second major issue in pathology GME: lack of opportunity for effective progressive responsibility**, which a more educationally specific reformulation such as that described above would afford. To make the educational defect we are seeking to cure more clear, let us compare two typical clinical services, based on consideration of the second parameter of our proposed taxonomy.

This parameter is the mode of supervision actually provided. In our taxonomy there are three varieties of supervision actually applied in the course of GME: real-time presence *(R-T P)* of the supervisory attending physician ("*over-the-shoulder supervision*", IOM Report 4-5); prospective off-line *(P O-L)* supervision, where the attending is not constantly physically present, but reviews all trainee activities with potential impact on patient care prior to their implementation or reporting; retrospective off-line *(R O-L)* supervision, where the attending is available to the trainee at need, but at least some of the trainee's activities with potential impact on patient care are implemented/reported prior to review by the supervisory attending physician.

It is obvious the vast majority of daily clinical activities provided by house staff on time-based, continuous care (ward "shift" services) fall into the third category of supervision *(R O-L),* with the senior resident or fellow actually present personally performing or delegating the clinical assessments, and then making and implementing the hourly clinical care decisions. As discussed above, in a well-run, soundly-designed training program, the senior trainee present has been adequately trained and appropriately assessed for these tasks, and has (and is encouraged to use) ready access to attending physician supervision when he or she determines it is needed.

Significantly, senior trainees on consultation services in disciplines other than pathology regularly progress to a level of documented competency at which they are expected to chart their consultation notes, with diagnostic impressions and/or therapeutic recommendations, prior to attending review, confirmation or correction.

Although explicitly envisioned by Medicare (Medicare Claims Processing Manual, Chapter 12 - Physicians / Nonphysician Practitioners, (Rev. 1643, 12-05-08), http://www.cms.hhs.gov/manuals/downloads/clm104c12.pdf, Interpretation of Diagnostic Radiology and Other Diagnostic Tests, "*If a resident prepares and signs the interpretation, the teaching physician must indicate that he/she has personally reviewed the image and the resident's interpretation and either agrees with it or edits the findings. Medicare does not pay for an interpretation if the teaching physician only countersigns the resident's interpretation.*"), such progression in responsibility is a relative rarity in pathology training programs, with the clinically significant decision point in much of pathology being so singularly focused on the release of the diagnosis. Until a GME taxonomy such as the one described herein is officially promulgated, making clear specific expectations for both duty hours and the learning environment, it is unlikely that such meaningful progression, analogous to that nearly universally present in our peer clinical specialties, will be more widely implemented.

A very fundamental beneficial effect of the widespread adoption of such expectations would be that pathology programs would not take in or keep on trainees for the purpose of "getting the work done" without ensuring that they all actually progress to being able to practice without direct supervision (the ultimate in protection of trainees from abusively non-educational environments).

For the reasons described above, appropriate drivers for duty hours and learning environment expectations in pathology training programs are different from those that drive the standard "one size fits all", single-common-mode-of-training rules applicable to continuous coverage, in-house call rotations. The acknowledged principal driver for these latter rotations is ensuring protected time for recovery sleep (IOM Report 7-19). The secondary driver is quality of life (IOM Report 5-10, "*The measures of quality of life in this review encompassed several of the factors examined in this chapter, including mood factors, sleep, relationships, health, and education.*"), and this quality of life driver is what is most relevant to pathology training programs. Without, however, the specificity of analysis supported by this proposed GME taxonomy, application of the "one size fits all", single-common-mode-of-training standard rule to pathology training programs actually produces effects contrary to the goal of protecting resident quality of life, as described below.

This paradoxical effect arises with **the third and last duty hour expectation with which pathology programs have any significant difficulty complying: the one-day-in-seven off rule** (frequency 1.4% in the 2007-2008 ACGME Survey Data). Ironically this mostly arises due to residents on surgical pathology services choosing to distribute their work between both days of the weekend, better to accommodate their personal quality of life. Disallowing this behavior in order to ensure a consecutive twenty-four period (intended for sleep recovery) would be inconsistent with the quality of life benefits this rule has the potential to enhance. This would be resolved by application of the third parameter of our proposed taxonomy: real-time patient interaction versus off-line processing/preparation of information/images/specimens. We propose a more reliable way to benefit from this weekend time-off rule for rotations involving off-line preparatory work would be to set a maximum number of work hours per non-call weekend (such as 10, the difference between 70 hours in five days and 80 hours in seven days) without specifying their distribution, while retaining the twenty-four consecutive hours off expectation (or 24 X 3 plus 48 X 1 in the IOM version) for rotations involving real-time patient interaction, which may reasonably be presumed not to be being scheduled across both weekend days at the trainees' sole behest.

Two additional considerations are pertinent fully to address the questions raised in your letter. These are: first, the economic cost of compliance; and second, how workload may affect duty hours and the learning environment, including specific opportunities for further investigation of the learning environment offered by the particular context of pathology training.

As stated at the very beginning of our response, we cannot meaningfully project the direct economic cost of present or prospective work hour compliance in pathology using available "one-size-fits-all", single-common-mode-of-training models, or from available data. In pathology the prevalent duty hour issue is the ten-hour rule, and to assess the cost of better compliance, information would be required on: first, the drivers of non-compliance (IOM Report 1-9, "*Moreover, there was uncertainty about the actual number of hours that residents currently work per week, how often the limits are violated, and the reasons for those violations (e.g., patient care needs, excessive workload) and whether residents were staying of their own volition versus program or institutional pressures.*"); and second, the extent of noncompliance. While there is no systematic information on the drivers of this noncompliance and whether, therefore, substitute staffing would be either necessary or sufficient to address this situation, the ACGME does collect and presumably compile detailed information in its periodic surveys on the quantitative characteristics of noncompliance. If the ACGME were to share this detailed quantitative information on noncompliance, calculation of an outside-limit estimate of the economic cost of full compliance could be performed.

Finally, workload, quantitative and qualitative, is recognized as the "flip side" of duty hours: too little impairs learning, as does too much, potentially together with trainee and patient safety (IOM Report 3-11, "*The committee believes that workload limits should reflect the practices of each specialty, and this is its reason for recommending the ACGME RRCs' role in determining the limits. Here is an opportunity for and a challenge to the RRCs to determine the number and characteristics of patients that are optimal for both resident learning and patient safety on a day-to-day basis and for developing competence over the long term.*" and IOM Report 5-7, "*It is important to note here that the committee's proposed changes in duty hours without appropriate adjustments of workload could possibly have an unintended consequence of leading to more stress or burnout. For example, one method of moderating resident workload is to reduce or limit the number of patient cases that a resident can handle per duty period. However, if all less complex patient cases are taken over by physician extenders and only more complex patients are concentrated on resident teams (as a way to increase the educational value of time spent on duty), the new level of work intensity could cause some degree of burnout unless caseload is adjusted for patient severity.*"). Pathology offers the ACGME a unique opportunity to act on the IOM's recommendations, in that the majority of each resident's clinical activities are already tracked in considerable detail through laboratory information systems, including patient demographics, CPT (procedural) codes, ICD (diagnostic) codes and dates of service. In aggregate, this constitutes a veritable bonanza of information that would immediately lend itself to a far more precise and less tedious mechanism for assessing the impact of workload on training outcome than the presently required manual entry of a handful of unrepresentative services by each resident into the ACGME's online system. Requests for permission at the level of the program either to interface to the ACGME's online system directly for this purpose, or even for a standard file format to upload information including all the above, with the resident identification, have repeatedly been denied by the ACGME. Perhaps it is now at last time to remove these obstacles and take advantage of this opportunity.

In conclusion, we thank you again for your invitation, allowing us to propose a thorough rethinking of the modes of GME in a way that, when input of other specialties has been incorporated, will support more specific, appropriate and comprehensive rule-making. If this is adopted, then addressing challenging duty hour and workload circumstances need no longer be compromised by the need to accommodate less, or differently demanding rotations either between or within programs. Such a precisely structured taxonomy of training will also surely be conducive to the optimal expenditure of limited resources in supporting both the trainees' experience and patient safety. In pursuit of these goals, if invited, Dr. Black-Schaffer will gladly participate this June in your proposed Resident Duty Hours and the Learning Environment Congress in Chicago.

Respect fully submitted on behalf of the Association of Pathology Chairs,

W. Stephen Black-Schaffer, M.D.
Chair, Program Directors Section, Association of Pathology Chairs
Associate Chief of Pathology and Pathology Program Director
Massachusetts General Hospital and Harvard Medical School

J. Charles Jennette, M.D.
President, Association of Pathology Chairs
Brinkhous Distinguished Professor and Chair
Department of Pathology and Laboratory Medicine
University of North Carolina

Pathology Program Directors Three-Parameter Taxonomy of Modes of Training in GME

Parameter 1: Clinical training - organization

Time-based	Shifts for continuous care (ward services, interval note)*
(coverage)	Sessions for periodic care (clinic services, episode note)**
Case-based	Consultative care (case eval/invest, diagnostic/therapeutic note)**
(assignment)	Procedural service (procedure prep/perform, descript/op report)**
Project-based	Lab investigation (scientific presentation/publication)***
(research)	Clinical investigation (clinical presentation/publication)***

Call coverage	*In house
(typically)	**From home
	***None required

Parameter 2: Clinical training - supervision

Real-time presence	*R-T P*	Supervisory physician in continuous presence
Prospective off-line	*P O-L*	Supervisor available and involved prior to any patient care
Retrospective off-line	*R O-L*	Supervisor available but not always involved prior to care

Benefits:

R-T P	Enables trainee to develop additional competence with no compromise to care
P O-L	Enables trainee to demonstrate current competence with no compromise to care
R O-L	Enables trainee to demonstrate current competence and clinical judgment

Risks:

R-T P	Does not encourage/allow comprehensive development/assessment of complex (multi-step) clinical reasoning/judgment
P O-L	Does not allow trainee to develop or supervisor to assess appropriateness of trainee confidence level/judgment in clinical decision-making
R O-L	Requires methodical prior assessment of trainee readiness and thorough assurance of availability and accessibility of timely supervisory assistance to assure patient safety, but failure to provide this level of progression of responsibility potentially more risky to patient safety, as acquisition/assessment of knowledge, skills and attitudes then outside confines of training program, in realms of practice where direct supervision no longer assumed to be necessary and may not therefore be provided

NOTE The above distinguish among supervisory modes of clinical training specifically appropriate to GME in the overall continuum of medical education. Critically important are didactic learning that takes place from undergraduate through post-graduate medical education and practice-based learning and improvement that takes place in the graduate and post-graduate setting of independent practice

Parameter 3: Clinical training - patient proximity

Real-time patient contact	evaluation & management/procedural services (clinical/operative note)
Off-line info processing	clinical info, patient image/specimen processing (clinical consult/ancillary report)

Summary of APC Rationale and Recommendations to ACGME

1 Both current ACGME and proposed IOM duty hour rules and learning environment expectations have been narrowly based on a single, non-parametric "default" model of GME

2 This narrow basis limits the specificity with which these rules and expectations can be applied to many actual GME rotations, including in particular almost all pathology rotations

3 Application of these rules and expectations non-specifically necessarily compromises both educational and operational efficiency of these rotations

4 We therefore propose a three-parameter taxonomy of GME that provides for much more specific applicability of rules and expectations across a range GME rotations, especially in pathology (but also prevalent in other specialties):

  The organization of the clinical learning environment (including the ways in which clinically relevant on-call coverage is provided)

  The mode of supervision that is provided for each level of training

  The nature of the work in terms of the trainee-patient interactions

5 Using these parameters to address duty hour/learning environment issues prevalent in pathology we make the following proposals:

  For rotations typical of pathology training programs, combination of an eight-hour nightly minimum time off with a non-averaged eighty-hour work week rule would be a better balance between optimal educational opportunity and ideal resident rest conditions than the ten-hours off between shifts rule

  To provide pathology residents a level of independence that permits confident certification of their readiness for practice without direct supervision, we propose that the legitimacy of retrospective off-line supervision at an appropriate level of training be made explicit by the ACGME, to remove what is widely perceived as a barrier to giving qualified senior residents the necessary level of independence

  For rotations typical of pathology training programs we propose a maximum total number of non-call hours of work such as ten be specified per weekend off, rather than twenty-four consecutive hours off work

6 Finally, two requests are made, one for more quantitative aggregate information from the ACGME surveys on compliance with the ten-hour rule, and the other for the opportunity for pathology programs to upload the resident activity data that is routinely tracked in our laboratory information systems, providing a unique opportunity for our RRC to relate the timing, amount and distribution of clinical work to efficacy of training, thereby taking a step toward rationalization of the workload assumptions underlying our residents' education in pathology

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April 29, 2009

Thomas J. Nasca, M.D., MACP
Chief Executive Officer
Accreditation Council for Graduate Medical Education
515 North State Street
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Chicago, IL 60654

Dear Dr. Nasca:

Thank you for your letter of February 16 to major stakeholders in graduate medical education. We applaud your efforts to bring our various constituent groups together in an effort to respond thoughtfully to the questions and recommendations of the Institute of Medicine's recent report, "Resident Duty Hours: Enhancing Sleep, Supervision, and Safety."

The purpose of this letter is to provide you with recommendations from the leadership of the American Association of Directors of Psychiatric Residency Training (AADPRT), the American Board of Psychiatry and Neurology, and the American Association of Chairs of Departments of Psychiatry. This letter has been based in part upon review of a survey AADPRT conducted of its membership. A summary of the survey's results is attached.

AADPRT, ABPN, and AACDP support evidence-based changes that will enhance patient safety, resident education, and resident well-being. The AADPRT survey results highlight the widely variable effects that implementation of the recommendations would have on our many residency programs based upon such factors as their size, the number of institutions involved in training, the size of the faculty, and the nature of their financial support for training. Some of the recommended changes could well have deleterious, possibly disastrous, effects in our smaller programs while other recommended changes could have similarly adverse consequences for training in larger programs. While proposals for increased supervision and improved handovers of patient care are widely perceived as positive goals, members are unconvinced that the proposed duty hour changes will improve overall resident education or well-being. There is also concern that these changes may adversely affect the development of residents' professionalism and sense of what it means to "be a doctor". Accordingly, we strongly recommend that the ACGME carefully study the impact of the proposed changes on a pilot of selected, representative residency programs and their residents before putting into place specific, detailed program and institutional requirements. We also recommend maintaining as much flexibility as possible so that individual programs can accomplish over-riding goals in ways that best fit local circumstances and clinical care systems. AADPRT urges that any final changes be based on solid evidence of an analysis of risks and benefits.

In reviewing the data of the AADPRT survey, members' concerns fell into three areas. We will now address each of those areas. First, one size does not fit all in regard to the many disciplines in medicine in their efforts to meet the goals articulated in the IOM. For example, regulations that might further these goals for surgery programs might not make sense for psychiatry programs, and vice versa. As such, we recommend discipline-specific requirements as much as possible. Toward that end, duty hour requirements as part of the general requirements make sense only up to a point (e.g. total number of hours per week, etc.) Beyond that, more specific duty hours requirements, including levels of supervision, for example, should be set by the individual RRC's which typically include members who understand the educational challenges, goals, and clinical settings of their fields.

AADPRT, AACDP, and ABPN have major concerns also about the prospect of oversight of residency education by funders such as CMS or accreditation groups that have little expertise in education such as JCAHO. We recommend that the ACGME continue as the sole body that monitors program compliance with any and all requirements. CMS and/or JCAHO should not be invited in to this realm.

Finally, psychiatric leaders have serious concerns about the costs that would be entailed in meeting the proposed changes and that this would become an unfunded mandate that, in the end, would place terrible burdens upon many programs and would ultimately erode the quality of resident education. As such, we recommend that ACGME partner with other organizations to help identify and ensure adequate funding necessary to implement any and all changes and that no changes be put into place until this is accomplished.

We hope that these recommendations and the results of our survey will be of help to you and the ACGME. We are grateful for your comprehensive, methodical and considered approach. Anything less will risk causing unintended serious and potentially irreversible disruption in many excellent programs which are already committed to the goals of improving patient care, resident education, and resident health and well-being. Together we look forward to working with you in the next months and years to continue to improve the education of our residents and, ultimately, the care provided to the patients we serve.

Sincerely yours,

William Greenberg, M.D.
Chair, AADPRT Taskforce on
Resident Duty Hours
Director, Harvard Longwood
Psychiatry Residency Program

David Kaye, M.D.
President, AADPRT
Professor of Psychiatry
Director of Training, Child & Adol Psychiatry
University at Buffalo

Larry R. Faulkner, M.D.
President and CEO
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Laura Roberts, M.D.
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Charles E. Kubly Professor and Chairman
Department of Psychiatry and Behavioral
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Attachment 1: The AADPRT Survey

In mid-January, AADPRT developed a survey which we sent to our membership, together with summary documents from the IOM report. With a one week turnaround time, we received responses from 109 of our members. Our survey was divided into four sections based upon the areas of recommendations in the report, as follows: 1. Duty Hours and Moonlighting, 2. Workload Adjustment, 3. Enhancing Supervision, and 4. Improving Handovers. This summary will be divided into these same sections as well.

Section 1. Duty Hours and Moonlighting

As shown in the attached summary of our survey results, only a minority of our members think that the recommended duty hour and moonlighting restrictions would improve the quality of patient care (25%) or improve resident education (24.1%) Most respondents (51.9%) think that they would improve resident health and well-being.

We asked our members to comment about which of the recommended changes would be most difficult to implement, which would be easiest, and what they see as the likely costs and benefits of these changes. We learned the following:

- While some of our respondents currently have relatively little resident on call in their programs and think that all of the recommended changes would be easy to implement, a substantial number of our respondents are concerned about implementing the new moonlighting requirements.
- Many of our respondents note that it would be particularly difficult to implement the new requirement limiting patient care to 16 consecutive hours, the requirement for mandated sleep for 5 hours thereafter, and the limitation of night float to four, rather than five, consecutive nights.
- The easiest requirements to implement would be the requirements regarding every third night on call and 48 consecutive hours off at least once monthly. There is varying opinion about how easy it would be to implement the recommendation regarding one day off per week without averaging over time.

We asked our members to comment on the likely costs and benefits of the proposed changes as well as for any other comments. Although it is difficult to summarize the many thoughtful and nuanced responses of our members, we can report that a small minority of our respondents see the likely impact to be positive—better rested residents who are better able to learn and better able to provide care for patients. That having been said, more of our respondents voice a variety of concerns including the following:

- Concern about the need for more people to be on call in any 24 hour period and in any week-long period to meet these requirements. This would have its own consequences including the following:
  - It would also likely mean more frequent call for residents and, as such, a decline in resident satisfaction.
  - More residents on call overnight or on night float rotations would mean fewer residents available for classes, seminars, and conferences during the day. This will lead to a disruption in continuity of current teaching activities.
- Concern that smaller programs will not be able to meet the requirements and will be forced to close.
- Enormous concern about cost.
- Concern that these requirements will become an "unfunded mandate".
- Concern about the loss of continuity in care.
- Concern about limitation on opportunities for learning and fragmentation of the residents' clinical and classroom experiences
- Concern about adverse impact on residents' view of patient "ownership" and professionalism
- Concern that limitations on moonlighting would add to resident financial hardship

Section 2. Workload Adjustment

Although 45% of our respondents think the workload adjustments described in the report would improve the quality of care and 47.2% think these would improve resident education, only 13.8% or our respondents would like the Psychiatry RRC to specify "caps" in the number of patients treated on any given service or the number of patients evaluated on any given shift.

In many of their comments, our respondents discuss their endorsement of efforts to keep residents from being treated like "work horses". However, several of our respondents remind us that "doing windows" is a part of all jobs, and that residency remains, among other things, a job as well as preparation for future jobs which will include "doing windows" as well. In keeping with the overwhelming opposition to "caps", many of our respondents are concerned that "one size fits all" caps do not take into account variability in patient acuity and clinical care settings, will inevitably be arbitrary and, as such, are likely to be deleterious.

Section 3. Enhancing Supervision

60.4% of our respondents think the recommended requirements regarding supervision would improve the quality of care and 63.2% think that they would improve resident education. 74.6% of our respondents think that it would be somewhat to very difficult to implement these changes in their programs.

In their comments, many of our respondents comment on the lack of clarity in the recommended requirement for in-house supervision. Many comment that if this is to be a staff physician, rather than a more senior resident, it will be very expensive and, for many systems, unaffordable. As noted, there is some difference of opinion about impact on patient care and on resident education. Regarding the latter, a number of respondents are concerned that the requirements would interfere with the development of autonomy in residents and in current efforts toward providing graded levels of responsibility.

Section 4. Improving Handovers

82.1% of our respondents think that recommended requirements in this area would improve patient care and 70.5% think they would improve resident education. 49.9% of our respondents think that it would be somewhat to very difficult to implement these changes in their programs.

The comments of many of our respondents reflect their support for these recommendations and the fact that many of our members have already implemented these changes. There is some concern about crafting new requirements in a way that leaves programs free to develop systems that work best for their specific systems and clinical needs.

General Comments

Our members were asked for any other comments regarding the report recommendations and a number of themes were prominent:

- Reiteration of concerns about cost and adverse impact on education.
- Concern that "shift work" will lead to (further) erosion in professionalism and the readiness of our residents to function independently post-residency.
- Concern that over-regulation will interfere with initiative, creativity and situation-specific adaptations in programs.
- Concern about whether the recommendations are, in fact, evidence-based in regard to resident well-being, patient safety, and resident education.
- Concern that the recommended implementation timetable is too short, the hope that the ACGME will work toward a consensus view on these difficult issues, and suggestions that no additional requirements be put into place before funding has been identified.

AADPRT Duty Hours Survey

January 2009

1. Duty Hours

Do you think these recommendations, if implemented, would:

	Yes	No	No opin.	N
Improve the quality of patient care?	27 (25%)	72 (67%)	9 (8%)	108
Improve resident education?	26 (24%)	76 (70%)	6 (6%)	108
Improve resident health and well being?	56 (52%)	40 (37%)	12 (11%)	108

2. Workload adjustment

Do you think that these recommended changes would:

	Yes	No	No opin.	N
Improve the quality of care	49 (45%)	53 (49%)	7 (6%)	109
Improve resident education	51 (47%)	54 (50%)	3 (3%)	108

Would you like the Psychiatry RRC to specify "caps" in the number of patients treated on any given service or the number of patients evaluated on any given shift?

Yes	No	No opin.	N
15 (14%)	82 (75%)	12 (11%)	109

3. Enhancing Supervision

Do you think these changes would:

	Yes	No	No opin.	N
Improve the quality of care	64 (60%)	36 (34%)	6 (6%)	106
Improve resident education	67 (63%)	34 (32%)	5 (5%)	106

How difficult would it be to implement these changes in your program? (106 responses)

Very difficult	2 (2%)
Difficult	12 (12%)
Somewhat difficult	38 (37%)
Easy	37 (36%)
Very easy	15 (14%)

4. Improving Handovers

Do you think these recommended changes would:

	Yes	No	No opin.	N
Improve the quality of care?	87 (82%)	11 (10%)	8 (8%)	106
Improve resident education?	74 (71%)	24 (23%)	7 (7%)	105

How difficult would it be for you to implement these changes in your program? (104 responses)

Very difficult	2(2%)
Difficult	12 (12%)
Somewhat difficult	38 (37%)
Easy	37 (36%)
Very easy	11 (10%)

AMERICAN ACADEMY OF
NEUROLOGY

American Academy of Neurology

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March 2, 2009

Thomas J. Nasca, MD, MACP
Chief Executive Officer
Accreditation Council for Graduate Medical Education
515 North State Street
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Dear Dr. Nasca,

The American Academy of Neurology's (AAN) Graduate Education Subcommittee (GES) and Consortium of Neurology Program Directors (CNPD) and the American Board of Psychiatry and Neurology (ABPN) appreciate this opportunity to provide the Accreditation Council for Graduate Medical Education (ACGME) feedback from their constituents on the proposed changes to resident work duty hours recommended by the Institute of Medicine (IOM). Neurology program directors and others within the GES, the AAN and the ABPN feel strongly that these recommendations, if adopted, would have serious negative consequences to neurology resident education and patient safety. Specifically:

- Small neurology residency programs would struggle with a plan for night coverage. About 25% of neurology residency program have nine or fewer residents. Unless new manpower resources were provided, the logistical changes needed to implement the new requirements would produce inadequate, disrupted educational training to provide the same level of clinical service. It is possible that some programs would discontinue resident training. Many programs would simply not be able to create a "night-float" system.

- Most programs would need to have two night float rotations per month. The addition of largely non-educational night float rotations would replace higher priority educational experiences such as electives and outpatient months.

- The shift work needed would significantly reduce resident participation in lectures and conferences. Lectures could be videotaped, but the face-to-face interactions and ability to ask questions would be lost and education would suffer.

- Formal bedside teaching will not be available to all residents since some will be on alternate shift schedules.

- We estimate if all rules were adopted there would need to be a 35% increase in resident or physician extenders. Given Medicare and hospital budgets, this is very unlikely to happen. Finding qualified physician extenders in neurology is a challenge. Use of other hospitalists, non-neurologists, is not acceptable medically for most seriously ill neurology inpatients, and attending physicians are not paid nor typically available for this kind of work.

- For some neurology residency training programs to survive, it would be necessary to eliminate primary neurology inpatient ward services and have residents work in consultative roles only. The enormous educational benefits of having ward responsibilities would be lost. In addition, the Neurology Review Committee (NRC) requires inpatient care as part of its requirements.

- There is no convincing evidence in the literature that current work duty hour requirements have improved patient safety. Limited studies demonstrate improved individual resident safety, but there are increased errors as a result of the frequent hand-offs of patient information from provider to provider. We do not believe the recommended changes would increase patient safety, as the number of hand-offs would significantly increase.

- The proposed changes would negatively impact continuity of patient care. Neurology program directors are concerned that the IOM has not sufficiently weighed patient dissatisfaction with the discontinuity of care inherent in shift work.

- Further changes in duty hours requirements for residents ignore the work hours and patient safety realities facing many physicians in practice. Some neurology program directors have stated that recent graduates report they were unprepared for the reality of private practice which may require call every third night, hospital work seven days a week, or extended office hours.

- The costs for this would be enormous at $1.8 billion and this at a time when the nation is mired in a recession.

The AAN, GES, CNPD, and the ABPN request the ACGME not adopt the IOM recommendations unless unequivocal evidence from well-designed and controlled studies in health care settings (not proxies) can prove these changes result in significant improvements in the safety of patients without sacrificing the educational integrity of residency training programs, and financial support is provided to allow for transition to a mandatory night float system.

We look forward to hearing from you. Please contact Lucy Persaud Samaroo, Program Manager Education, via email at *lpersaud@aan.com* or via phone at (651) 695-2741.

Sincerely,

Stephen M Sergay

Stephen M. Sergay, MB BCh, FAAN
President
American Academy of Neurology

Larry R. Faulkner, MD
President and CEO
American Board of Psychiatry and Neurology

cc.
Ralph F. Jozefowicz MD, FAAN, Chair, Education Committee
Cynthia L. Comella, MD, FAAN, In-Coming Chair, Education Committee
John R. Corboy, MD, FAAN, Chair, Graduate Education Subcommittee
Lori Ann Schuh, MD, Chair, Consortium of Neurology Program Directors
John Engstrom MD, FAAN, Chair Elect, Consortium of Neurology Program Directors
Brett M. Kissela, MD, Past Chair, Consortium of Neurology Program Directors
Catherine M. Rydell, CAE, Executive Director/CEO, AAN/AAN Foundation
Christine E. Phelps, Deputy Executive Director, AAN/AAN Foundation
Susan Rodmyre, Director, Education
Lucy Persaud Samaroo, Program Manager, Education

May 4, 2009

Thomas J. Nasca, M.D., MACP
Chief Executive Officer
Accreditation Council for Graduate Medical Education

Dear Dr. Nasca,

As per your request, the American Academy of Allergy, Asthma and Immunology, in consultation with Allergy and Immunology Program Directors, have prepared the following responses to your questions.

<u>The below responses are germane only to our Allergy and Immunology (A/I) (and closely related) specialties.</u>

- *Your organization's formal position on the recommendations contained in the Institute of Medicine Report, including impact analysis, from your organization's perspective, on costs and impact of implementation*

In general, the IOM recommendations on duty hours, enhancing sleep, supervision and safety are unlikely to affect substantially the Allergy and Immunology subspecialty training. In general, residents are not exceeding current ACGME duty hour limits and are unlikely to have difficulty meeting the current IOM recommendation. In-house call, long shifts, nighttime shifts are rare in our program. Our specialty is not in favor of changing mandatory time off duty from one day off per week average over 4 weeks to one day off per week, no averaging. We do not support changing from mandatory 4 days off per month to 5 days off per month. We believe our programs can benefit from this greater flexibility without inappropriate burden on our residents. Complying with IOM recommendations to host unannounced visits will add burden and cost to programs (i.e. support staff) that already are having trouble meeting budgetary constraints and may become disruptive to our educational programs. For programs without documented violations in duty hours or other safety items, our organization disagrees with this latter recommendation.
Our organization believes that the impact analysis and impact of implementation appear reasonable, without the benefit of independent review.
We all agree that patient safety is of utmost importance.

- *Your organization's formal position on the current ACGME Resident Duty Hours Standards including impact analysis, from your organization's perspective, on costs and impact of implementation*

Our organization has a particular concern about the impact of the implementation of the proposed IOM duty hours change on the economics of subspecialty (fellowship) training in general. Given that the proposed duty hours will impose a need for a large additional number of residents in primary specialties, funds will not be available from institutions for specialty (fellowship) training. This impact may be the largest on smaller outpatient based specialties like Allergy and Immunology. An alternative to an increase in the number of residents in primary specialties to accommodate the IOM duty hour requirements is a prolongation of primary training duration. This possibility will likely decrease the desire and the availability of residents to pursue longer training in subspecialties.

In summary, the IOM recommendations should be evaluated in the context of the whole of graduate medical education.

- *Your organization's formal recommendations regarding dimensions of Resident Duty Hours standards, and justification (wherever possible) for this position with evidence*

As above.

- *Your organization's formal recommendations regarding standards governing key aspects of the Learning Environment, and justification (wherever possible) for this position with evidence*

Allergy and Immunology offers the following responses to specific recommendations provided in the IOM report:

IOM recommendation: Residents should be taught error detection, correction, reporting, and monitoring so they can participate fully in the hospital's quality improvement effort.

Response: Our organization agrees in principle that this training should be provided, but also believes that fellowship programs should retain the freedom and independence to decide how and to what extent the material should be incorporated into the curriculum. Because Allergy/Immunology residents have already completed residency training in Pediatrics, Medicine or both, teaching error detection, correction, etc. should have occurred already. A/I programs and their directors should be able to determine whether or not additional training of residents in that competency is necessary.

IOM recommendation: The committee recommends monitoring and evaluation of the implementation of all the proposed changes to assess the impact, detect any unintended consequences, and provide information to guide future fine-tuning of duty hours.

Response: Because our organization does not have difficulty complying with current or future duty hour requirements, we also believe that we should not be responsible for monitoring and evaluating the implementation of all the proposed changes. Such a role would add undue cost and burden to A/I programs. However, we believe that such initiatives can be encouraged among programs that choose to engage in such activities.

IOM recommendation: The committee recommends that Residency Review Committees (RRCs) set specialty specific guidelines for the number of patients residents should be permitted to treat during a shift, based on the level of residents' competency and patient characteristics. The committee found that closer supervision leads to fewer errors, lower patient mortality, and improved quality of care. Particularly, first-year residents should not be on duty without immediate access to an in-house supervisor.

Response: This organization agrees with appropriate supervision of patient care. However, A/I fellowship programs themselves, under the direction of the Program Director, should determine the appropriate number of patients permitted to be treated during a shift.

IOM recommendation: Shift changeovers be scheduled to ensure adequate overlap time to conduct effective handovers

Response: Scheduling of shift changeovers is not necessary for our organization.

- *Your organization's willingness to participate, if invited, in a Resident Duty Hours and the Learning Environment Congress, to be held in June, 2009 in Chicago Illinois. This Congress will be configured to provide the ACGME leadership will the breadth of perspectives of the medical community as they embark on review and revision of the Resident Duty Hours and Learning Environment Standards*

To be determined.

We ask that in any of the responses to the above topics, that you note where your organization believes that the response is germane only to your (and closely related) specialties, and where the response is general (across all or most specialties).

Thank you for your attention,

Sincerely,
American Academy of Allergy, Asthma and Immunology
Allergy and Immunology Program Directors

AMERICAN ACADEMY OF
FAMILY PHYSICIANS
STRONG MEDICINE FOR AMERICA

February 16, 2009

Thomas J. Nasca, MD, MACP
Chief Executive Officer
Accreditation Council for Graduate Medical Education (ACGME)
515 North State Street, Suite 2000
Chicago, Illinois 60654

RE: ACGME Request for Comment – IOM Report on Resident Duty Hours

Dear Dr. Nasca:

Thank you for your letter of February 12, 2009, inviting comments and recommendations regarding the Institute of Medicine (IOM) Report on Resident Duty Hours. The American Academy of Family Physicians (AAFP) has already collaborated with the organizations of academic family medicine in submitting to you such a response (copy attached). We hope that it will be helpful input to the ACGME as you deliberate on an appropriate response to the IOM report.

With respect to the potential invitation, we would welcome the opportunity to participate in a *Resident Duty Hours and the Learning Environment Congress* in June 2009 in Chicago, Illinois. Thank you for notifying us of yet another chance to contribute to this important process.

Sincerely yours,

Perry A. Pugno MD, MPH

Perry A. Pugno, MD, MPH, CPE, FAAFP
Director, Division of Medical Education

Cc: Douglas Henley, MD, FAAFP
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April 30, 2009

Thomas J. Nasca, MD, MACP
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RE: ACGME Congress on Resident Duty Hours

Dear Dr. Nasca:

The Association of Family Medicine Residency Directors (AFMRD) would like to submit the nomination of Stanley M. Kozakowski, MD to represent our organization at the upcoming ACGME Congress on Resident Duty Hours. Dr. Kozakowski is currently the President Elect of AFMRD and he will assume the presidency of the organization at the beginning of June. Dr. Kozakowski also attended the recent ACGME pre-conference on the IOM Duty Hours representing the interests of family medicine residency program directors.

The AFMRD Board contributed to the writing of the attached position statement previously submitted to the ACGME on behalf of all of the organizations of family medicine. As the organization representing the training leadership in GME for family medicine, we feel that it is important for the voice of program directors to be heard at the Congress.

We fully endorse the above referenced position statement. In addition, the AFMRD Board surveyed our membership and the results of that survey will be included in an upcoming article in the Annals of Family Medicine.

The AFMRD believes that ACGME must not relinquish control for the oversight of resident duty hours to governmental or other regulatory organizations. Most importantly programs must focus on appropriate resident supervision to reduce inevitable errors of resident training. Any proposed duty hours changes must be practical to implement and potential unintended consequences related to loss of continuity and/or professional development must be mitigated.

Family Medicine welcomes the opportunity to participate in this important national dialogue which must protect patient safety and resident well being, while maintaining excellence in education.

Elissa J. Palmer, MD

Eilssa Palmer, MD, President
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Advocating for Family Medicine

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May 4, 2009

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RE: ACGME Request for Comment – IOM Report on Resident Duty Hours

Dear Dr. Nasca:

In response to your communication of December 22, 2008, the organizations representing the discipline of Family Medicine would like to take this opportunity to provide you with our observations, comments and recommendations related to the Institute of Medicine (IOM) Report entitled *Resident Duty Hours: Enhancing Sleep, Supervision and Safety*. In the interest of efficiency, we have consolidated the input from all of our organizations into this brief analysis. We respectfully request that you take under advisement the following observations:

- Additional work restrictions will result in more frequent patient hand-offs that have been demonstrated to increase the likelihood of medical errors.
- Implementation of the proposed standards will further compromise continuity of care, disconnect residents from patient care processes and the evolution of illness, and decrease resident investment in their patients.
- Concerns regarding patient safety in the educational environment fail to acknowledge the protection to patients afforded by supervision of physicians in training (interns by junior residents, junior residents by senior residents, and senior residents by faculty attendings).
- There is an no data documenting that previous work restrictions have improved patient safety or that the benefits of further restrictions will outweigh harm from more frequent patient handoffs.
- A January 2009 survey of family medicine residency directors found that the majority of programs could not implement the IOM recommendations without additional resources, and for many, attempting to do so would threaten the viability of their residency programs.
- The IOM acknowledged in its report the high cost of implementing additional restrictions on resident duty hours. Doing so *without* a call for Congress to better support the rising costs of training the nation's physicians suggests an unfair, unfunded mandate and an unreasonable expectation of the medical education community.

In light of the above-noted observations, the organizations of family medicine respectfully submit the following recommendations to the ACGME for consideration:

1. Develop and implement pilot studies in which different duty hour requirements are measured against medical errors and patient safety guidelines. No new duty hour standards should be adopted until these studies are completed.
2. The ACGME should acknowledge that additional duty hours restrictions will necessarily require an increase in training program faculty, with attendant substantial increases in program costs at a time when financial resources for graduate medical education are at a premium.
3. The ACGME should demonstrate its commitment to addressing the hazards of excess fatigue and sleep deprivation among residents through the development of educational materials for use by all graduate medical education programs.
4. Revise the core competencies to focus on patient safety as a system property and enhance resident skills in patient handoffs rather than disproportionately emphasizing duty hours.

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5. The recommendation that internal and external moonlighting comply with duty hours standards is a potentially important step in minimizing resident fatigue.
6. The ACGME should devise a process to assess periodic technical violations of the duty hours standards in circumstances where patient care priorities or an exceptional educational opportunity chosen by the resident occur.
7. The ACGME's duty hours monitoring system needs to be better communicated to the public so that there is a greater appreciation of the safeguards and supervision built into it.
8. The ACGME should define and better communicate the parameters under which duty hour violations trigger a complete accreditation review of the entire residency program.
9. The ACGME needs to clearly differentiate between the occasional minimal technical violation of a duty hours standard with no significant impact on patient safety and a pattern of consistent resident exploitation through excessive work hours scheduling and demands.
10. The ACGME should publicly acknowledge that the education of medical professionals is an extraordinarily complex and dynamic process, with multiple safeguards in place and the greatest concern for patient safety. It is in the best interests of the American public that the medical education community continues to be charged with the responsibility to optimize that careful balance between graded responsibility in the development of the physician and the highest standards of patient safety.

We sincerely appreciate this opportunity to provide the ACGME with our perspectives and suggestions related to the IOM Report on Resident Duty Hours. Our organizational representatives will also be participating in the *International Symposium on Resident Duty Hours and the Learning Environment* in early March, and we look forward to the opportunity to contribute to the discussions that will emanate from it. Thank you for providing us with these valuable avenues for input.

Respectfully submitted,

Ted Epperly MD

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American Medical Student Association/Foundation

- Quality, Affordable Healthcare for All
- Global Health Equity
- Enriching Medicine through Diversity
- Professional Integrity, Development, and Student Well-Being

May 1, 2009

Thomas J. Nasca, M.D., MACP
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Dear Dr. Nasca and AGME Board Members:

As the national Jack Rutledge Legislative Director for the American Medical Student Association (AMSA), I speak for our National Office and for our membership of over 67,000 physicians in training to express our pleasure at your request for our policy position on the current state of resident work hours in the U.S.

The mission of AMSA is built upon a commitment of our membership to advocate for a better, higher quality health care system for our patients and future patients at the same time that we work to create an environment for physicians in training all over the world to achieve an environment of excellence in their medical training.

As the voice of students in the midst of our country's medical educational system, our Director of Student Programming, Rebecca Sadun, PhD, and I will use the following pages to address the impact of resident work hour regulation policy on our area of expertise – on the impact of the quality of medical education.

The following policy positions are corroborated in a broad base of evidence, drawn from membership responses to our formal solicitation of input, and finalized through the process of an intensive working group held in March 2009.

Regards,
Mary Carol Jennings

Mary Carol Jennings

Jack Rutledge Legislative Director
American Medical Student Association

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Cost analysis

We do not pretend in this document to improve upon the cost estimates of the IOM or of other organizations who are accustomed and equipped to focus on financial analyses.

We do note, however, that articles on this topic often claim that hospitals would be devastated financially if residents were to residents work shorter hours and earn salaries more commensurate with the extent of their education. Long, unregulated hours and low salaries do not necessarily save hospitals money. Errors - including those related to fatigue - can be hugely expensive if one includes extra days in the hospital for which Medicare does not reimburse (even worse for charity care), typical rates of resulting malpractice suits, etc. Reducing hours - and thereby reducing the likelihood and occurrence of errors – can eliminate even just one or two large mistakes for a hospital in the span of a year and result in more prompt discharges. The reduction of these significant costs holds the potential to leave hospitals with the funds in hand to pay for floaters, hospitalists and additional house staff to create a healthy environment with the capacity for effective continuity of care.

Cost considerations of meeting workforce capacity needs

Our medical teaching system will need to hire more providers to cut out the "crutches" we have come to rely too heavily upon, such as every other night call shifts and 24 hour shifts
We will need the resources to train an adequate number of health professionals to meet projected shortages and to ensure capacity to keep work hour standards

Positions on existing dimensions of resident work hour and learning environment standards

A. Improving and ensuring patient safety

We should support further public health research to examine the links between errors in judgment and the number of hours a resident has worked.
Residents dose more on days following fewer hours of sleep.[i]

Sleep deprivation and fatigue have a much-demonstrated negative effect on resident mood and attitude toward resident duty and patient care. These negative effects on mood and attitude are corroborated by poorer results on more performance tests correlated to routine patient care decisions in acutely sleep-deprived residents.[ii]

B. Achieving excellence in medical training

Lifelong learning:

Quality residency programs train physicians to embrace a career of lifelong learning. Training a physician through a process with little or no balance between professional and personal life will translate to a workforce too overworked to appreciate the large picture of medicine and the perspective needed to provide rich and holistic care for our patients. An increased patient workload while on-call is associated with more sleep loss and less resident participation in educational activities.[iii]

Resident well-being:

Resident quality of life improves on any number of measures in programs that follow an 80 hour work week.[iv]

The driving force behind resident work hour restrictions has always been patient safety. Resident health and safety have consistently taken a back seat. In keeping with our national principles as stated above, these two forces are equally important reasons to actually limit work hours to 80 hours a week.

Improving patients' physical and mental health are the heart of medicine. Physicians cannot truly take care of others to the best of their abilities if we do not permit and encourage them to take care of themselves first.

Such conditions appear to leave many residents who are otherwise happy, productive physicians dissatisfied in their career choice and so exhausted and demoralized that they would rather be somewhere else. Working long hours with little sleep and off-hours time is detrimental to the physical and mental health of residents - as it is for anyone working such hours in any profession.

The long-term psychological impact of long work hours should also be considered to ensure that residents maintain a good learning efficiency throughout their residency years. For example, maybe we can find a good balance of short vacations/breaks that may improve the net learning of the residents during residency years.

Learning environment

Residency is, above all else, about learning. Residency is a time for newly-minted physicians to practice under the supervision of more experienced physicians and to acquire the knowledge, skills, confidence, and character necessary for delivering excellent care when they graduate from their residency programs and practice independently. Though efficient and affordable patient care and community service are appropriate aspects of residency, these elements should never come at the expense of learning.

Whether in the realm of information consolidation and recall or in the realm of motor learning and skill building, extensive research shows that sleep deprivation is a detriment to the learning environment.[v] [vi] [vii] [viii] [ix] Furthermore, high levels of stress, associated with high levels of cortisol, have been shown to reduce learning.[x] Sleep deprivation increases cortisol levels[xi] and thus compounds the negative effects of stress on the learning environment. Both sleep and days off from work are known to reduce cortisol levels and thus protect against high-stress environments,[xii] protecting the learning environment and promoting learning.

For residency to be the learning experience that, by design, it can and should be, residents must be given opportunity to *both* achieve sufficient hours of sleep (for most adults, this necessitates an average of >7hrs/night) and engage in non-work activities that reduce overall levels of stress and break the "cortisol cycle." In order to both sleep sufficiently and have opportunity to "de-stress," residents need a minimum of 88 off-duty hours, which should include one work-free day per week.

Separately but equally importantly, pressure from residency programs to falsify hours in order to keep within regulations, creates a prevalent ethical dilemma for residents that is destructive to the learning environment and antithetical to the learning objectives of the residency, which include accurate patient charting, academic honesty, and willingness to admit to and correct system failures.[xiii]

There are enough procedures to go around

The idea has been expressed that limiting work shifts to 16 hours will result in residents deprived of adequate numbers of operations or procedures.
This opinion is baseless and misinformed. Simply limiting shifts to 16 hours does not entail a decrease in absolute hours per week, will not entail task shifting to other professions, and currently is not decreasing the patient per resident workload. Residents leaving the hospital at the end of their shift will pass scheduled procedures off to their colleagues, and their colleagues will do the same for them at the next shift change.

Programs have been able to reduce work hours without harming efficiency or reducing the number of patients residents are able to see, and resident programs in a study of 2 teaching centers that were classified by resident reporting as having actually reduced their hours in 2003 showed a decrease in the proportion of residents indicating that working too many hours or cross covering too many patients contributed to mistakes in patient care.[xiv]

Enforcement authority:

We don't need to cut hours down from 80; we need instead to enforce this limit in a meaningful manner. The IOM report attempts to address protections for residents who would report program failures to adhere to work hour limits, but it fails to demonstrate a robust understanding of the incentives and disincentives driving incidence of resident whistle-blowing. It fails to disaggregate 2 separate problems: it states that residents report accurately and directors retaliate (this problem is addressed); the real situation is that residents under-report because they know their programs will lose their accreditation (there is too much authority for this second problem vested in ACGME)

It is clear that existing reporting methods don't work on a broad scale. Residents are encouraged to lie, and they fear – accurately, in many cases - that they will be penalized if they report their actual hours worked.

This causes us to raise the question: What body could most effectively and transparently be tasked with tracking and enforcing work hours? Does program self-monitoring and reporting - particularly when it is not anonymous – have the chance of being effective? Have we placed this enforcement authority in the most appropriate hands?

What is needed is a truly independent system to record and verify the accuracy of reported work hours.

Enforcement mechanism

Current penalties for residency programs that fail to adhere to the ACGME requirements are insufficient and in many cases ineffective. An adequate incentive structure must be created and put into practice so that we can begin to realize broad adherence to existing requirements.

Flexibilities

While we need more robust mechanisms at the program level, we must also ensure that our policies respect physician autonomy and honor the physician-patient relationship and associated educational opportunities. Though a physician may pass patient care decisions off to his or her on-duty colleagues at the end of a shift, we need to allow physicians the flexibility and autonomy to stay in the hospital with a dying patient, to run a code, to hold an end-of-life discussion with a patient's family: to practice humanistic medicine. We can handle extenuating circumstances such as the imminent death of a long-term patient with attention to enforcement of required length of time off between shifts.

Rigid "clock in-clock out" systems can place residents in professionally challenging positions, when they genuinely want to stay to help patients, and should not be a mechanism we adopt.

Continuity of care during patient handoffs
Patient handoffs at the end of current shifts are often inadequate regardless of the severity of a patient's illness or the experience of the medical team. Too many residents report that their handoffs are a mere surface recap of the day's tasks, a few words about the patient's status, followed by walking out the door. We would like to implement an hour of semi-protected time built in at the end of each shift dedicated to patient handoffs. Incoming and outgoing residents would be expected to use this overlap of shifts in a manner ensuring meaningful continuity of care and minimizing medical errors.
We would like to see a comprehensive analysis of the relationship between the implementation of effective, structured handoffs and the incidence of medical errors between programs across the country.

We hope that future national investments in health information technology can be streamlines to increase the availability of tools that can improve patient handoffs and reduce medical errors.

Content and quality of time away from the hospital
We should have standards for how much time should be spent on paperwork – and when paperwork is meant to be done – that focus on increasing accuracy and minimizing repetitive or unnecessary documentation. Record-keeping mechanisms could be structured into the changing of every shift to achieve this goal.

Workforce capacity:
The medical community agrees that we face a growing shortage of physicians and other health care workers in our country. To ensure that we are not compounding the problem of an inadequate workforce as we move to enforce actual practice of 80 hour weeks and the safer work standards the implementation of these limits encompass, we will need to lift residency slot caps and engage in other approaches to increase the number of residents and physician workforce training in our country.

Positions on IOM report recommendations and current duty hour standards

i. maximum hours of work per week

We agree that our system should do away with loopholes such as averaging a week's work hours over a month, and agree with IOM reaffirmation of sticking to an 80 hour work week.

ii. maximum shift length

The practice of working 24 hour or 30 hour shifts should not be allowed. On-call residents on shifts more than 16 hours have twice as many attentional failures when working overnight and commit 36% more serious medical errors. They also report making 300% more fatigue-related medical errors that lead to a patient's death.[xv]

We should implement the recommendation of 16 hour shifts with no included protected sleep period. In addition, the implementation of an "enforced" 5 hour nap would double the number of handoffs – one of the periods of patient care associated with a large proportion of overall medical errors – increasing the overall opportunity for associated medical errors in those patients' care.

Residents unanimously report difficulty falling asleep and reduced quality of sleep while sleeping at the hospital. There is no basis to suggest that 5 hour naps in the middle of 2 periods of patient care duty would increase the restedness or even the hours of sleep residents attain. We recommend against the adoption of this practice, and take this guideline as a message from the IOM committee that current practice of working more than 16 hour shifts is a dangerous practice that must be ameliorated. We would like to see residents go home, within the flexibilities mentioned above, at the end of each 16 hour shift, after an additional hour of non-patient-care time spent transitioning patient care between resident shifts. There is no scientific basis for recommending a practice of 5 hour naps, especially not when this nap would be used to justify the practice of working total shifts longer than the evidence-based 16 hour shift.

Implementing an 80 hour work week without concurrent adjustments in time off and in shift limits is neither sufficient nor effective. In a study of pediatric programs that made scheduling changes to accommodate the 2003 80 hour standards, 24- to 30-hour shifts remained common, and the frequency of on-call periods was not significantly adjusted. The total number of hours of resident sleep and of resident work did not change, and neither did medication errors or resident psychological well-being or motor vehicle crashes. Burnout was shown to decrease, but physician ordering errors actually increased a small though non-significant amount.[xvi]

iii. maximum in-hospital on-call frequency

We agree with the IOM recommendation to limit call frequency to no more than Q3 call shifts, with no averaging.

iv. minimum time off between shifts

We agree with the IOM recommendation that down-time must be meaningful, and recommend adoption of the new recommendation of extending hours off between shifts.

v. maximum frequency of in-hospital night shifts

We agree that consecutive night shifts should be limited to 4 nights maximum, with IOM recommended breaks in between.

vi. mandatory time off duty

We agree with the recommendation not to average and with the recommendation to increase mandatory time away from duty from existing minimal time away from duty.

vii. moonlighting
Moonlighting should count toward the overall 80 hours, but in the current system, regulatory bodies – ACGME, residency programs – do not have the correct incentives, resources or authority to monitor or enforce moonlighting to keep real number of hour worked throughout various systems in compliance with 80 hour work weeks. We welcome creative solutions to the current inadequate ability to regulate moonlighting.

viii. limit on hours for exceptions
We agree with the additional 8 hours of flexible time to allow residents the above-discussed autonomy and ability to respond to demands of personal life demands and unforeseen occasions.

ix. emergency room limits
We agree with emergency room work hour limit recommendations, though would like to see these standards decreased if further evidence corroborates increased productivity with even shorter shifts. Shorter shift lengths have been associated with an increase in patients evaluated per hour by second-year residents, along with an overall increase in patient encounters. In a retrospective chart review of ED residents in New York, residents who worked 12-hour shifts evaluated 1.06 patients per hour, and residents working 9-hour shifts evaluated 1.15 patients per hour.[xvii]

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The Position Statement from the

Committee of Interns and Residents

Is Expected to Be Submitted by

May 27, 2009

The Position Statement from the

Organization of Resident Representatives (AAMC)

Is Expected to Be Submitted by

May 27, 2009

Resident and Associate Society
RAS ACS
American College of Surgeons

Jacob Moalem, MD
Chair
Joshua Broghammer, MD
Vice-Chair
Joshua Mammen, MD
Secretary

May 2, 2009

Thomas J. Nasca, MD
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Dear Dr. Nasca,

On behalf of the Resident and Associate Society of the American College of Surgeons (RAS-ACS), I wanted to thank you for your talk at the APDS/ASE meeting this past Wednesday. I know that everyone in the room was comforted to hear and believe that the ACGME is working with us to try and come up with a reasonable solution to the duty-hours question.

With 12,000 members, and membership across every surgical specialty and subspecialty, ACS-RAS is the largest professional organization representing trainees in surgery in the country. We recently surveyed our entire membership on the work-hours issue. The Position Paper attached incorporates some of the findings from that important survey, the full results of which will be published in the Journal of the American College of Surgeons this June.

I hope that you find our position statement useful as you continue to fight to preserve the quality and integrity of resident education in this country. Of course, I would be delighted to provide you with additional information or to be of further assistance in any way that you request.

Sincerely,

Jacob Moalem, MD
Chair, RAS-ACS

Cc: Peggy Simpson, PhD, ACGME
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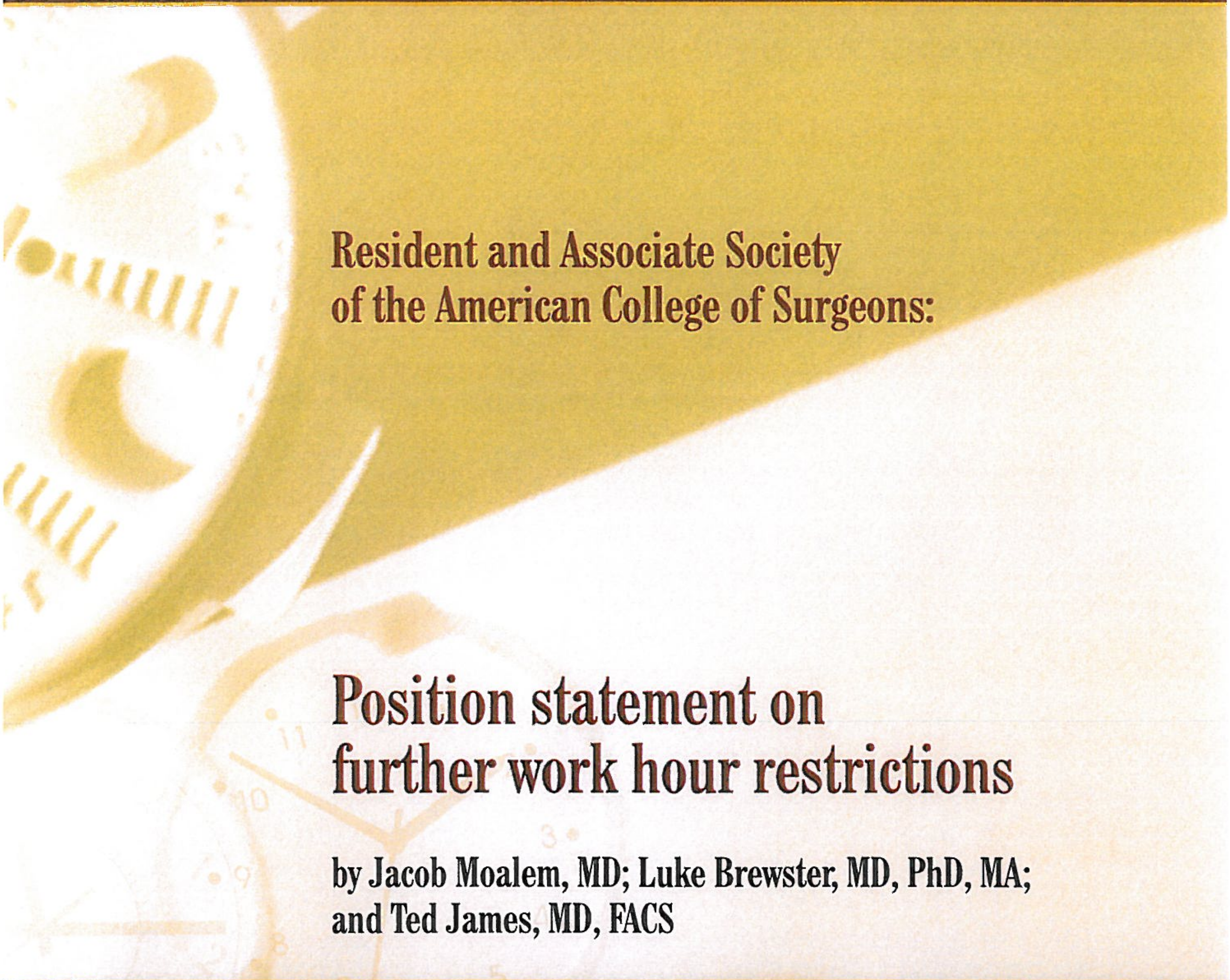

Resident and Associate Society of the American College of Surgeons:

Position statement on further work hour restrictions

by Jacob Moalem, MD; Luke Brewster, MD, PhD, MA; and Ted James, MD, FACS

The following statement was developed by the Resident and Associate Society of the American College of Surgeons (RAS-ACS) and approved by the Board of Regents at its October 2008 meeting.

While the adoption and implementation of the 80-hour workweek by the Accreditation Council for Graduate Medical Educations (ACGME) and its Resident Review Committees have had disparate effects on the various specialties within medicine, these regulations have had their greatest impact on surgical training programs. The restrictions on resident work hours have sparked the widespread overhauling of rotation and call schedules; hiring of physician extenders; and proliferation of resident cross-coverage, particularly at night.

Two years before the enactment of the duty-hour regulations in 2003, resident attendees at the American College of Surgeons Clinical Congress were surveyed about their opinions on resident work hours. Though the majority of residents at that time believed that some regulation of work hours would be beneficial, most believed that more than 80 hours would be required to train competent surgeons.[1]

We recently surveyed the RAS membership again, to assess whether their opinions had changed after a five-year "adjustment period." Although surgical residents' opinions on the subject reflected their adaptation to the regulations four years after the implementation of the ACGME's regulations, their feelings had not changed dramatically. Representing 15 surgical specialties, nearly 600 respondents to the survey were evenly split on this issue: half thought that residents should work no more than 80 hours per week (in line with current regulations), and half still believed that more than 80 hours per week were needed for optimal surgical education. Only 3 percent believed that fewer than 60 hours per week would suffice to adequately train surgeons. Compared with their more junior colleagues, senior residents (postgraduate year four and higher) were more likely to think that more than 80 hours per week are necessary to train surgical residents. Moreover, nearly half of senior residents believed that the 80-hour work hour restrictions were, in and of themselves, a moderate or severe barrier to resident education (unpublished data). Clearly, surgical trainees, particularly senior residents, do not uniformly agree that the 80-hour workweek has been beneficial.

We have recently celebrated the 80-hour workweek's fifth anniversary. In the time that has elapsed, numerous studies have attempted to relate the reduced work hours to patient outcomes. Some studies have demonstrated a decrease in attention lapses or medication errors in association with reduced work hours.[2] To date, however, no peer-reviewed study has demonstrated improved patient safety or improved outcomes in surgical patients as a result of the duty hour limitations.[3] In addition, there are no reliable national data that demonstrate a positive effect of the 80-hour work week on resident education or patient care.[4] Conversely, multiple recent studies have raised serious concerns regarding the increased need for transfer of care responsibilities and decreased continuity of care that is necessary to accommodate the new work hour regulations.[5-13] Specifically, studies have demonstrated adverse effects of decreased continuity of care on medication errors,[5,10] communication errors,[6,8,10,12] resident–patient relationships,[9,13] and resident attitudes and professionalism.[9]

Beyond the impact on individual surgeons and patients, more global implications must also be considered. As the requisite knowledge base required of surgeons continues to expand, fewer and fewer trainees progress directly to practice. Thus, in an era when surgery is a decreasingly popular career choice among medical students[14,15] and the burden of educational loans is peaking,[16-18] many residents are lengthening their training period and accumulating debt during this pursuit of additional training. Lack of preparedness for the realities of independent practice is thought to have been a major contributing factor to more than 75 percent of U.S. graduating general surgical chief residents' choices to pursue fellowship training in 2007.[19] Further shortening of work hours could only be anticipated to augment this alarming trend.

The mission statement of the American College of Surgeons is in line with the putative mission of every surgical training program in this country: It is "dedicated to improving the care of the surgical patient and to safeguarding standards of care in an optimal and ethical practice environment." Quality surgical training and care is founded on a longitudinal, comprehensive curriculum, which applies the six core competencies outlined by the ACGME to the care of the preoperative, intraoperative, and postoperative surgical patient.

We believe that the increasing trend of graduating chief residents to pursue additional training is consistent with our survey results. As residents mature and the reality of independent practice becomes increasingly daunting, trainees thirst for opportunities to enhance their knowledge, skills, and readiness. With profound differences in scope of practice among medical and surgical specialties, and even among the various surgical specialties, we believe that perhaps uniform regulations should not be applied across the board.

As a subsidiary organization of the ACS, the RAS fully supports any initiative designed to improve the care of surgical patients in this country, so long as it is evidence based and founded on a comprehensive study of all major contributing factors and possible ramifications. Although we readily acknowledge the concerns about resident fatigue and inefficiencies in our training programs, these issues should not be considered in isolation. We implore any regulatory body that is considering further restrictions on resident experiences to also consider the impact and consequences of such restrictions on (1) continuity of care, (2) burden on this country's health care system, and (3) the overall quality of surgical training—and thereby on surgical care. Ω

Acknowledgment

The authors wish to thank L. D. Britt, MD, FACS, Chair of the Board of Regents; Barbara Bass, MD, FACS, Regent of the College; and Peg Haar, Administrator in the College's Division of Member Services, for their help in developing this position statement.

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continued on page 62

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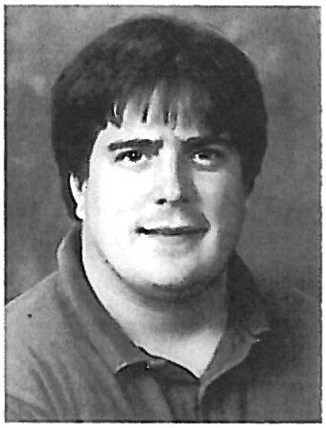

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May 1, 2009

Thomas J. Nasca, MD, MACP
Chief Executive Officer
Accreditation Council for Graduate Medical Education
515 North State Street, Suite 2000
Chicago, Illinois 60654

Dear Dr. Nasca:

The Association for Hospital Medical Education (AHME) appreciates your invitation to comment on the current Accreditation Council on Graduate Medical Education (ACGME) Resident Duty Hours Standards as well as the Recommendations contained in the December 2008 Institute of Medicine (IOM) Report on Resident Duty Hours: Enhancing Sleep, Supervision, and Safety.

AHME is a national, non-profit professional organization involved in the continuum of hospital-based medical education. Our more than 600 members represent more than 200 teaching hospitals, academic medical centers, and consortia involved in the delivery of undergraduate, graduate, and continuing medical education. The majority of our members are located in independent teaching hospitals while a smaller but significant contingent are in large university systems.

Because of the diverse nature of the residency programs for which AHME members are responsible, it will not be possible for us to address issues at the individual specialty level in this document. These will undoubtedly be covered by other organizations. Rather, we would like to comment on issues that we see as more general, and involving independent teaching hospitals, where much of graduate medical education (GME) is provided.

As asserted in the prelude to the IOM Recommendations, "It is necessary to look beyond hours of work alone as a risk factor during training and put into place practices – including time for sufficient sleep, enhanced supervision, appropriate workload, and clear and effective handovers of patient care – that will minimize the risk of error in the training environment." Our organization believes that, during the past five years, ACGME's leadership has resulted in steady and substantial movement of the graduate medical education community toward an appreciation of the importance of these goals, an overall commitment to achieving them, as well as a great deal of progress with respect to their realization.

This has not been an easy transition for teaching institutions. The changes necessitated by the duty hour requirements have produced mixed results, most clearly beneficial but some perhaps detrimental. For example, night float systems are more common, resident schedules have become very complex, and educational opportunities have sometimes suffered. The strain induced by these changes has been seen not only in our residents but also in faculty who already faced significant pressures. Nonetheless, we believe that our members strive to be in substantial compliance with these regulations and that they remain committed to working with ACGME to critically review the impact of the current standards and to very carefully refine these requirements to optimize the educational experience and the quality of care in teaching hospitals.

AHME enthusiastically supports the majority of the IOM recommendations. Specifically, we believe the recommendations listed under the headings of Improving the Safety of Residents and the Public, Work Load Adjustment, Enhancing Supervision, Improving Handovers and Safety Reporting, Additional Resources for Implementation, Monitoring and Evaluation, and Moonlighting are helpful. We note that many of these recommendations are areas which have already been receiving attention from the ACGME but we believe that the IOM Report will further focus the GME community on their full and timely incorporation into our standard practices.

We would offer just a few qualifications to our support of these recommendations. (1) In relation to the first of the Workload Adjustment recommendations, we are concerned about the availability of a sufficient number of physician extenders to pick up the work residents are currently doing that "can be done well by others." We also note that physician extenders have been reluctant to work at night which will complicate the transition to a number of the Duty Hour Adjustments recommended by the IOM. (2) In relation to the Additional Resources for Implementation recommendation, given the current precarious financial situation of hospitals, we emphasize the importance of ensuring that these resources are made available prior to the expectation that hospitals comply with a number of the IOM recommendations. We also propose that there should be a commitment to sustaining this additional support over the long term, so we don't find ourselves in a scenario in which this support is provided initially only to be subsequently withdrawn. (3) In relation to the Moonlighting recommendations, while supporting these ideas, we wonder whether there might be any legal ramifications involved in virtually eliminating the option of moonlighting for residents in a number of specialties.

AHME also supports the IOM recommendation regarding Improving Adherence to Duty Hours. Any accreditation system must provide effective oversight, with recognition of substantial compliance and significant penalties for noncompliance. We believe that the ACGME has done an excellent job with these responsibilities overall and we have noted the steadily increasing vigor with which the duty hour standards are being enforced. We are very pleased to see that the IOM recommended that ACGME remain at the controls of the monitoring and enforcement mechanisms of the duty hour requirements because we know that it will continue to carry out these functions within the context of a profession which is dedicated both to the care of patients and to helping residents develop the professional behaviors which will sustain them throughout their careers. We also trust that ACGME will do so through processes which will be effective yet no more administratively burdensome at the hospital level than absolutely necessary.

AHME supports some of the Duty Hour Adjustments recommended by the IOM but is quite concerned about others. In the interest of brevity, these comments will be limited to those about which we have reservations.

> *Scheduled continuous duty period must not exceed 16 hours unless a 5-hour uninterrupted continuous sleep period is provided between 10PM and 8AM.* While we recognize that there is some evidence to support this change in the requirements, we are quite concerned about the feasibility of implementing this requirement within the context of an educational program. Furthermore, if a program elects to employ the extended duty period option, we think it will be quite difficult for hospitals to document compliance with the nap period.
>
> *After completing duty periods, residents must be allowed a continuous off-duty interval of a minimum of 10 hours following a daytime duty period that is not part of an extended duty period.* In order to allow residents to fully participate in the ongoing management of their patients the following morning, we believe an 8-hour rest period after an occasional 16-hour duty period is sufficient.
>
> *After completing duty periods, residents must be allowed a continuous off-duty interval of a minimum of 12 hours following a night float or night shift work that is not part of an extended duty period.* In order to allow sufficient time for an effective sign out and educational amplification of the patient care experience for residents on night float rotations, we believe a 10-hour rest period is sufficient. This recommendation is based on an extensive ongoing experience with night float rotations in multiple hospitals.
>
> *After completing duty periods, residents must be allowed a continuous off-duty interval of a minimum of 14 hours following an extended duty period; and residents should not return to service earlier than 6AM the next day.* While the recommended minimum off-duty interval seems quite reasonable, we are concerned that a 6AM start time could be problematic on some surgical services.
>
> *Night float or night shift duty must not exceed four consecutive nights and must be followed by a minimum of 48 continuous hours off duty after three or four consecutive nights.* In order to avoid rotating residents from day to night assignments more frequently than necessary, we believe that five consecutive days assigned to a night float rotation followed by a minimum of 48 continuous hours off duty is sufficient. Again, this recommendation is based on an extensive ongoing experience with night float rotations in multiple hospitals.

> *At least one 24-hour off-duty period must be provided per 7-day period without averaging; one additional (consecutive) 24-hour period off duty must be provided to ensure at least one continuous 48-hour period off duty per month.* We believe this target can be achieved on many rotations but that it may not be feasible to implement this requirement on every rotation. Therefore, we propose that this type of scheduling could be required on a percentage of the rotations a resident experiences each year and that there could be a requirement that at least every other rotation employ this type of scheduling in order to avoid long stretches when residents could have difficulty addressing personal matters.

Taken as a whole, the Duty Hour Adjustments recommended by the IOM would dramatically reduce the little flexibility which now remains in resident scheduling. This will make it very challenging for residency programs to effectively deliver a curriculum and for teaching hospitals to care for patients.

Our organization has concerns about the extent of the data upon which this constellation of recommendations has been based. Therefore, we support the ACGME's desire to study the impact of the duty hour requirements already in place. We also urge very careful consideration of the impact of those which have been proposed by the IOM before further changes are implemented.

Complying with these recommendations would be a very expensive proposition at a time when the majority of hospitals which are already in financial distress. While the IOM recommendation for additional resources is welcome, it raises more questions than answers. For example, will these funds be forthcoming? Will they be sufficient to address the new mandates? How soon and for how long will these monies be made available when the federal government has so many other issues with which to deal?

AHME hospitals train physicians for their communities and recognize that there are costs and benefits to having medical education as a part of their mission. With an eye on the horizon, most will remain involved in the GME enterprise. However, as the regulatory environment for training programs becomes increasingly difficult, some have worried whether institutions could began to question if the costs outweigh the benefits – to the detriment of medicine and health care in the United States.

The IOM noted the following in the introduction to its recommendations. "While some recommendations should be implemented immediately, changes to duty hours, adjustments in workload, and the funding needed for these changes might require an integrated phase-in. The recommendations will require additional resources – both financial and human. Without the necessary restructuring in resource allocation, attempts to implement the recommendations will fail to have the desired benefits and could result in reduced patient safety."

Given that the quality of patient care has been repeatedly demonstrated to be better in teaching hospitals than nonteaching hospitals, we agree that the GME community should proceed with the implementation of these recommendations only after very careful study and our organization would be pleased to participate in the Resident Duty Hours and the Learning Environment Congress being planned by the ACGME as a part of this process.

In closing, thanks again for the opportunity to comment on the current ACGME Resident Duty Hours Standards and the IOM Recommendations.

Sincerely,

Kimball Mohn

Kimball Mohn, MD, Executive Director
Association for Hospital Medical Education

Alliance of Independent
Academic Medical Centers

May 1, 2009

Thomas J. Nasca, MD
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515 North State Street, Suite 2000
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Dear Tom:

The Alliance of Independent Academic Medical Centers (AIAMC) appreciates the opportunity to comment on the ACGME's review of standards for resident duty hours and key dimensions of the learning environment.

The AIAMC is an organization representing teaching hospitals and health systems with graduate medical education programs and active research programs. Member institutions are often affiliated with multiple medical schools, but are not owned or operated by them. Our sixty-eight member institutions train more than 9,000 residents in 650 ACGME accredited residency and fellowship programs. Representatives from member institutions at our annual Spring and Fall meetings are frequently Program Directors, DIOs or GME Deans, but also include CEOs, CMOs, CFOs, Department Chairpersons and other operational leaders. Alliance members, therefore, have a substantial commitment to Graduate Medical Education and resident well-being.

The AIAMC focuses many of its activities on improving patient safety and quality of care through graduate medical education. Currently twenty member institutions are completing Phase I of a National Initiative linking graduate medical education programs with improved patient safety. The Initiative received recognition at the 2008 IHI Annual meeting and several projects within the Initiative are in preparation for publication. Planning has begun for Phase II. Through the Initiative, Alliance members have developed a unique awareness of the relationship between residency training, patient care and resident work environment. Graduate medical education requires a balance between education and patient care. The AIAMC membership strives to create an environment in our teaching hospitals and clinics that supports both resident education and patient safety. Although the current ACGME work hours requirements have added largely unreimbursed costs to GME budgets at member hospitals, the necessity for work hours restrictions has been accepted in the spirit of maintaining a better learning environment and lifestyle for residents. Now, however, the Alliance is concerned that many institutions are close to a tipping point for GME. Operating margins of many teaching hospitals are thin, at best. Therefore, despite the commitment to GME, further duty hour restrictions and increased complexity may necessitate the reduction or elimination of GME positions because of perceptions that graduate medical education is becoming a financial burden that institutions are unable to meet.

Your letter requests a "formal position paper" to include responses to five specific questions. The responses below summarize the findings of an AIAMC Board of Director's Task Force with data and other information from multiple sources within the Alliance membership:

- *The AIAMC's position on the recommendations contained in the Institute of Medicine Report on Resident Duty Hours including an impact analysis on costs and impact of implementation.*

  While we have great respect for the IOM, more evidence from sleep research and patient safety initiatives must enter into the decision to change current duty hour regulations. For example, data on handoffs, communication, and clinical outcomes should be a part of the discussion. The IOM recommendations would make the ACGME duty hours requirements less flexible and more difficult to implement. The effect on members of our organization would be to increase the resources necessary to maintain clinical services, guarantee an optimal educational experience, and remain compliant with accreditation standards. Member teaching hospitals have used a number of strategies in response to the ACGME work hours requirements including: increasing the number of residents; adding mid-level practitioners or hospitalists, or simply increasing the work hours for supervising faculty physicians.

  At some member institutions the size of resident teaching services has been reduced and, while this may be an effective tactic to achieve compliance with restricted duty hours, it has the potential to produce a sub-optimal learning experience with lower patient volume and less favorable case mix. Patients hitherto cared for on teaching services now receive care from non-teaching service physicians or mid-level practitioners, an operational expense; alternatively, some institutions have been forced to reduce services, negatively impacting access to care.

  Most member institutions have created night float teams that have had a favorable effect on meeting duty hours requirements and on resident lifestyle. The IOM recommendation restricting the night float week to four nights would render current night float systems impractical without an increased number of residents and a consequent increase in program costs. In addition, the proposal for a "five-hour rest period" seems impractical, and would be difficult to implement, monitor, and enforce.

- *The AIAMC's formal position on the current ACGME Duty Hours Standards including impact analysis on costs and impact of implementation.*

  The AIAMC endorses and supports the ACGME's current duty hours standards for many residency training programs. Despite the increased resources needed to implement the Standards, the Alliance membership concurs that, in many specialties, they promote a healthier balance between education and service. This organization does, however, question the need for a single standard across all specialties and urges flexibility for some specialties which have legitimate concerns about the impact of a reduction in educational experiences. We refer specifically to reduced opportunities for residents to perform procedures under supervision – reduced opportunities that may threaten a resident's ability to comply with specialty board requirements without increasing the duration of training. Clearly, this impacts procedure oriented specialties such as general surgery. Increasing the duration of training is undesirable because it increases society's expense to train our next generation of physicians.

- *The AIAMC's formal recommendations regarding the dimensions of Resident Duty Hours Standards, and justification of this position with evidence.*

  As outlined above, the AIAMC supports the current duty hours standards in general. The organization's members are concerned, however, about the lack of flexibility that sometimes places residents in the uncomfortable position of choosing between professional responsibilities and rigid duty hour requirements. The AIAMC believes that there should be provision in the ACGME's policies for flexibility to allow for the continuity of care of critically ill patients and their families, and for the completion of operative procedures once started. The AIAMC also believes that the Standards should include accountability to assure that the spirit of the Standards is not abused.

- *The AIAMC's formal recommendations regarding standards governing key aspects of the Learning Environment, and justification (wherever possible) for this position, with evidence.*

  The AIAMC endorses the ACGME's current standards governing key aspects of the learning environment. We are, however, concerned about situations that place residents and fellows in conflict with the Standards because of reasonable professional responsibilities. While "reasonable" can be difficult to define, the exercise of judgment on the part of residents, their program directors and faculty is a hallmark of good medical practice and professional behavior.

We urge the modification of the current Standards to allow residents to make choices motivated by professional concern for their patients. We also urge that Standards include language to minimize or eliminate coercion and other abuse.

- *Your organization's willingness to participate, if invited, in a Resident Duty Hours and Learning Environment Congress.*

  The AIAMC has much to offer, as outlined in this response, to the national conversation about resident duty hours and the learning environment. The Alliance represents a substantial constituency of teaching hospitals with a commitment to both Graduate Medical Education and patient safety. We wish to offer the expertise and collective wisdom of our membership and will participate in the Congress with enthusiasm.

The AIAMC embraces the charge to train physicians who practice in our communities. As a result of their training in our member institutions it is expected that they will provide patient-centered care and respond to the needs of their patients in professional practices without duty hour restrictions. The Alliance acknowledges the need for time to relax and study. At the same time the principle of uncompromising dedication to the care of their patients is an equally important value to instill in future physicians.

We support flexibility in duty hours with better monitoring to ensure compliance. We believe that the definition of professional behavior with reference to duty hours should be driven by the profession rather than by arbitrary limits set because of outside pressures. Good data from defensible studies should guide decisions in a system that recognizes education and professionalism as the priorities. Positive rewards rather than negative consequences should be encouraged with firm action implemented swiftly and consistently against offenders.

For the AIAMC Board of Directors,

William W. Pinsky, MD
EVP for System Medical Affairs and Chief Academic Officer
Ochsner Health System
and
Immediate Past President
Alliance of Independent Academic Medical Centers

DEPARTMENT OF VETERANS AFFAIRS
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May 14, 2009

In Reply Refer To: 14

Thomas J. Nasca, M.D., MACP
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Dear Dr. Nasca,

The Department of Veterans Affairs (VA) is pleased to provide input regarding our position with respect to the Institute of Medicine Institute of Medicine (IOM) Report on Resident Duty Hours issued in December, 2008. As the second largest funding source for graduate medical education (GME), VA is extremely interested in the outcome of the review process for duty hours that the ACGME has launched. Moreover, given our extensive involvement in GME program management and support for innovation in GME, we believe that it is important for VA to be involved in these deliberations.

In response to your specific questions, the following responses are provided. Please note that the responses pertain to all specialties.

- *Your organization's formal position on the recommendations contained in the Institute of Medicine Report, including impact analysis, from your organization's perspective, on costs and impact of implementation*
    - VA requires all GME programs to be ACGME (or AOA) accredited and will abide by duty hour limits established by ACGME.
    - If the IOM recommendations are fully adopted, the estimated cost for implementation would be about $150 million per year, based upon VA's proportionate share of GME positions (range $70 to $220 million).

- *Your organization's formal position on the current ACGME Resident Duty Hours Standards including impact analysis, from your organization's perspective, on costs and impact of implementation*
    - Many VA facilities have already been faced with replacing residents with attending or mid-level staff.
    - Some of our affiliates appear to be pulling residents from VA rotations to cover "university hospital" rotations.
    - VA in-house resident call may be sub-optimal for certain rotations, especially on surgical services.
    - Some facilities have requested more resident positions through VA's GME Enhancement initiative. However, the major rationale for increasing resident positions should be to address long-term workforce issues, not to provide hospital coverage.
    - VA facilities may be better able to cope with the non-duty hour recommendations of the IOM Report, because:
        - IOM's emphasis on handoffs, team-based care and patient safety is in line with VA initiatives;
        - VA 's Resident supervision policy was tightened in 2004-05;
        - VA has been shifting its emergency department (ED) staffing model to one with less reliance on resident "moonlighters"; and

    - Resident expansion is already underway as part of VA's five-year GME Enhancement Initiative.

- *Your organization's formal recommendations regarding dimensions of Resident Duty Hours standards, and justification (wherever possible) for this position with evidence*
    - The IOM Report found no credible evidence to link duty hours with patient safety. Thus, from an evidence-based perspective, there is no rationale for adopting the IOM recommendations.
    - The IOM recommendations regarding duty hours are needlessly complex, which would present difficulties in monitoring and enforcement. If duty hours are changed, implementation and monitoring should be as simple and flexible as possible.
    - Although some have argued that the real issue is resident fatigue or "fitness for duty", there is no reliable way to measure this at present. Future research should focus on developing such tools.
    - VA believes that duty hours are not the major issue we should be addressing. Rather supervision policies and procedures, patient safety programs, the process and content of training programs must receive more attention than they have to date.
    - In the recent past, VA has made major investments in enhancing the clinical care environment including electronic medical records (EMR), quality improvement and patient safety programs and advanced clinic access, amongst others. Expanding opportunities for resident involvement in these programs should take precedence over a monolithic focus on work hours.

- *Your organization's formal recommendations regarding standards governing key aspects of the Learning Environment, and justification (wherever possible) for this position with evidence*
    - VA supports ACGME's commitment to competency-based medical education.
    - VA believes that the clinical learning environment should emphasize the delivery of integrated, patient-centered care, as exemplified by the "medical home" and similar models.
    - Research and demonstration projects are needed to better assess the progression of learning during training. VA is committed to supporting and participating in this effort.
    - Training programs should also take into account the well-being of the resident and the type of experiences to which residents are exposed (not all of which are learning experiences).

- *Your organization's willingness to participate, if invited, in a Resident Duty Hours and the Learning Environment Congress, to be held in June, 2009 in Chicago Illinois.*
    - VA is willing to participate in the ACGME Resident Duty Hours and the Learning Environment Congress in June 2009 and the ongoing deliberations of the ACGME to address this issue.

VA appreciates the opportunity to comment on these important issues. As the ACGME moves forward with its deliberations, we look forward to assisting in any manner possible.

Sincerely yours,

Malcolm Cox, M.D.
Chief Academic Affiliations Officer

AAMC

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April 22, 2009

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Dear Dr. Nasca:

The AAMC has supported limits on resident duty hours since 1988 in the interest of optimal patient care and resident education. We were active participants with the ACGME in formulating the 2003 policy and subsequently have supported the duty hour requirements and the ACGME's good work in monitoring and enforcing them.

In response to your letter of February 12, 2009, we offer some specific comments on the recent recommendations of an IOM committee about duty hours and related issues below. **In general we believe that resident duty hours and schedules ultimately are not the central issue.** Despite agreement that duty hours are important to consider, there is very little solid evidence that links resident schedules to patient care outcomes. Focusing on resident duty schedules will not address—and may distract academic medicine from—the larger issues of detection and management of fatigue, quality of resident supervision, appropriateness of resident workloads, and effectiveness of information transfer among residents and other members of the patient care team. If these larger issues are addressed, the need to regulate resident duty schedules can and should lessen or disappear.

Fatigue assessment (so-called "fitness for duty") is a more rational and, ultimately, more effective approach than regulating shift lengths. Not only do individual tolerances for sleep deprivation and long hours on duty vary greatly, but even individuals who are not tired or sleep deprived can make errors. Research efforts should be directed toward improved methods to systematically assess and manage fatigue as an element of an institutional culture of quality and safety that encompasses all members of the health care team. This culture also must be one in which systems are in place to prevent and mitigate the effects of human errors, whether they are attributable to fatigue or to other causes.

Counting hours and clocking in and out are incompatible with the goal of teaching residents the professional ethos of service and commitment, beyond personal comfort or gain, that characterizes medicine. At the same time, professionalism encompasses physicians' responsibility to report for duty rested and ready to take care of patients and to learn. These elements of professionalism should be incorporated throughout medical education beginning at the undergraduate level.

We believe that the AAMC, the ACGME, and the other ACGME member organizations must communicate more effectively to the public our overriding commitment to patients and to the quality and safety of the care in our institutions. High quality care leads to better patient outcomes and also provides the environment in which future physicians can be educated for high quality independent practice that will affect patient safety for decades to come. Graduated responsibility is an essential component of professional development for physicians – and, with appropriate supervision, is entirely compatible with safe and effective patient care. At the same time, the faculty (attending) physician of record ultimately is responsible for the care provided his or her patients.

As to the specific recommendations of the Institute of Medicine:

Duty hour limits: The AAMC supports a maximum of 80 hours of duty per week, averaged over four weeks, limits on continuous duty, and appropriate time off between periods of duty (see pages 6-8 of the enclosed "AAMC Policy Guidance on Graduate Medical Education"). Any additional changes in requirements for resident duty schedules should be informed by research evidence and developed by individual specialties and their residency review committees under the auspices of the ACGME. Schedules should be flexible enough to accommodate differences in the patient care delivery and educational needs among specialties. They also should be flexible enough to accommodate circumstances when residents need to remain on duty longer than the standard provides, and also to accommodate circumstances when they need to be taken off duty because of fatigue or other circumstances that adversely affect patient care or resident well-being. Schedules should provide residents sufficient time for group learning activities and for individual study and reflection on their clinical experiences. They should provide sufficient time for rest and recovery.

Moonlighting. The AAMC believes that time spent in moonlighting should be included in the 80-hour limit or prohibited altogether. These activities are not educationally based, cannot be readily monitored, and often are detrimental to residents' ability to focus on their education programs and associated patient care responsibilities.

Monitoring and enforcing adherence. The ACGME, with its specialty and institutional review committees, is the appropriate organization to monitor and enforce resident duty hours. As the AAMC stated in its testimony to the IOM committee May 8, 2008, "The ACGME considers resident schedules in the context of the whole educational program and its institutional environment, as is appropriate." It assesses adherence in the context of both education and health care delivery. Its deliberations involve all the key constituencies of medical education and medical practice, and its staff has a nuanced understanding of the complexities of education in clinical settings and their relationship to patient safety. The ACGME should continue its practice of responding to resident complaints and surveying all residents about their hours. Institutional sponsors should continue their oversight of duty hours as called for in the ACGME institutional requirements. Sponsors should provide for confidential, protected resident complaints to an institutional office that is not directly responsible for GME.

Resident safety: transportation. Driving when fatigued is a potential risk to residents and the public. Programs and institutional sponsors should take steps to reduce this risk by, e.g., providing residents going off duty a place to nap in the hospital before going home or paying for transportation home. Team members need to help each other decide when not to drive, since the ability to self-assess is itself impaired by fatigue. Handovers of patient responsibility afford opportunities for assessing fatigue.

Workload. Workloads of residents, especially in their first year, should be examined, and appropriate limits defined by individual review committees. The types and severity of cases should be taken into account. Resident tasks that are of limited or no educational value should be minimized or eliminated, while the educational value of all resident tasks should be maximized. Duty schedules should be informed, but not determined, by clinical case loads.

Supervision. Supervision commensurate with the level of the resident and the condition of the patient strengthens the educational experience and safeguards patients from potential errors. **Resident supervision should be enhanced, with measurable standards established by individual review committees.** These standards should go beyond defining geographic proximity of faculty to patients or residents. They might include, for example, specific guidelines about when a resident should consult with the attending physician or a more senior resident in person, by phone, or through electronic communication. Or they might call for attending/supervising physicians to "check-in" with residents on duty rather than waiting to be contacted for guidance. They might require that first year residents not be on duty without on-site supervision, and take into consideration the practice in anesthesiology, obstetrics-gynecology, and emergency medicine of having attending physicians on site at all times. In any event, supervision standards should be matched to patient acuity and faculty skills in supervision should be improved through faculty development.

Patient handovers. Handovers should include processes that incorporate a robust exchange of information about patient management. These transitions are opportunities for consulting with the supervising physician about the key patient information that needs to be transferred, in the interest both of patient care and education. The effective transfer of information about patients should be an element of the quality and safety programs of hospitals. It is not an issue only for residents and teaching settings, but for all members of the care team as they change shifts or roles in the clinical care of a patient. **Specific handover processes should be developed at each institution, with necessary variations to fit the care provided by the different specialties.** A best practice is to use handovers as additional learning opportunities for the residents, a means for improving care to the patient, and an opportunity to assess fatigue. Resident schedules should provide for enough overlap between the outgoing and incoming clinician to support best practices in handovers, which may also increase time requirements.

Resources to support change. Additional resources would be required to shift non-educational responsibilities to others, and/or to expand the pool of residents in training. (This does not mean that specialties that currently have a greater burden of duty hours should automatically be expanded. Any change in the size of residency programs should be related to both national and community needs in the context of providing a high-quality training program.) Cost estimates for the use of substitute health care providers in teaching hospitals as a consequence of the changes in resident duty hours proposed by the Institute of Medicine range from $375 million to $1.6 billion per year. **These costs should not fall solely on teaching hospitals, which are already bearing the majority of costs of the 2003 reforms, but should be borne by health care payers.** A lack of external support for these changes is likely to undermine the institutions' educational effectiveness and further jeopardize their financial health.

The knowledge gap/research. The evidence base on which the 2003 duty hours standards were based was weak, and subsequent efforts to evaluate the effects of those standards have been of mixed quality. Most studies were conducted shortly after the standards were implemented, too early to observe important effects; they were limited to small numbers of residents in a single specialty or setting and thus cannot be generalized; and there are multiple intervening variables that make it very difficult to draw cause-and-effect conclusions. Studies of large numbers of patient records have shown little or no change in mortality before and after the 2003 standards were implemented. **Any changes in the standards should be based on the best available evidence about the relationship between resident schedules and patient outcomes. Research also is needed on educational outcomes, including residents' preparedness for independent practice. Methods to assess and mitigate the effects of fatigue should be studied.** Institutions and programs that have implemented policies that are educationally sound and that support safe care, in accordance with the 2003 duty hour regulations, should be studied. **Equally important, evaluation studies should be carried out if any new standards are put in place, so that, five years from now, a better body of evidence will be available on the relationship between resident schedules and duty environments and both patient care and educational outcomes.**

We appreciate the opportunity to share our perspective on these critical issues. The AAMC looks forward to working with the ACGME to review the existing standards, consider the need for new standards, and define a research agenda that will provide better guidance for future action than is available currently.

Sincerely yours,

Darrell G. Kirch

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Enclosure

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AAMC Policy Guidance on Graduate Medical Education

Assuring Quality Patient Care and Quality Education

October 2001

Background

Graduate medical education (GME) comprises the second phase of the formal educational process that prepares doctors for medical practice. GME is required of all medical school graduates seeking full medical licensure and board certification in one of the specialties and/or subspecialties of medicine. This phase of medical education is, of necessity, conducted primarily in clinical settings, and requires direct participation by residents in the delivery of patient care services.

Conducting high quality GME has always been a demanding undertaking. Ensuring an optimal learning environment and creating a proper balance between education and patient care activities have been the principal challenges to medical educators. In recent years, those challenges have become increasingly formidable due to the impact that the myriad changes in the health care delivery system have had on the patient care environments in which GME is conducted.

Certain of these changes have presented particularly difficult challenges for GME. Of special note, the shortened length of hospital stays, the increased emphasis on ambulatory care, the reductions in support staff, and the increased acuity of the average in-patient have placed increased demands on resident time and energy. These changes, in conjunction with the long hours that residents are required to be on duty, have raised mounting concerns that resident fatigue may be posing a threat to the quality of patient care (including patient safety), to resident well-being, and to the quality of the GME experience.

The AAMC has long advocated limitations on resident duty hours. However, the Association believes that focusing on excessive duty hours is to focus on the symptoms, not the root cause of the problems affecting GME. If fundamental improvements are to be made in the quality of residents' education and in the quality of residents' life, the academic community must rededicate itself to the core educational mission of GME, and focus its attention on enhancing the learning environments where GME is conducted.

Unfortunately, the academic medicine community has not yet succeeded in uniformly addressing the concerns about the nature of modern residency training. Specifically, not all training programs have restructured their residents' duty schedules in ways that deal effectively with the growing public apprehension about the potentially adverse impact that resident fatigue may have on the quality of patient care provided by resident physicians. It is not surprising, therefore, that calls for limiting resident duty hours through government regulation are becoming more frequent and more strident.

The Accreditation Council for Graduate Medical Education (ACGME) plays a key role in improving the quality of GME in this country. Members of the Council include all of the key national stakeholder organizations.[1] Each of the 26 specialty-specific Residency Review Committees of the ACGME is composed of nationally recognized experts and experienced educators in their discipline. As an accrediting body, the ACGME provides the means whereby the profession reaches consensus about the minimum standards for residency training, monitors compliance with those standards, and sanctions deviations from them.

The vigilance with which the ACGME scrutinizes adherence to its standards and the rigor with which it enforces compliance with its requirements are crucial manifestations of the medical profession's commitment to self-regulation. Sustaining society's trust in the nation's GME system necessitates strong support from all segments of the profession for the ACGME's efforts to strengthen its regulatory role. No matter how effective the ACGME is in fulfilling its role, however, the success of the GME enterprise ultimately depends upon the commitment of the individuals and institutions overseeing GME programs to ensure that their programs are of high quality.

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A. Institutional Oversight and Program Support
B. The Educational Program
C. Supervision of Residents in Patient Care
D. Resident Duty Hours

Adherence to these guidelines is essential for ensuring quality patient care in teaching settings, for minimizing the risk to patient safety, for optimizing the quality of resident education, and for reducing the threats currently posed to resident health and welfare.

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Institutional Oversight and Program Support

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- Institutional sponsors of GME should exercise strong, centralized oversight for all of their GME programs; to do so requires establishing appropriate mechanisms and committing the necessary resources to assure that each program meets its educational goals and remains in compliance with applicable national, state, and institutional policies and regulations.

- Institutional sponsors of GME should authorize a single individual at a sufficiently high level in the organization to take overall responsibility for the quality of all GME programs, and for ensuring that the interests of the GME mission are well represented within the institution's top leadership.

- The institution's governing board should have explicit mechanisms for monitoring the institution's GME activities, and for assuring itself that the institution is fulfilling its responsibilities to serve the interests of patients, residents, and the public.

- Institutional sponsors and individual residency programs should have written policies and established procedures specifying the level of supervision attending physicians are required to exercise over residents at the various stages of their training and at the various sites of training (e.g., in-patient units, doctors offices, ambulatory treatment centers).

- Institutional resources must be adequate to create and sustain the safe and supportive learning environments required for high quality graduate medical education.

The Educational Program

Some 800 institutions sponsor approximately 8,000 individual GME programs. To remain accredited, a program must comply with the relevant set of minimum educational requirements established by the ACGME for each of the respective primary specialties and their various subspecialties. The faculty of individual programs is responsible for:

a) establishing specific learning objectives that are consonant with ACGME requirements and with the expectations set forth by specialty boards and specialty societies;

b) designing and implementing the educational program to meet those objectives;

c) judging the progress of residents in achieving the established learning objectives; and

d) determining whether a given resident has, at the completion of training, acquired the competencies and demonstrated the professional values and attitudes required for delivering quality medical care.

To fulfill these responsibilities, institutions and program directors must insure that all residents have appropriate educational opportunities within a supportive environment.

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- Resident physicians must have opportunities to participate, under supervision, in patient care activities of sufficient variety and with sufficient frequency to achieve the competencies required by their discipline.

- Resident physicians must have opportunities to exercise, under supervision, graded, progressive responsibility for the care of patients, so that they can learn how to practice their specialty and recognize when, and under what circumstances, they should seek assistance from colleagues.

- Resident physicians must have opportunities to participate in required conferences, seminars, and other non-patient care learning experiences and must have sufficient time to pursue the independent, self-directed learning essential for acquiring the knowledge, skills, attitudes, and behaviors required for practice.

- Appropriate, specialty-specific assessment methodologies must be used to document attainment of the knowledge, skills, attitudes, and behaviors required for practice, before attesting that a resident has satisfactorily completed the program.

Supervision of Residents in Patient Care

Quality graduate medical education can occur only in settings that are characterized by the provision of high quality patient care. As a practical matter, preparing future practitioners to meet patients' expectations for excellence requires that they learn in environments epitomizing the highest standards of medical practice. Even more important, as an ethical matter, justifying the participation of residents in the care of patients requires adherence to uncompromised standards of quality medical care.

Fulfilling these obligations necessitates the availability of program faculty to supervise all patient care services provided by resident physicians. Although residents are medical school graduates, they are by definition insufficiently experienced to practice their intended specialty or subspecialty independently. The intensity of supervision required is not the same under all circumstances; it naturally varies by specialty, level of residency training, the experience and competency of the individual resident, and the acuity of the specific clinical circumstance. Under circumstances in which urgent judgments by highly experienced physicians are typically required (e.g., certain critical care units, emergency rooms, obstetrical services, high-level trauma centers, certain surgical units), meeting this obligation requires that attending physicians be immediately available on site at all times. Under other, less precarious circumstances, attending physicians can provide adequate supervision off site as long as their physical presence within a reasonable time (e.g., 30 minutes) can be assured in case of need.

AAMC Policy Statements

- The faculty physician of record is responsible for the quality of all of the clinical care services provided to his or her patients.

- All clinical services provided by resident physicians must be supervised appropriately to maintain high standards of care, safeguard patient safety, and ensure high quality education.

- Individual residency programs should have written guidelines governing supervision of residents; these guidelines will vary according to specialty, intensity of patient care responsibilities on a given rotation, level of experience, and educational requirements.

- Program faculty directly responsible for the supervision of patient care services provided by resident physicians must be as available to participate in that care as if residents were not involved; the presence of residents to "cover" patients on in-patient services or to provide care in ambulatory settings does not diminish the standard of availability required of the physician of record.

- Program faculty are responsible for determining when a resident physician is unable to function at the level required to provide safe, high quality care to assigned patients, and must have the authority to adjust assigned duty hours as necessary to ensure that patients are not placed at risk by resident physicians who are overly fatigued or otherwise impaired.

Resident Duty Hours

Each of the 24 certifying boards composing the American Board of Medical Specialties determines the minimum number of years of graduate medical education required before a resident may apply for examination. The years of training required reflect the judgments of experts in each specialty about how long, given reasonable duty schedules, residents need to acquire the expected competencies in that specialty. Thus, residents enrolled in a well-designed educational program with appropriate patient care opportunities and adequate institutional support should be able to meet all educational objectives without recourse to harsh workloads.

For purposes of discussion, one can consider the totality of time available to residents as being composed of the following:

a) scheduled on-duty time required to participate in those direct patient care responsibilities deemed necessary to achieve specialty-specific learning objectives;

b) scheduled on-duty time required to participate in the residency program's organized teaching activities (e.g., conferences, seminars, grand rounds);

c) scheduled on-duty time spent, as a matter of course, delivering patient care services of marginal or no educational value;

d) off-duty time required to meet educational objectives through independent, self-directed learning; and

e) off-duty time required for rest, recreation, social obligations, and personal and family needs.

Given that the primary purpose of GME is educational, the patient care services that a resident is required to perform while on duty should be determined primarily by the resident's educational needs. Moreover, a resident's patient care responsibilities should be arranged so as not to preclude participation in the program's organized teaching activities. However arranged, the overall number of on-duty hours assigned must be limited to accommodate the residents' need for off-duty time. Within any allotment of overall duty hours, limits also must be placed on the duration of uninterrupted patient care responsibilities, taking into account the intensity of the work involved, in order to avoid excessive fatigue.

Disagreement still exists among medical educators about whether the reasoning in the foregoing paragraph constitutes a cogent argument for placing an upper limit on resident duty hours. Some argue passionately and reasonably that no limits can be justified, believing instead that the ethic of the medical profession and the need to ensure continuity of care run counter to setting time limits for patient care responsibilities. Others argue just as passionately and reasonably that some limits must be established in order to avoid undue fatigue and, as just noted, to respect the residents' need for sufficient personal time. After years of debate, we believe that prudence favors the establishment of a reasonable upper limit. We conclude, along with countless others, that 80 hours per week constitutes such a reasonable limit, albeit a generous one by any conventional standard. Experience indicates that this allotment of on-duty time, properly distributed, provides sufficient flexibility both to satisfy educational and patient care needs and to safeguard patient and resident well-being.

Limiting required duty hours does not imply that residents must cease providing essential patient care services at arbitrary cut-off times. Priority must always be given to patient safety and well-being and to avoiding transferring patient care responsibilities to others at inappropriate times in the continuum of care (e.g., during an operative procedure, in the midst of a rapidly evolving clinical event). A tired resident who is intimately familiar with a sick patient is often better able to provide quality care than is a fully rested resident who is unfamiliar with the details of the case. But by the same token, invoking continuity of care as a rationale for routinely requiring residents to provide patient care services while fatigued invites substandard care and risks patient safety. Moreover, residents must acquire the ability to recognize when their competency is impaired by fatigue and must gain experience with transferring responsibility for the care of their patients to trusted colleagues.

AAMC Policy Statements

- Institutional sponsors and individual residency programs should have written guidelines governing resident duty hours; these guidelines will vary according to specialty, intensity of patient care responsibilities on a given rotation, level of experience, and educational requirements.

- In no case should residents be scheduled to be on duty more than 80 hours in any week. On typical clinical rotations, residents should not be scheduled to be on duty for more than 24 hours consecutively; continuous duty in high intensity settings (e.g., emergency rooms, critical care units) should, in general, be scheduled for no more than12 hours. These guidelines must be applied with sufficient flexibility, as noted above, to ensure that thorough exchange of information and proper transfer of patient care responsibilities occurs whenever residents who are going off duty sign over the care of patients to other residents or to teaching physicians.

- Duty-free intervals between periods on call should be at least 8 hours long.

- If moonlighting is authorized, the time spent doing so should be included within the parent program's duty hour limits; unauthorized moonlighting should be prohibited.

- Residents should not be required to have overnight, on-call duty more frequently than one night in three, as averaged over 4 weeks.

- Residents should have at least 24 consecutive hours free of all assigned duty every seven days.

- The on-duty time residents spend delivering patient care services of marginal or no educational value should be minimized.

Summary

The Policy Statements set forth in this document address issues requiring urgent attention by the academic medicine community. The quality of resident education and the well-being of residents themselves are among our most solemn professional obligations. Persistent calls for reforming GME to better meet these obligations have come both from within our community and from external sources. We must heed these calls, not because government regulation is the likely alternative if we do not, but because it is the right thing to do.

The AAMC recognizes that implementing these policies will require many sponsoring institutions and individual training programs to allocate additional resources to their GME mission. Finding the necessary resources in an era of significant financial stress will undoubtedly pose a major challenge for more than a few. Unfortunately, that challenge is made even greater by the reluctance of many payers of patient care services to assume their fair share of GME costs and by the presence of regulatory constraints within current public programs affecting GME. While the AAMC will continue to call for appropriate funding for all GME-related activities and for relief from overly restrictive regulations, sponsors of GME programs should find these policy positions helpful in setting priorities for the expenditure of existing resources.

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April 22, 2009

Thomas Nasca, M.D., MACP
Chief Executive Officer
Accreditation Council for Graduate Medical Education
515 North State Street
Suite 2000
Chicago, IL 60654

Dear Dr. Nasca:

The AAMC has supported limits on resident duty hours since 1988 in the interest of optimal patient care and resident education. We were active participants with the ACGME in formulating the 2003 policy and subsequently have supported the duty hour requirements and the ACGME's good work in monitoring and enforcing them.

In response to your letter of February 12, 2009, we offer some specific comments on the recent recommendations of an IOM committee about duty hours and related issues below. **In general we believe that resident duty hours and schedules ultimately are not the central issue.** Despite agreement that duty hours are important to consider, there is very little solid evidence that links resident schedules to patient care outcomes. Focusing on resident duty schedules will not address—and may distract academic medicine from—the larger issues of detection and management of fatigue, quality of resident supervision, appropriateness of resident workloads, and effectiveness of information transfer among residents and other members of the patient care team. If these larger issues are addressed, the need to regulate resident duty schedules can and should lessen or disappear.

Fatigue assessment (so-called "fitness for duty") is a more rational and, ultimately, more effective approach than regulating shift lengths. Not only do individual tolerances for sleep deprivation and long hours on duty vary greatly, but even individuals who are not tired or sleep deprived can make errors. Research efforts should be directed toward improved methods to systematically assess and manage fatigue as an element of an institutional culture of quality and safety that encompasses all members of the health care team. This culture also must be one in which systems are in place to prevent and mitigate the effects of human errors, whether they are attributable to fatigue or to other causes.

Counting hours and clocking in and out are incompatible with the goal of teaching residents the professional ethos of service and commitment, beyond personal comfort or gain, that characterizes medicine. At the same time, professionalism encompasses physicians' responsibility to report for duty rested and ready to take care of patients and to learn. These elements of professionalism should be incorporated throughout medical education beginning at the undergraduate level.

We believe that the AAMC, the ACGME, and the other ACGME member organizations must communicate more effectively to the public our overriding commitment to patients and to the quality and safety of the care in our institutions. High quality care leads to better patient outcomes and also provides the environment in which future physicians can be educated for high quality independent practice that will affect patient safety for decades to come. Graduated responsibility is an essential component of professional development for physicians – and, with appropriate supervision, is entirely compatible with safe and effective patient care. At the same time, the faculty (attending) physician of record ultimately is responsible for the care provided his or her patients.

As to the specific recommendations of the Institute of Medicine:

Duty hour limits: The AAMC supports a maximum of 80 hours of duty per week, averaged over four weeks, limits on continuous duty, and appropriate time off between periods of duty (see pages 6-8 of the enclosed "AAMC Policy Guidance on Graduate Medical Education"). Any additional changes in requirements for resident duty schedules should be informed by research evidence and developed by individual specialties and their residency review committees under the auspices of the ACGME. Schedules should be flexible enough to accommodate differences in the patient care delivery and educational needs among specialties. They also should be flexible enough to accommodate circumstances when residents need to remain on duty longer than the standard provides, and also to accommodate circumstances when they need to be taken off duty because of fatigue or other circumstances that adversely affect patient care or resident well-being. Schedules should provide residents sufficient time for group learning activities and for individual study and reflection on their clinical experiences. They should provide sufficient time for rest and recovery.

Moonlighting. The AAMC believes that time spent in moonlighting should be included in the 80-hour limit or prohibited altogether. These activities are not educationally based, cannot be readily monitored, and often are detrimental to residents' ability to focus on their education programs and associated patient care responsibilities.

Monitoring and enforcing adherence. The ACGME, with its specialty and institutional review committees, is the appropriate organization to monitor and enforce resident duty hours. As the AAMC stated in its testimony to the IOM committee May 8, 2008, "The ACGME considers resident schedules in the context of the whole educational program and its institutional environment, as is appropriate." It assesses adherence in the context of both education and health care delivery. Its deliberations involve all the key constituencies of medical education and medical practice, and its staff has a nuanced understanding of the complexities of education in clinical settings and their relationship to patient safety. The ACGME should continue its practice of responding to resident complaints and surveying all residents about their hours. Institutional sponsors should continue their oversight of duty hours as called for in the ACGME institutional requirements. Sponsors should provide for confidential, protected resident complaints to an institutional office that is not directly responsible for GME.

Resident safety: transportation. Driving when fatigued is a potential risk to residents and the public. Programs and institutional sponsors should take steps to reduce this risk by, e.g., providing residents going off duty a place to nap in the hospital before going home or paying for transportation home. Team members need to help each other decide when not to drive, since the ability to self-assess is itself impaired by fatigue. Handovers of patient responsibility afford opportunities for assessing fatigue.

Workload. Workloads of residents, especially in their first year, should be examined, and appropriate limits defined by individual review committees. The types and severity of cases should be taken into account. Resident tasks that are of limited or no educational value should be minimized or eliminated, while the educational value of all resident tasks should be maximized. Duty schedules should be informed, but not determined, by clinical case loads.

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The sponsors of GME programs (e.g., teaching hospitals, medical schools, regional consortia) have ultimate responsibility for the management and quality of all GME-related activities conducted under their purview. In maintaining full accreditation for their programs, sponsors of GME must comply with the Institutional Requirements promulgated by the ACGME. These requirements overarch the ACGME's specialty-specific Program Requirements and represent the medical profession's consensus as to the minimum levels of oversight and support required for GME programs to meet expectations. AAMC member institutions can and should strive to exceed those standards.

AAMC Policy Statements

- Institutional sponsors of GME should exercise strong, centralized oversight for all of their GME programs; to do so requires establishing appropriate mechanisms and committing the necessary resources to assure that each program meets its educational goals and remains in compliance with applicable national, state, and institutional policies and regulations.

- Institutional sponsors of GME should authorize a single individual at a sufficiently high level in the organization to take overall responsibility for the quality of all GME programs, and for ensuring that the interests of the GME mission are well represented within the institution's top leadership.

- The institution's governing board should have explicit mechanisms for monitoring the institution's GME activities, and for assuring itself that the institution is fulfilling its responsibilities to serve the interests of patients, residents, and the public.

- Institutional sponsors and individual residency programs should have written policies and established procedures specifying the level of supervision attending physicians are required to exercise over residents at the various stages of their training and at the various sites of training (e.g., in-patient units, doctors offices, ambulatory treatment centers).

- Institutional resources must be adequate to create and sustain the safe and supportive learning environments required for high quality graduate medical education.

The Educational Program

Some 800 institutions sponsor approximately 8,000 individual GME programs. To remain accredited, a program must comply with the relevant set of minimum educational requirements established by the ACGME for each of the respective primary specialties and their various subspecialties. The faculty of individual programs is responsible for:

a) establishing specific learning objectives that are consonant with ACGME requirements and with the expectations set forth by specialty boards and specialty societies;

b) designing and implementing the educational program to meet those objectives;

c) judging the progress of residents in achieving the established learning objectives; and

d) determining whether a given resident has, at the completion of training, acquired the competencies and demonstrated the professional values and attitudes required for delivering quality medical care.

To fulfill these responsibilities, institutions and program directors must insure that all residents have appropriate educational opportunities within a supportive environment.

AAMC Policy Statements

- Resident physicians must have opportunities to participate, under supervision, in patient care activities of sufficient variety and with sufficient frequency to achieve the competencies required by their discipline.

- Resident physicians must have opportunities to exercise, under supervision, graded, progressive responsibility for the care of patients, so that they can learn how to practice their specialty and recognize when, and under what circumstances, they should seek assistance from colleagues.

- Resident physicians must have opportunities to participate in required conferences, seminars, and other non-patient care learning experiences and must have sufficient time to pursue the independent, self-directed learning essential for acquiring the knowledge, skills, attitudes, and behaviors required for practice.

- Appropriate, specialty-specific assessment methodologies must be used to document attainment of the knowledge, skills, attitudes, and behaviors required for practice, before attesting that a resident has satisfactorily completed the program.

Supervision of Residents in Patient Care

Quality graduate medical education can occur only in settings that are characterized by the provision of high quality patient care. As a practical matter, preparing future practitioners to meet patients' expectations for excellence requires that they learn in environments epitomizing the highest standards of medical practice. Even more important, as an ethical matter, justifying the participation of residents in the care of patients requires adherence to uncompromised standards of quality medical care.

Fulfilling these obligations necessitates the availability of program faculty to supervise all patient care services provided by resident physicians. Although residents are medical school graduates, they are by definition insufficiently experienced to practice their intended specialty or subspecialty independently. The intensity of supervision required is not the same under all circumstances; it naturally varies by specialty, level of residency training, the experience and competency of the individual resident, and the acuity of the specific clinical circumstance. Under circumstances in which urgent judgments by highly experienced physicians are typically required (e.g., certain critical care units, emergency rooms, obstetrical services, high-level trauma centers, certain surgical units), meeting this obligation requires that attending physicians be immediately available on site at all times. Under other, less precarious circumstances, attending physicians can provide adequate supervision off site as long as their physical presence within a reasonable time (e.g., 30 minutes) can be assured in case of need.

AAMC Policy Statements

- The faculty physician of record is responsible for the quality of all of the clinical care services provided to his or her patients.

- All clinical services provided by resident physicians must be supervised appropriately to maintain high standards of care, safeguard patient safety, and ensure high quality education.

- Individual residency programs should have written guidelines governing supervision of residents; these guidelines will vary according to specialty, intensity of patient care responsibilities on a given rotation, level of experience, and educational requirements.

- Program faculty directly responsible for the supervision of patient care services provided by resident physicians must be as available to participate in that care as if residents were not involved; the presence of residents to "cover" patients on in-patient services or to provide care in ambulatory settings does not diminish the standard of availability required of the physician of record.

- Program faculty are responsible for determining when a resident physician is unable to function at the level required to provide safe, high quality care to assigned patients, and must have the authority to adjust assigned duty hours as necessary to ensure that patients are not placed at risk by resident physicians who are overly fatigued or otherwise impaired.

Resident Duty Hours

Each of the 24 certifying boards composing the American Board of Medical Specialties determines the minimum number of years of graduate medical education required before a resident may apply for examination. The years of training required reflect the judgments of experts in each specialty about how long, given reasonable duty schedules, residents need to acquire the expected competencies in that specialty. Thus, residents enrolled in a well-designed educational program with appropriate patient care opportunities and adequate institutional support should be able to meet all educational objectives without recourse to harsh workloads.

For purposes of discussion, one can consider the totality of time available to residents as being composed of the following:

a) scheduled on-duty time required to participate in those direct patient care responsibilities deemed necessary to achieve specialty-specific learning objectives;

b) scheduled on-duty time required to participate in the residency program's organized teaching activities (e.g., conferences, seminars, grand rounds);

c) scheduled on-duty time spent, as a matter of course, delivering patient care services of marginal or no educational value;

d) off-duty time required to meet educational objectives through independent, self-directed learning; and

e) off-duty time required for rest, recreation, social obligations, and personal and family needs.

Given that the primary purpose of GME is educational, the patient care services that a resident is required to perform while on duty should be determined primarily by the resident's educational needs. Moreover, a resident's patient care responsibilities should be arranged so as not to preclude participation in the program's organized teaching activities. However arranged, the overall number of on-duty hours assigned must be limited to accommodate the residents' need for off-duty time. Within any allotment of overall duty hours, limits also must be placed on the duration of uninterrupted patient care responsibilities, taking into account the intensity of the work involved, in order to avoid excessive fatigue.

Disagreement still exists among medical educators about whether the reasoning in the foregoing paragraph constitutes a cogent argument for placing an upper limit on resident duty hours. Some argue passionately and reasonably that no limits can be justified, believing instead that the ethic of the medical profession and the need to ensure continuity of care run counter to setting time limits for patient care responsibilities. Others argue just as passionately and reasonably that some limits must be established in order to avoid undue fatigue and, as just noted, to respect the residents' need for sufficient personal time. After years of debate, we believe that prudence favors the establishment of a reasonable upper limit. We conclude, along with countless others, that 80 hours per week constitutes such a reasonable limit, albeit a generous one by any conventional standard. Experience indicates that this allotment of on-duty time, properly distributed, provides sufficient flexibility both to satisfy educational and patient care needs and to safeguard patient and resident well-being.

Limiting required duty hours does not imply that residents must cease providing essential patient care services at arbitrary cut-off times. Priority must always be given to patient safety and well-being and to avoiding transferring patient care responsibilities to others at inappropriate times in the continuum of care (e.g., during an operative procedure, in the midst of a rapidly evolving clinical event). A tired resident who is intimately familiar with a sick patient is often better able to provide quality care than is a fully rested resident who is unfamiliar with the details of the case. But by the same token, invoking continuity of care as a rationale for routinely requiring residents to provide patient care services while fatigued invites substandard care and risks patient safety. Moreover, residents must acquire the ability to recognize when their competency is impaired by fatigue and must gain experience with transferring responsibility for the care of their patients to trusted colleagues.

AAMC Policy Statements

- Institutional sponsors and individual residency programs should have written guidelines governing resident duty hours; these guidelines will vary according to specialty, intensity of patient care responsibilities on a given rotation, level of experience, and educational requirements.

- In no case should residents be scheduled to be on duty more than 80 hours in any week. On typical clinical rotations, residents should not be scheduled to be on duty for more than 24 hours consecutively; continuous duty in high intensity settings (e.g., emergency rooms, critical care units) should, in general, be scheduled for no more than12 hours. These guidelines must be applied with sufficient flexibility, as noted above, to ensure that thorough exchange of information and proper transfer of patient care responsibilities occurs whenever residents who are going off duty sign over the care of patients to other residents or to teaching physicians.

- Duty-free intervals between periods on call should be at least 8 hours long.

- If moonlighting is authorized, the time spent doing so should be included within the parent program's duty hour limits; unauthorized moonlighting should be prohibited.

- Residents should not be required to have overnight, on-call duty more frequently than one night in three, as averaged over 4 weeks.

- Residents should have at least 24 consecutive hours free of all assigned duty every seven days.

- The on-duty time residents spend delivering patient care services of marginal or no educational value should be minimized.

Summary

The Policy Statements set forth in this document address issues requiring urgent attention by the academic medicine community. The quality of resident education and the well-being of residents themselves are among our most solemn professional obligations. Persistent calls for reforming GME to better meet these obligations have come both from within our community and from external sources. We must heed these calls, not because government regulation is the likely alternative if we do not, but because it is the right thing to do.

The AAMC recognizes that implementing these policies will require many sponsoring institutions and individual training programs to allocate additional resources to their GME mission. Finding the necessary resources in an era of significant financial stress will undoubtedly pose a major challenge for more than a few. Unfortunately, that challenge is made even greater by the reluctance of many payers of patient care services to assume their fair share of GME costs and by the presence of regulatory constraints within current public programs affecting GME. While the AAMC will continue to call for appropriate funding for all GME-related activities and for relief from overly restrictive regulations, sponsors of GME programs should find these policy positions helpful in setting priorities for the expenditure of existing resources.

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May 1, 2009

Thomas J. Nasca, MD
Chief Executive Officer
Accreditation Council for Graduate Medical Education
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Dear Dr. Nasca:

Thank you for the opportunity to present the views of the American Board of Medical Specialties (ABMS) and its 24 Member Boards to the ACGME on the current ACGME Resident Duty Hour Standards and the recommendations of the IOM Report on Resident Duty Hours issued in December 2008.

Residents work in systems that provide both patient care and graduate medical education. Ideally, these systems, acting in the public interest, should increase patient safety, improve the quality of care, promote continuity of care, and enhance resident education/training. Whenever possible, we must ensure that system changes, such as resident duty hour standards, concurrently promote patient safety, quality of care, resident education/training, and resident safety, and do not lead to serious unintended consequences.

ABMS supports the 2003 ACGME standard that limits resident duty hours to 80 hours per week, averaged over 4 weeks. However, we feel that flexibility is needed in implementing these standards as one size does not fit all specialties or all programs. Flexibility of duty hours may be especially important for specialties that perform major surgeries or procedures.

ABMS supports a number of the IOM recommendations that we believe are likely to improve patient safety, patient care and resident education/training including:

- ACGME should ensure that programs provide timely, adequate, direct, onsite supervision for residents (We believe the supervision should be of high quality and provide timely feedback to the resident.)
- ACGME and the Residency Review Committees should strengthen their current monitoring practices and strictly enforce resident duty hours (We feel ACGME is the appropriate organization to monitor these practices, as it was

established to do this and has the requisite knowledge and experience. We do not feel that the Centers for Medicare and Medicaid Services or The Joint Commission are appropriate agencies to monitor or take an active oversight or enforcement role.)

- Teaching hospitals should design, implement and institutionalize structured handover processes to ensure continuity of care and patient safety (Minimizing the number of handoffs should be a major component of such processes.)
- Graduate medical education – sponsoring institutions should fully involve residents in their safety reporting, learning and quality improvement systems, and this should become an important part of the resident's educational experience.
- Count internal and external moonlighting against 80-hour weekly limit. We suggest that moonlighting requests be approved prospectively by the Designated Institutional Official (DIO). (However, we feel that external moonlighting is a complex problem in that it would be difficult to monitor and in many cases is a financial necessity for residents due to high medical school debt obligations. It is of concern, however, that rapid enforcement of such a recommendation would likely lead to many training programs responding by creating barriers or exclusions from moonlighting. For individual physicians, this may also lead to increasing their stress during training in managing their educational loan obligations.)

Concern for the lack of an evidence base guiding further changes or restrictions.

While we recognize the potential value in the IOM recommendations, we also have concerns that further restrictions in work hour and work schedule policies could lead to unintended consequences in the quality and safety in patient care, and adversely impact physician training. It is important to emphasize that there is almost no evidence base for understanding the impact (positive or negative) from the work hour policies that were instituted by ACGME in 2003. The little available research on this topic does not provide a clear outcome . For example, no improvement in surgical patient outcomes[1] or surgical patient safety[2] has been reported, and Hutter suggested that the 80-hour resident workweek did not increase resident sleep.[3] Based on this limited research it is possible that further restrictions of surgical resident work hours may be associated with: decreased continuity of care;[4] increased risk of error due to handoffs;[1]decreased resident involvement in complex cases, technically advanced cases and first assistant experience;[5] decreased volume of surgery;[5] and decreased resident participation in reoperation on the same patient.[5]

Specific concerns about how some of the IOM recommendations might negatively impact the training of competent physicians.

For more than 75 years, ABMS through its policies and its Member Boards through their individual certification programs have set standards for a high quality specialty-based workforce. Over the decades, subspecialty certification has been a key motivating factor in achieving a high quality physician workforce. For more than a decade, ABMS, working with ACGME, have promoted a framework of six competencies as part of training; competencies that require sufficient exposure to the practice of medicine prior to certification. We believe that some of the restrictions recommended by the IOM Committee would potentially have a serious negative impact on physician competencies.

First, a key part of the professionalism of medicine is a physician's commitment to their patient. This commitment is an attribute that is part of training and often requires extraordinary efforts by the physician community to serve their patient needs. We believe that the IOM Committee recommendations for resident duty hour reform has significant potential for development of a "shift-work" mentality with less personal commitment to patients and patient outcomes. By emphasizing a strict, regulated approach to duty hours, physicians are confronted with untenable professionalism choices, specifically bedside care and compassion versus following duty hours rules. We believe that this could undermine the development of the trainee's sense of personal responsibility for patients, a core component of medical professionalism, and a fundamental quality that is valued by both patients and physicians.[6]

Secondly, recognizing that the ABMS Boards will not compromise on the quality of training required to prepare for board certifications, we believe that further constraints on resident hours may lengthen training requirements. This lengthening of training requirements may therefore impact the workforce. Any increase in training periods likely would have an impact on physician choice for the type of specialty training. That in turn would lead to potentially unanticipated consequences regarding how trainees enter the workforce and, years later, would have a downstream effect on specialty training among providers in the U.S. workforce. To our knowledge, none of this has been adequately explored or modeled.[7]

Lastly, we are concerned about the financial impact to the health care system and nation in applying the IOM recommendations. The IOM Committee estimated that "national costs of personnel to substitute for the reduced resident work could be approximately $1.7 billion, according to an economic model of selected scenarios."[1] It is not clear from the IOM report if they also conducted an economic evaluation of the gains from such changes. As part of good financial stewardship, we believe that such an economic evaluation should be conducted prior to making any additional significant changes to resident duty hours.

Further Research Needed [7]

We believe it is too early to fully assess the impact of the 2003 ACGME resident work hour reductions on patient safety, quality of care, and resident education/training. Although several studies that have emerged since 2003 suggest a slight improvement in the trainee's quality of life, there is a dearth of data and many of the current studies are inadequate. We feel strongly that the enactment of additional duty hour restrictions would be premature before the consequences of the 2003 restrictions are better understood.

We suggest and strongly support building a research program that would lead to evidence-based understanding of the impact of the 2003 reduction in residency work hours. One example is a prospective study by Kevin Volpp, supported by the Agency for Healthcare Research and Quality (AHRQ), to which a few ABMS Boards are providing data. Research on the link between work hours and supervision, studied in tandem and not as separate entities, is a fruitful area for study.

Perhaps the strongest concern for interpreting the data is that there is not enough cohort experience of trainees who have completed residencies under the new work hours. Since implementation of the 2003 restrictions, many residencies with four or five years of training have had only their first cohort emerge. Thus, in early 2009, a pre-period analysis is possible, but a post-analysis is not. In addition, some residencies are six or seven years and have yet to graduate the first person who began training under the 2003 duty hour restrictions.

Conclusion and Recommendations

In summary, ABMS supports the ACGME standard that limits resident duty hours to 80 hours per week and the IOM recommendations that we believe are likely to improve patient safety, patient care, and resident education/training. However, we are concerned that further restrictions of work hours may constrain the trainees' ability to achieve competency and preparedness for practice in most community settings and may not improve patient safety, patient care or resident welfare.

We therefore recommend that:

- Flexibility be employed in implementing resident work hour and work schedule standards as one size does not fit all specialties or all programs.
- No further reduction of residency work hours or constraints on work schedule be considered until the impact of the 2003 reduction in residency work hours has been better studied.
- Studies of residency work hours be achieved through prospective specialty-related outcome studies. These studies could be piloted in several specialties in which there may be concerns of resident fatigue related to current work hour rules.
- We suggest that the Agency for Healthcare Research and Quality, the Centers for Medicare and Medicaid Services, ACGME, ABMS, and other stakeholders strongly commit to building a research program that would lead to evidence-based understanding of the impact of the 2003 reduction in residency work hours on the well being of patients and residents.
- Finally, any research in this area should focus on multiple outcomes including: patient safety and quality of care; training experience; training preparedness for board certification; and workforce implications.

We thank the ACGME for the opportunity to present our views.

Sincerely,

Kevin B. Weiss, MD
President and CEO
American Board of Medical Specialties

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April 20, 2009

Dr. Thomas Nasca
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Dear Dr Nasca:

When the Accreditation Council for Graduate Medical Education (ACGME) adopted its standards for resident duty hours in 2003, a review after five years was promised. The American Hospital Association (AHA) is delighted that the ACGME has now undertaken a comprehensive review.

The primary purpose of all hospitals is to provide patients with medically appropriate, safe services of high quality. For hospitals that provide residency training, an additional purpose is to provide physician-in-training with the clinical education, experience and supervision necessary to develop into physicians capable of practicing independently. Teaching hospitals simultaneously pursue both of these goals without diminishing their performance in either area.

The introduction of specific standards for resident duty hours in 2003 was a significant break with tradition for most residency programs. The standards addressed a clear public concern that at least some residents were providing services during long duty periods when their clinical judgment and learning capacity could be impaired. The ACGME provided genuine leadership in setting these standards, and the AHA supported the standards and their implementation. The AHA also supports the ACGME's evolving initiatives to monitor compliance with the duty hour standards.

The AHA recognizes that only five years has passed since implementation of the duty hour standards. As a result, some specialties have yet to have a cohort of residents complete programs under the new standards while others have had only a couple of cohorts complete their programs. Thus, there is not a long history or extensive base of data to use in evaluating the 2003 standards. As an example, for many programs, there are not yet available performance data such as specialty board scores.

In evaluating the standards, the AHA recognizes that the primary interest of society is in assuring that residents have had sufficient sleep so that the medical care they provide is safe and of high quality. Since our society views the time outside one's work or training program as personal time, we use duty hours as an implied proxy for measuring sleep and alertness. This is at best an inadequate proxy because the hospital and residency program director have no information on what the resident actually did during the hours not on duty.

Because a quantitative standard for duty hours is a less-than-ideal proxy for the resident's alertness, the preferred approach presently available for assessing resident alertness to both provide safe patient services and learn from the experience is on-site observation of the resident by more senior residents and by faculty. It should not be assumed that all residents under all conditions are able to provide patient care or learn effectively just because they are within the 80 hour standard and its sub-standards. Moreover, because residents in their initial year of training generally require more time to perform diagnostic and treatment services, it is especially necessary to observe their performance and judge their alertness and capabilities.

The generic sleep research literature suggests that mental alertness and task performance decline after about 16 hours of time or after 4 consecutive night shifts for most persons. However, it is unclear if these general findings are applicable to physicians-in-training who are young and intellectually engaged in their activities. Until further research is available, it is reasonable to use this information to inform the evaluation of the present standards. At the same time, if the duty hour standards are modified to incorporate these limitations, it is critically important that their impact on resident education and competence be assessed. Finally, it is also reasonable to include "moonlighting" time within the standard so that the assumed rest of non-duty hours is not compromised by on-duty (and often unsupervised) moonlighting.

The issue of duty hours has implications for several other issues in graduate medical education, including:

- Whether resident programs will have to be lengthened to provide adequate clinical experience?

- What impact has the limitation on duty hours had upon the resident's concept of personal responsibility for the patient?

- When resident hours are limited, how can handovers from one resident to another be improved to assure the receiving physician has complete knowledge of the patient condition and treatment plan?

The ACGME should encourage these related topics to be studied as part of its review of resident duty hours.

Many of the hospitals that participate in graduate medical education are operating at a loss or with very small margins. As a result, some hospitals are considering reducing the number of residency positions or substituting either employed physicians (such as hospitalists) or Advance Practice Nurses for residents. Should the ACGME adopt changes in the duty hour standards that increase residency program costs, it is important that the ACGME clearly state the financial impact of the new standards so that it is clear to society and health care payers.

In sum, the AHA believes:

1. Hospitals participating in graduate medical education must assure that residents have the breadth and depth of experience necessary to develop into independent practitioners and provide organize patient care so that it is safe, appropriate, and of high quality.

2. Restful sleep is a good proxy for the resident's likely alertness; duty hours are a much weaker measure of alertness because no attention is given to what the resident does during non-duty hours.

3. The present research data on the relationship between resident duty hours and the safety and quality of patient care services is underdeveloped and inadequate. In particular, studies should be undertaken to determine if the generic sleep research showing degradation of performance after 16 hours consecutive duty and four consecutive nights holds for physicians-in-training.

4. The duty hour standard of 80 hours per week when averaged over four weeks continues to be an appropriate standard. The standard should include on-site and off-site "moonlighting" because the resident clearly is not resting during that time.

5. There is very limited information to set standards for the frequency of in-house call, at-home call, or mandatory unassigned time (or time off). Therefore, the AHA finds no basis for changing the 2003 ACGME standards of no more than every third night for in-hospital call or one day off per week at this time.

6. If the ACGME makes changes to the duty hour standards, it is important to assure that the several components, when taken together, are logistically coherent and capable of measurement. Given that hospitals provide care 24 hours a day and seven days a week, it is critical that duty hour standards fit within these operational requirements and do not disrupt them.

7. The AHA recognizes that patients and residents are not homogeneous. Regardless of the standards adopted, there needs to be flexibility to meet the needs of patients for continuity of care and residents for continuity of case experience provided that on-site supervision is adequate to limit the responsibility of a fatigued resident.

8. The AHA recognizes that programs with a larger number of residents have an easier time accommodating any standards for resident duty hours.

9. If the ACGME makes changes in the duty hours that increase the cost of operating the graduate medical education programs, it is essential that the ACGME clearly identify the expected increase and its potential, if unfunded, to result in a decline in the number of residency positions available.

The AHA appreciates the opportunity to comment on the review of duty hour standards and will continue to work with and support the ACGME's efforts to set and enforce reasonable standards that protect patient safety and promote resident learning.

Sincerely,

James Bentley

James Bentley, Ph.D.
Senior Vice President, Strategic Policy Planning

AMA
AMERICAN
MEDICAL
ASSOCIATION

Michael D. Maves, MD, MBA, Executive Vice President, CEO

April 30, 2009

Thomas J. Nasca, MD, MACP
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Dear Dr. Nasca:

I am writing in response to your February 12, 2009 request for a position paper on the recommendations in the recent Institute of Medicine report on resident/fellow duty hours.

Specifically, your communication requested the following information:

- *Your organization's formal position on the recommendations contained in the Institute of Medicine Report, including impact analysis, from your organization's perspective, on costs and impact of implementation;*

- *Your organization's formal position on the current ACGME Resident Duty Hours Standards including impact analysis, from your organization's perspective, on costs and impact of implementation;*

- *Your organization's formal recommendations regarding dimensions of Resident Duty Hours standards, and justification (wherever possible) for this position with evidence;*

- *Your organization's formal recommendations regarding standards governing key aspects of the Learning Environment, and justification (wherever possible) for this position with evidence; and*

- *Your organization's willingness to participate, if invited, in a Resident Duty Hours and the Learning Environment Congress, to be held in June 2009 in Chicago, Illinois. This Congress will be configured to provide the ACGME leadership with the breadth of perspectives of the medical community as they embark on review and revision of the Resident Duty Hours and Learning Environment Standards.*

With input from various constituent groups of the American Medical Association (AMA), including the AMA Resident and Fellow Section, Council on Medical Education, and Section on Medical Schools, I am pleased to provide to you the information on the following pages. As you review this document, please keep in mind that:

1. This document provides a summary statement of *current* AMA policies.
2. The AMA is committed to be involved in the ACGME process of responding to the IOM report.
3. The AMA continues to monitor resident duty hours and plans another report to the AMA House of Delegates in November 2009 on this issue.

Introduction

In September 2007, the Institute of Medicine (IOM) appointed the Committee on Optimizing Graduate Medical Trainee (Resident) Hours and Work Schedules to Improve Patient Safety, at the request of Congress and the Agency for Healthcare Research and Quality. The Committee's two primary objectives were to:

- Synthesize current evidence on medical resident schedules and healthcare safety; and
- Develop strategies for implementing optimal work schedules to improve safety in health care.

The Committee held five meetings and two conference calls between December 2007 and August 2008, with presentations from invited experts and an opportunity for questions and comments from the public at three of the five meetings. The Committee heard from presenters representing the perspectives of the accreditation and certification community, organized medicine, medical students, residents, patient safety advocates, and researchers on sleep and patient outcomes, as well as program directors in primary and surgical specialties. Specific organizations included:

- Accreditation Council for Graduate Medical Education
- AMA Medical Student Section
- AMA Resident and Fellow Section
- American Board of Medical Specialties
- American Hospital Association
- American Medical Students Association
- Association of American Medical Colleges
- Centers for Medicare and Medicaid Services
- Committee of Interns and Residents
- The Joint Commission
- Public Citizen

The Committee's report (*www.iom.edu/residenthours*) was released on December 2, 2008. It does not recommend a further reduction of residents' work hours from the current 80-hour limit, but calls for:

- Reducing the maximum number of hours that residents can work without time for sleep to 16;
- Increasing the number of days residents must have off; and
- Restricting moonlighting during residents' off-hours.

The Committee's recommendations also call for greater supervision of residents, limits on patient caseloads based on residents' experience and specialty, increased interdisciplinary teamwork, and overlap in schedules during shift changes to reduce the chances for error during handoffs. In addition, the Committee calls for continued research and more data on duty hours and patient safety. The report notes that the biggest barriers to these changes are financial costs (an estimated $1.7 billion per year) and an insufficient health care work force. Nonetheless, the report indicates that "action on all recommendations should be taken within 24 months," that is, by December 2010.

AMA Response to the IOM Report

The AMA's initial response to the IOM report congratulated the IOM on its support for the 80-hour weekly limit, which has been reflected in AMA policy since 2002. In addition, the AMA's monthly *GME e-Letter*, which goes to 13,000 residency/fellowship program directors, coordinators, and medical school/institutional officials noted that "the AMA applauds the IOM's proposal to spread the costs of implementing its proposal among all payers—which is consistent with AMA policy that all GME costs should be so shared." Early responses from some *e-Letter* readers, however, have been less supportive. One noted "problems with inpatient continuity and follow-up, growing resident knowledge-base deficits, declining sense of ownership of patient outcomes, and (anecdotally) an increase rather than decrease in medical errors."

The AMA House of Delegates (HOD) and its various student, resident, and academic physician component groups have not yet formulated a consensus response to the IOM report, so it is premature for the AMA to offer any detailed analysis as to potential costs and impact of implementation of the IOM's recommendations or to advise the ACGME's response to these recommendations.

AMA Reports/Policy on Duty Hours

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Before and since the ACGME standards went into effect in July 2003, the AMA has developed policy and written several reports on the effects of duty hour limits, as well as related topics such as physician burnout and at-home call (for more information, refer to *www.ama-assn.org/ama/pub/category/7094.html*). These reports and their recommendations have been thoughtfully informed by the AMA's Council on Medical Education (CME), Section on Medical Schools, Medical Student Section, and Resident and Fellow Section; vetted through Reference Committee C; and approved by the HOD.

The last CME report on this topic (Enforcement of Duty Hours Standards and Improving Resident, Fellow And Patient Safety, Report 5-A-08) collated recent research on duty hour limits vis-à-vis patient safety, which have shown improvements or neutral effects on clinical outcomes. It also touched upon an overarching concern among educators and residents about 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. The report called for continued monitoring and enforcement of the standards, as well as flexibility and responsiveness to emerging research on their effects. In addition, it stated that medical organizations should work collaboratively to ensure that federal legislative action is not seen by policymakers and the public as the only effective solution. The report included ten recommendations, seven of which are particularly relevant to the ACGME:

- That our AMA reaffirm support of the current Accreditation Council for Graduate Medical Education duty hour standards;

- 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;

- 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;

- 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;

- 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;

- 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; and

- That our AMA urges the ACGME and AOA to decrease the barriers to reporting duty hour violations and resident intimidation.

Discussion

In discussions of duty hours and the resident/fellow learning environment, there are two primary values at stake—quality patient outcomes and quality educational outcomes. The effect of limits on resident duty hours on either of these values may not be straightforward, with consequences that can vary for different constituencies. As the key organization representing all physicians in the United States across all specialties/subspecialties, and the most well-known physician association among the public, the AMA is in a unique position to monitor the responses of various groups to issues related to duty hours, the resident/fellow learning environment, and patient quality. These include:

- Program directors, attending physicians, and trainees. Although most residents favor duty hour limits and many program directors decry the rigidity of their implementation, some trainees and many attending physicians, especially in surgical specialties, believe residents' education may be shortchanged by the 80-hour weekly limit. Although evidence is anecdotal, there appear to be a number of attending physicians and program directors who feel that the current generation of trainees is not as well prepared for the rigors of practice post-GME. Also, work not completed by residents/fellows during shifts often falls to the attending physicians.

- Surgical specialties versus other specialties. The RRCs for pediatrics, internal medicine, and family medicine had 80-hour duty hour limits in place years before July 2003. In contrast, leading organizations in neurological surgery, for example, "registered serious concerns" about the IOM recommendations and argue that continuity of care will suffer and increased handoffs will lead to increased errors. Questions have also been raised about the possibility of the need to increase the length of training in some disciplines.

- Patient advocates versus the GME community. Public advocates continue to compare residents' schedules to those of truck drivers and airline pilots, among others, and to call for reduced hours to increase patient safety and reduce medical errors. Some residency program directors, educators, and residents/fellows counter that handoffs may be more risky than long shifts and that educational goals, and service needs, are already being stressed under the current standards.

Summary

The AMA will continue to track this issue and the viewpoints of trainees and program directors, as well as coverage of the issue in the national media and relevant research in peer-reviewed journals. AMA Resident and Fellow Section (AMA-RFS) staff will also share insights garnered via postings by AMA-RFS members on its listserv. The annual meeting of the AMA HOD in June will provide additional opportunity to discuss the association's response to the IOM report and duty hours. For example, the Council on Medical Education and the Section on Medical Schools will hold a symposium on unintended consequences of duty-hour limits, for which ACGME participation would be welcome. Division staff attended the ACGME symposium on duty hours in March, and AMA staff are planning to collaborate with ACGME staff on a survey of residents/fellows, to follow-up on similar AMA surveys from 1989 and 1999. These and other data points will help inform a planned Interim 2009 follow-up report to the AMA HOD on duty hours, which was rescheduled by the Council on Medical Education from Annual 2010 to Interim 2009. That report will summarize new and emerging issues and data and may articulate additional AMA policies and actions that will aid the ACGME in its response to the IOM report's recommendations.

At its February 2009 meeting, the AMA Board of Trustees committed to the following three actions:

1. The American Medical Association will 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, and monitor relevant research on duty hours, sleep, and resident and patient safety, with a report back at the 2009 Interim Meeting of the AMA House of Delegates.

2. The AMA will continue to disseminate information about duty hours, through its monthly *GME e-Letter* and other communications vehicles.

3. The AMA continue to work closely with the ACGME (as one of the ACGME's member organizations) to help the ACGME respond to the recommendations of the Institute of Medicine's report.

In closing, the AMA is committed to continuing its close working relationship with the ACGME and to helping the ACGME respond to the IOM's recommendations. Accordingly, the AMA is willing to commit to full participation in the ACGME's planned congress in June.

Thank you for this opportunity, and please let me know if you have any questions or would like additional information.

Sincerely,

Michael D. Maves, MD, MBA

cc: AMA Council on Medical Education

AMA
AMERICAN
MEDICAL
ASSOCIATION

Michael D. Maves, MD, MBA, Executive Vice President, CEO

April 30, 2009

Thomas J. Nasca, MD, MACP
Chief Executive Officer
Accreditation Council for Graduate
Medical Education
515 N. State Street
Chicago, IL 60654

Dear Dr. Nasca:

I am writing in response to your February 12, 2009 request for a position paper on the recommendations in the recent Institute of Medicine report on resident/fellow duty hours.

Specifically, your communication requested the following information:

- *Your organization's formal position on the recommendations contained in the Institute of Medicine Report, including impact analysis, from your organization's perspective, on costs and impact of implementation;*

- *Your organization's formal position on the current ACGME Resident Duty Hours Standards including impact analysis, from your organization's perspective, on costs and impact of implementation;*

- *Your organization's formal recommendations regarding dimensions of Resident Duty Hours standards, and justification (wherever possible) for this position with evidence;*

- *Your organization's formal recommendations regarding standards governing key aspects of the Learning Environment, and justification (wherever possible) for this position with evidence; and*

- *Your organization's willingness to participate, if invited, in a Resident Duty Hours and the Learning Environment Congress, to be held in June 2009 in Chicago, Illinois. This Congress will be configured to provide the ACGME leadership with the breadth of perspectives of the medical community as they embark on review and revision of the Resident Duty Hours and Learning Environment Standards.*

With input from various constituent groups of the American Medical Association (AMA), including the AMA Resident and Fellow Section, Council on Medical Education, and Section on Medical Schools, I am pleased to provide to you the information on the following pages. As you review this document, please keep in mind that:

1. This document provides a summary statement of *current* AMA policies.
2. The AMA is committed to be involved in the ACGME process of responding to the IOM report.
3. The AMA continues to monitor resident duty hours and plans another report to the AMA House of Delegates in November 2009 on this issue.

Introduction

In September 2007, the Institute of Medicine (IOM) appointed the Committee on Optimizing Graduate Medical Trainee (Resident) Hours and Work Schedules to Improve Patient Safety, at the request of Congress and the Agency for Healthcare Research and Quality. The Committee's two primary objectives were to:

- Synthesize current evidence on medical resident schedules and healthcare safety; and
- Develop strategies for implementing optimal work schedules to improve safety in health care.

The Committee held five meetings and two conference calls between December 2007 and August 2008, with presentations from invited experts and an opportunity for questions and comments from the public at three of the five meetings. The Committee heard from presenters representing the perspectives of the accreditation and certification community, organized medicine, medical students, residents, patient safety advocates, and researchers on sleep and patient outcomes, as well as program directors in primary and surgical specialties. Specific organizations included:

- Accreditation Council for Graduate Medical Education
- AMA Medical Student Section
- AMA Resident and Fellow Section
- American Board of Medical Specialties
- American Hospital Association
- American Medical Students Association
- Association of American Medical Colleges
- Centers for Medicare and Medicaid Services
- Committee of Interns and Residents
- The Joint Commission
- Public Citizen

The Committee's report (*www.iom.edu/residenthours*) was released on December 2, 2008. It does not recommend a further reduction of residents' work hours from the current 80-hour limit, but calls for:

- Reducing the maximum number of hours that residents can work without time for sleep to 16;
- Increasing the number of days residents must have off; and
- Restricting moonlighting during residents' off-hours.

The Committee's recommendations also call for greater supervision of residents, limits on patient caseloads based on residents' experience and specialty, increased interdisciplinary teamwork, and overlap in schedules during shift changes to reduce the chances for error during handoffs. In addition, the Committee calls for continued research and more data on duty hours and patient safety. The report notes that the biggest barriers to these changes are financial costs (an estimated $1.7 billion per year) and an insufficient health care work force. Nonetheless, the report indicates that "action on all recommendations should be taken within 24 months," that is, by December 2010.

AMA Response to the IOM Report

The AMA's initial response to the IOM report congratulated the IOM on its support for the 80-hour weekly limit, which has been reflected in AMA policy since 2002. In addition, the AMA's monthly *GME e-Letter*, which goes to 13,000 residency/fellowship program directors, coordinators, and medical school/institutional officials noted that "the AMA applauds the IOM's proposal to spread the costs of implementing its proposal among all payers—which is consistent with AMA policy that all GME costs should be so shared." Early responses from some *e-Letter* readers, however, have been less supportive. One noted "problems with inpatient continuity and follow-up, growing resident knowledge-base deficits, declining sense of ownership of patient outcomes, and (anecdotally) an increase rather than decrease in medical errors."

The AMA House of Delegates (HOD) and its various student, resident, and academic physician component groups have not yet formulated a consensus response to the IOM report, so it is premature for the AMA to offer any detailed analysis as to potential costs and impact of implementation of the IOM's recommendations or to advise the ACGME's response to these recommendations.

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The last CME report on this topic (Enforcement of Duty Hours Standards and Improving Resident, Fellow And Patient Safety, Report 5-A-08) collated recent research on duty hour limits vis-à-vis patient safety, which have shown improvements or neutral effects on clinical outcomes. It also touched upon an overarching concern among educators and residents about 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. The report called for continued monitoring and enforcement of the standards, as well as flexibility and responsiveness to emerging research on their effects. In addition, it stated that medical organizations should work collaboratively to ensure that federal legislative action is not seen by policymakers and the public as the only effective solution. The report included ten recommendations, seven of which are particularly relevant to the ACGME:

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Thank you for this opportunity, and please let me know if you have any questions or would like additional information.

Sincerely,

Michael D. Maves, MD, MBA

cc: AMA Council on Medical Education

COUNCIL OF MEDICAL SPECIALTY SOCIETIES

COMMITTED TO EXCELLENCE IN PROFESSIONALISM, EDUCATION AND QUALITY OF CARE

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Thomas J. Nasca MD
Chief Executive Officer
Accreditation Council for Graduate Medical Education
515 N. State St., Ste 2000
Chicago, Illinois 60654

May 11, 2009

Dear Dr. Nasca,

The Council of Medical Specialty Societies (CMSS) is pleased to respond to your request for input on the recurring issue of Resident Duty Hours.

Few issues have generated more loss of sleep than the efforts of all involved to find a better approach to the difficult challenge of resident working hours. Clearly, the IOM worked hard to help address this challenging issue. Unfortunately, as with any issue of this complexity, it is difficult to both find common ground and to address recommended changes rapidly. CMSS has sympathy with virtually all of the positions and recommendations.

CMSS' positions on this important issue are drawn from surveying the leadership of the member organizations of the Organization of Program Director Associations (OPDA), convened by CMSS. Program director organizations responding reflected the spectrum of medicine and surgery. CMSS then convened a special session on resident duty hours, and re-opened the issue to discussion at the full CMSS Council.

Institute of Medicine Report:

Maximum hours of work per week –

CMSS supports the IOM recommendation not to change the current ACGME duty-hours limits of 80 hours, averaged over 4 weeks.

Maximum shift length –

CMSS does not support the IOM recommendation to require a protected 5 hour sleep period between 10 PM and 8 AM.

- Recognizing the contributions of sleep science to the recommendation for a 5 hour "nap", we do not believe requiring such a nap is a practical solution in the teaching hospital environment. Interventions such as enhanced supervision, team care and regular night shifts with supervised and documented patient hand-offs may be a more realistic intervention in the training environment.

Maximum in-hospital on-call frequency –

CMSS does not support the IOM recommendation to remove the ability of programs to average every third night in-hospital on-call frequency.

Minimum time off between scheduled shifts –
CMSS supports the IOM recommendation to retain a minimum of 10 hours off duty after a day shift, and 14 hours off duty after any extended duty period of 30 hours (not to return until 6 AM the next day).

- However, CMSS does not support the IOM recommendation for 12 hours off after a night shift. If all other duty hours rules are followed, there is no need for this additional rule. Further, moving directly from a night shift to a day shift, without on-call responsibilities the next night, is consistent with the overall duty hours and shift length requirements.

Maximum frequency of in-hospital night shifts –
CMSS does not support the IOM recommendation for a four night maximum for in-hospital night shifts, with 48 hours off after 3 or 4 nights of consecutive duty.

- Night shifts are one of the new paradigms of providing care that resulted from the institution of the original resident duty hours rules, an intervention that has been highly successful in the teaching hospital environment. It seems counterproductive to disturb re-balancing of circadian rhythms among residents every three to four days.

Mandatory time off duty –
CMSS does not support the IOM recommendation to remove the ability of programs to average over 4 weeks the 1 day (24 hours) off per week.

Moonlighting –
CMSS supports the IOM recommendation to count internal and external moonlighting against the 80-hour weekly limit, and to include all other scheduled work in the duty hour limits.

Limit on hours for exceptions –
CMSS supports the IOM recommendation not to change the ACGME limits of 88 hours for select programs with a sound educational rationale.

Emergency room limits –
CMSS supports the IOM recommendation not to change the ACGME limits on hours, shifts and workweeks in the emergency room.

Current ACGME Resident Duty Hours Standards:

CMSS supports the current ACGME Resident Duty Hours Standards, instituted in 2003. We believe that insufficient time has elapsed to evaluate the 2003 changes. We recommend strategies to enforce the current duty hours limits, so that effective evaluation of their results can be obtained.

Background:

Since the Libby Zion tragedy, issues of fatigue and duty hours have taken precedence over the issue of adequate supervision of trainees. CMSS recognizes that the issue of resident duty hours reflects a concern for patient safety, to protect patients from potential errors made by fatigued residents. Duty hours rules do not, however, protect against the other major variable of inadequate resident supervision. These complex and inter-related issues make it difficult to causally link sleep loss with errors, when the notion of resident supervision is ignored in the evaluation. Further, the protective effect of the training team has not been sufficiently explored.

Variation –

There is significant variation in the ability of individuals to function with varying amounts of sleep, and significant variation in the amount of sleep enjoyed by individuals when off duty. Unfortunately, reducing work hours does not always equate with increasing sleep.

Different specialties have variable abilities to limit hours of trainees (trauma surgery vs. dermatology, for example), resulting in the recognition that a one-size-fits-all approach stretches regulation potentially beyond realistic strategies. Residents at different levels of training (interns vs. chief residents) need significantly different supervision, and should manage workloads and hours differently.

Unintended consequences -

Limitations on duty hours compress learning opportunities, potentially resulting in less fully trained and experienced graduate physicians, or in increasing the length of training for residents. Other strategies may ease work burdens of trainees, such as reducing resident "scut" work. Adding midlevel providers to manage patients when residents are off duty, results in significantly increased costs to teaching hospitals, in an environment when additional reimbursement for teaching expenses is unlikely. Additionally, adding increased patient care responsibilities to faculty physicians creates the same problem of fatigue in those who are supposed to be supervising the trainees.

Strategies aimed at reducing one variable (work hours limits) have unintended consequences with similar potential risks of errors (hand-offs of patient responsibilities between residents, midlevel providers, and attending physicians). Continuity of care between physician and patient may decrease errors, enhance learning, increase patient and resident satisfaction, and potentially improve patient outcomes.

Professional Responsibility:

The mission of the CMSS is to provide a voice for medical specialty societies, working with other medical organizations, to promote adoption of policies that will improve the United States' healthcare system and health of the public. Among the purposes of CMSS are improved quality of patient care, improved standards for delivery of care, effective programs for graduate medical education, studied responses to medical issues, and professionalism in medicine.

Attributes of professionalism include altruism (putting patients' needs first), voluntary self-regulation, and transparency. CMSS believes that ACGME, in concert with other organizations of medicine, has the responsibility to voluntarily self-regulate graduate training to achieve optimum patient care outcomes, patient safety, resident training and physician well-being.

We remain open to continued dialogue on this issue to help deal with the difficult change management challenges. CMSS is willing to participate, if invited, in a resident Duty Hours and the Learning Environment Congress, to be held June 11-12, 2009, in Chicago.

Thank you for the opportunity to contribute to this critically important discussion.

Sincerely,

Norman Kahn MD

Norman Kahn MD
Executive Vice-president and CEO

May 1, 2009

5808 Jarvis Lane
Bethesda, MD 20814

Dr. Thomas J. Nasca, M.D., MACP
Chief Executive Officer
Accreditation Council for Graduate Medical Education
515 North State Street
Suite 2000
Chicago, Illinois 60654

Dr. Nasca,

The proposal for changes in residency regulations put forth by the Institute of Medicine will have a drastic effect on medical training in the United States. Whether or not the specific recommendations are implemented, the fact remains that the committee advising the United States government on all things medical has effectively mandated a change. Members of the medical education community must act quickly and decisively to propose our own recommendations for improvements in medical education lest our ability to regulate our own profession be taken away.

Although the proposed changes would have little direct impact on some medical specialties individually, the effects will permeate through every level and aspect of training affecting the entire system and culture of medical education. Allergy/Immunology training programs, for example, will not immediately feel the impact of many of the more draconian recommendations of the IOM such as the severe limitation of weekly duty hours or limitations on the consecutive hours on duty. We will, however, see the "downstream" effects as Internal Medicine and Pediatrics programs that feed into our specialty graduate residents who train very differently than they do currently. Nobody knows what the impact of these changes will be. Certainly, the IOM expects that patient safety will be improved, but as has been discussed, the correlation between duty hours and patient safety is far from clear. Teaching hospitals routinely provide medical care that is superior to that of non-teaching institutions which seriously calls into question the notion that fatal medical errors are the result of resident fatigue. In fact, one of the irreplaceable benefits of teaching hospitals is the redundancy and supervision required to permit decision-making autonomy while also providing the feedback and criticism that are required to allow residents to learn. What is conspicuously missing from the IOM report is an analysis of long-term consequences of their recommendations. Instead, the report focuses on the single aspect of duty hours with the only end-point being a reduction of medical errors in the short term. While this makes for an excellent "sound-byte" for the news or for testimony before Congress, it does little or nothing to improve care as it is not based on research into the causes of the medical errors they hope to lessen.

Furthermore, by limiting the hands-on experience of residents, these recommendations may actually have the effect of reducing the overall quality of medical education and cause more harm to patients in the long-run. According to Dr. Marisa Weiss, author of the book "7 Minutes: How to get the most from your doctor's visit", patient surveys reveal that patients want several things from their doctor. These include a doctor:

1) with adequate expertise, training, and experience (often preferring to see a leader in the field),
2) who is up to date with the most recent advances,
3) who communicates with colleagues to deal with difficult questions and for continuity of care,
4) who stays on top of all developments in the patient's care including test results or new opportunities for treatment,
5) who has superior medical judgment under pressure and over time as they are followed by the same physician,
6) who listens to them and takes their concerns seriously,
7) who returns phone calls promptly,
8) and for whom they do not have to wait too long to make an appointment.

In short, patients rightly expect a professional. Someone who knows the field of medicine generally with tremendous depth and their own specific field with zealous enthusiasm and absolute understanding. Someone who is always available to care for them in their time of need, night or day interrupting birthday parties, soccer games, school plays, meals, or a good night's sleep. A doctor must be willing to provide this or the patient will seek out someone who will. But more importantly, being a doctor is not a job. It is a profession and a privilege that each of us chooses because we are willing to sacrifice for the benefit and well-being of others. This choice begins to impact our lives the day we enter medical school and encounter the sheer mass of basic medical knowledge we must master which causes us to sacrifice much of the life our friends and relatives take for granted. During residency we are finally honored with the opportunity to care for patients we can call our own. But in return, a new level of sacrifice is expected. Caring for patients takes time, but there is no end to the amount that we can learn from them. There is no replacement for sitting at the bedside and speaking with a patient, feeling the skin and pulse, looking in their eyes and watching their breathing. Nothing can replace the experience of following a patient from their initial presentation through initiation of treatment and recovery. Nothing can replace being called to a patient's bedside to assess whether they are becoming septic and following them closely to see if your judgment was correct. Medical judgment is not the same as medical knowledge and cannot be learned from a book or simulator. Although knowledge is a prerequisite, judgment also requires experience, practice, and time. Patients want, need, and deserve doctors who can take care of them. Medical training must produce physicians who can care for patients.

In order to produce competent physicians who are able to safely and effectively practice on their own, it is essential that training programs have several key elements. Among these are provision of an environment conducive to learning, opportunities to make decisions about patient care that are supervised and critiqued, and adequate patient exposure. The first round of duty hours modifications imposed by the ACGME significantly restricted the number of hours a resident could spend in the hospital. This had a significant impact on the first component by forcing hospitals that were utilizing residents for non-educational functions to alter this practice, often by hiring non-physicians to perform these duties. To some degree this was accomplished at the cost of resident experience because residents were required to give up care of their patients even if an important learning opportunity would be missed. Ultimately, however, these new rules had the overall effect of improving resident training by focusing the attention of the training program on efficiently providing both patient care and didactic learning opportunities for the residents. The IOM recommendations differ from the ACGME duty hours restrictions in several ways. First, they impose further restrictions on duty hours without any evidence that these more stringent restrictions will benefit either residents or patients and before the effect of the first round of duty hours restrictions has been assessed. This is unfortunate and represents a lost opportunity to address other more complex problems that may still exist in medical training while going after an easy, politically attractive target that is easy to regulate and has little recourse or means by which to defend itself. Instead, we should use this time to do the hard work of identifying why medical errors occur in the health care system as a whole and how to truly improve medical training. (e.g. better supervision, automation/electronic medical records).

Second, while hospitals responded to the ACGME duty hours restrictions by hiring non-professionals to perform non-professional tasks, the IOM recommendations would require hospitals to take away specialized professional activities from the professionals and distribute them to other professionals. Again, in Allergy/Immunology training programs, this is not likely to cause a significant administrative or cost burden, but in other more time-intensive programs such as Internal Medicine and Surgery, this would likely be impossible from a cost perspective. More importantly, however, patient care and safety will be compromised. Transferring non-professional or unskilled tasks such as patient transport to another individual is innocuous and unlikely to harm a patient. Transferring the active management of their care to another individual, however, is entirely different and will significantly alter the level of care provided to patients. Taking care of a patient is a dynamic process that involves knowledge of the patient's condition, medical history, current and prior therapeutic interventions and response to treatment. This knowledge can be easily transferred to another physician if needed. But in addition, the physician has personally interviewed the patient, laid hands on them, watched their emotional and physical reactions to good and bad news and to treatment. This information cannot be transferred or distributed to another team of care providers and is essential to the complete care of the patient. This will necessarily be lost if the IOM recommendations are adopted and patient care will suffer.

Third, unlike the ACGME duty hours restrictions, the IOM recommendations would necessarily have a deleterious impact on training. As previously mentioned, training programs must ensure provision of an environment conducive to learning, opportunities to make decisions about patient care that are supervised and critiqued, and adequate patient exposure. While the ACGME duty hours restrictions had the effect of improving the overall learning environment, the IOM recommended changes will not. The ACGME duty hours restrictions engendered an adversarial relationship between attending physicians, who are ultimately responsible for the care of the patient and training of residents, and trainees, who were required to leave whether or not their patient was stable and their care was complete. After several years, this has been improved to some degree as mechanisms have been put in place to address this problem. The IOM recommendations would put further strain on this relationship and likely cause many attending physicians to seriously question or even abandon their commitment to teaching. It goes without saying that this would harm resident training and, therefore, patient care as these physicians graduate from training without the same breadth of experience. The IOM recommendations would also make attendance at conferences and other didactic sessions nearly impossible as residents struggle to care for their patients in the allotted time. Again, this would seriously impair the education of residents. Similarly, the IOM recommendations would impair the second component of training, the opportunity to make decisions about patient care that are supervised and critiqued. Various constraints will prevent or impair the several steps involved in this process including time to evaluate the patient, research their condition if necessary, deliberate on the proper course of action, present and discuss this with the attending physician, institute the treatment, and monitor the results. This component of training is arguably the most important as it forms the basis for the independent practice of medicine after graduation. Interfering with any of the steps will prevent the resident from learning and practicing the skills necessary to apply the knowledge and judgment required to perform as a competent physician. Finally, as already mentioned, the IOM recommendations would seriously impair the primary component of residency training which is to provide adequate patient exposure. To develop medical judgement, physicians must see patients. Every patient is different with regard to presentation of their disease, emotional and physical manifestations of the disease, response to treatment, etc. It is only through treating many patients that one can develop a sense of how a patient will progress. Nothing can replace this. The IOM recommendations would severely limit patient exposure resulting in graduation of poorly trained, inexperienced physicians. Again, it goes without saying that this would negatively impact patient care in the long run as these inexperienced residents become inexperienced attending physicians who are ultimately responsible for patient care.

As a primarily outpatient specialty, Allergy/Immunology training is not likely to be significantly affected by the IOM recommendations directly. There are few emergencies or other medical issues that require patient interventions after "normal" business hours. Therefore, the cost and administrative burden will likely be minimal as we de facto already meet most of the IOM recommendations. Unlike many others, due to the nature of the specialty, Allergy/Immunology training programs can provide all of the necessary components of a training program including an environment conducive to learning, opportunities to make decisions about patient care that are supervised and critiqued, and adequate patient exposure primarily through outpatient clinics and limited inpatient exposure. One major impact on Allergy/Immunology training programs will be the quality of residents applying for training as these programs rely on Internal Medicine and Pediatrics training programs to establish a strong foundation in general medical knowledge and development of medical judgment. Another potential impact is that resources will be diverted from Allergy/Immunology training programs to more time and resource intensive programs such as Internal Medicine and Surgery. Allergy/Immunology training programs already suffer from limited resources and institutional support as they tend to be small programs that do not generate substantial revenue and do not routinely provide life-saving medical care. Institution of the IOM recommendations will further shift the focus of training institutions to the core specialties and away from specialty training. Although it can be argued that returning to a stronger focus on primary care specialties is beneficial, as medical knowledge continues to increase exponentially the importance and role of the specialist will become even greater. At present, in many areas of the country there are insufficient numbers of practicing Allergist/Immunologists and training programs are already producing fewer trainees each year than required to maintain current numbers. Institution of the IOM recommendations would almost certainly further reduce the number of Allergist/Immunologists nationwide making identification and specialty care of complicated immune diseases more difficult, time consuming, and costly for patients.

The very existence of the IOM recommendations insinuates that medical training in this country could be improved, and this is undoubtedly true. The ACGME duty hours restrictions chipped away at the institutional inertia against change resulting in some improvements, but certainly more can be done. Unfortunately, the IOM recommendations do nothing to address real problems or further the cause of improved medical training preferring instead to focus on changes that can be made quickly despite a lack of any evidence of need or efficacy. Rather than further limiting duty hours, which is an overly simplistic approach, the focus should be on improving the efficiency of healthcare generally, which will lessen the administrative burden on trainees and all other levels of medical care, and increasing resident training opportunities. Improved efficiency can be achieved in many ways including institution of electronic medical record keeping and ordering. Systems that import lab and test data into a central database for easy inclusion in daily notes are necessary, but these systems must also alert physicians to abnormal values in real time via mobile electronic devices. Data management and ordering systems must be centralized so that a physician does not need to access several independent databases to review pathology, laboratory data, procedure or surgical results, and other medical records. These are all simple solutions that can be implemented using currently available technology and on which resources should be spent now. Clinic and inpatient hospital design can be reformed to reduce redundancy of administrative and other non-medical tasks and promote a multidisciplinary patient approach. This will improve training by reducing the administrative burden on resident and attending physicians, and improve the patient's experience and care. Finally, insurance reform is necessary improve patient care. Currently, physicians spend an inordinate amount of time pleading with insurers to allow tests and procedures that are necessary for patients. Routine medical care is often made more difficulty, and specialty care requires hours of explanation and justification. Limitations on compensation to physicians have forced a restructuring of medical billing that has significantly increased overall costs as physicians and hospitals struggle to stay in business. The end result is a system that is adversarial between patients, physicians, and insurers and that is profoundly inefficient and costly. All of these impact medical training and patient well-being far more than resident duty hours and if the IOM is serious about protecting patients, these should be the focus.

The ACGME can help direct many of these changes by making rational recommendations for changes to resident training that will have a real impact on education and patient safety. Although no data suggest that fatigued residents make mistakes that harm patients, the rationale behind the IOM recommendations is that people make more mistakes when they are tired. A more rational approach is to increase supervision rather than limit duty hours further. This would serve several functions including acting as a check on incorrect decisions made by residents (whether due to fatigue, lack of knowledge, or lack of experience) that would improve patient safety and improve resident education. This might take the form of more senior resident input or even having attending physicians, pharmacists, and other more experienced staff review important decisions regarding patient care. With increased supervision must come approaches that decrease any fear or apprehension junior residents and interns have about approaching senior residents and staff. Teaching those responsible for resident education how to teach is extremely important and is not routinely done at present. Because the attending physician will be required to take a more active role in resident education, hospitals and government funding agencies must be willing to compensate physicians for this increased responsibility. Healthcare is a national priority and resources must be devoted to improving care from the very beginning which includes resident education.

There are many aspects of medical training that can and should be improved. Spending long hours taking care of patients can be difficult, but it is a necessary part of training that does not stop after graduation from a training program. It is important that medical education prepare trainees for real world medical practice. Limiting duty hours further will do little or nothing for patient safety in the short term, and will undermine training which will make patients less safe in the long term. The IOM and ACGME should endeavor to make real changes in medical training that will actually improve education and patient safety both now and into the future rather than focus on a short-term, easy approach that will do neither.

A representative of Allergy/Immunology training programs will certainly be willing to participate in the Resident Duty Hours and the Learning Environment Congress in June 2009. I would also personally be interested in participating if chosen.

Sincerely,

Benjamin P. Soule
Clinical Fellow, Allergy and Immunology
National Institute of Allergy and Infectious Disease
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Member
Residency Review Committee for Allergy and Immunology
ACGME

This statement is submitted on behalf of Allergy and Immunology fellows in training and the content has been discussed with several other Allergy/Immunology fellows. However, the views herein have not been widely distributed and do not necessarily represent the views of the American Academy of Allergy, Asthma, and Immunology, the American College of Allergy, Asthma, and Immunology, the National Institutes of Health, Department of Health and Human Services, or other fellows in training.

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April 29, 2009

Thomas J Nasca, MD, MACP
Chief Executive Officer
Accreditation Council for Graduate Medical Education

Re: Position Paper on IOM's Proposed Resident Duty Hour Rules

Thank you for soliciting our opinion on these proposed rules. There have been many opportunities for input, including through the Organization of Program Directors. I will summarize the comments from The Association of Anesthesiology Core Program Directors Council first. Then, I will respond directly to the topics you have requested in your February 19th letter.

The teaching of the specialty of Anesthesiology has largely conformed to the ACGME's duty hour requirements from 2002. We have had an easier time doing this than several other specialties (including surgery). The major responses to the new IOM rules revolve around understanding of the reasons why further restrictions are necessary. Why 16 hours? Why 4-night consecutive maximum for in-hospital shifts? Why the increase in mandatory days off to 5 per month? Where is the evidence that this is necessary?

Additionally, we find compelling arguments that promote daily averages for work hours and time away from work rather than strict day-to-day rules (like the 10-hour rule). We base this on the fact that the best opportunities for learning are episodic and in the flow of patients as they present to our residents. Adjustment of the rules to allow a resident to commence or continue the care of a patient who demonstrates a rare but classic anesthesia dilemma without breaking a rigid daily rule supports learning. Thus, education becomes case-based rather than shift-based. This supports professionalism, encourages commitment and builds confidence within the resident. We feel strongly that education is already being compromised due to the need to strictly adhere to the 10-hour rule.

There will be an unintended effect of the new 4-night maximum of in-hospital shifts: Hospitals will hire Physician Assistants (PA) and Advanced Registered Nurse Practitioners (ARNP) to cover their clinical load. As these alternative providers are integrated into the services, residents will be displaced in the critical elements of patient care that are needed for learning, decision-making and development of mature, confident clinicians. We fear there will be a decrement in the quality of these rotations as the residents become "junior" to the added providers in experience.

We feel the "nap concept" to be unacceptable.

Topics:

- *Costs*: implementation of the IOM's rules will result in vastly higher costs of patient care and resident education. This appears especially true for the 4 night maximum in-house night shifts. Additionally, quality of care may be compromised as additional hand-offs will occur.

- *Position on current ACGME Resident Duty Hours standards*: Many departments have already incurred additional costs due to the hiring of CRNA's and Anesthesiology Assistants. Overall, we feel the Anesthesiology training programs have adapted and accepted the changes as positive developments on education. However, some improvements can be made (see comments on first page).

- *Dimensions of Resident Duty Hour standards:* We feel that the standards should be adapted to allow average minimum time off between shifts. This would allow continuity of care and learning. We do not support the addition of a minimum frequency of in-hospital night shifts.

- *Key aspects of learning:* Progressive opportunities to learn to develop decision-making and technical skills as well as core competencies with eventual readiness to enter independent clinical practice.

- *Willingness to participate, if invited to Resident Duty Hour and Learning Environment Congress to be held in June 2009 in Chicago, IL.* Yes

Thank you for your consideration.

Respectfully submitted:

Stephen M. Rupp

Stephen M. Rupp, MD
President, Association of Anesthesiology Core Program Directors
Chief, Department of Anesthesiology
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The American Board of Colon and Rectal Surgery

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April 28, 2009

Thomas J. Nasca, M.D., MACP
Chief Executive Officer
Accreditation Council for Graduate Medical Education
515 North State Street, Suite 2000
Chicago, IL 60654

Dear Dr. Nasca:

The American Board of Colon and Rectal Surgery (ABCRS) strongly endorses the position paper from the American Board of Surgery (ABS) in response to the Institute of Medicine (IOM) report on resident duty hours. Certification by the ABCRS requires certification by the ABS; consequently, all trainees in colon and rectal surgery reflect the cumulative effects of the duty hours regulations enacted by the ACGME in 2003. Observations of substantial changes in technical competency are confirmed in practice by program directors in our specialty. Increasing complexity of abdominal and anorectal operations mandates greater technical training, a situation that is accomplished with greater difficulty in many residencies. Clearly, this affects our entire specialty.

Approximately 30% of colon and rectal surgeons practice some amount of general surgery, thereby contributing to the national general surgical workforce. Due to the strains on the training of colon and rectal surgeons, we have been exploring the possibility of decreasing the amount of general surgery training for each resident and increasing the duration of colon and rectal surgery training. This would effectively remove a third of our annual graduating class from a significantly challenged specialty.

Of course, there have been non-technical educational challenges resulting from the hours restrictions as well. Some of the improvements in communications and process improvements in hand-offs with patient safety as a primary focus are positive consequences of restricted work hours. Redesigning entire educational curricula, however, would ideally involve all of the stakeholders and is a much more complex and interactive process than the proposed timetable will reasonably allow. Training surgeons has a unique set of challenges associated with it, the specifics of which must be sensibly analyzed and reformatted. No one is suggesting that the former training paradigm of 120 hours of work per week is desirable or sustainable; nevertheless, time is required for continued sensible redesign.

Thank you for the opportunity to comment.

Sincerely,

David J Schoetz, Jr.

David J. Schoetz, MD
Executive Director

DJS:ib

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A Member Board of the American Board of Medical Specialties

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A Founding Member of the American Board of Medical Specialties (ABMS)

March 17, 2009

Thomas J. Nasca, MD, MACP
Chief Executive Officer
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Chicago, IL 60654

Dear Dr. Nasca:

The American Board of Dermatology appreciates the opportunity to respond to the ACGME regarding resident duty hours. Training in dermatology begins in the PGY-2 year after completion of a PGY-1 year either in a transitional year program or another primary care specialty, typically internal medicine. Therefore we are not directly responsible for residents who take call "in house" during their PGY-1 year. However, these residents come into our programs after that experience and it is clear to us that the educational quality of a PGY-1 year has a direct impact on their preparation for our training. We are concerned that the criticisms by the IOM associated with the 80-hour work week have been based on sleep deprivation research and not the quality of medical education needed to be a specialist in medicine. Adequate sleep and high quality medical education need not be mutually exclusive. We endorse the path that maximizes both, while acknowledging the difficulty in finding it. We also feel there are PGY-1 programs that use residents for service work in an inefficient manner when other options exist. When doing so these programs compromise the medical education gained by the on-call experience in lieu of tasks that could be delegated or managed by more efficient systems.

<u>Call from Home</u>

Dermatology residents (PGY-2-4) do not take in-house call. Many programs arrange call schedules from home that may encompass an uninterrupted 7-day period of duty. With no averaging, this results in less than one day off per week. In programs with a minimum complement of residents (3), this would result in less than 5 days per month off duty. Call from home typically does not require the resident be onsite when he/she would normally be sleeping. The only other restrictions are limitations to their travel to the surrounding community or use of alcohol. In our experience we do not feel that such scheduling is burdensome or dangerous to the trainee or our patients. In most cases, this rule could be eliminated or substantially modified to increase flexibility for programs.

Moonlighting

Many programs allow moonlighting but often cannot accurately track these extra duty hours. The RRC may wish to consider a requirement whereby moonlighting hours are tracked and reported to assure compliance with the 80 hour maximum. Alternatively, if outside the scope of the program, consider whether the ACGME should relinquish oversight of a non-program activity as long as the resident fulfills his/her responsibilities of the program. For example, if the resident moonlights in a non-medical activity, such as an all night security guard, would that count towards the 80 hours? Does it matter? How much oversight is appropriate when the resident is off duty?

In general we support the current ACGME Resident Duty Hour Standards and endorse the measures it contains. Implementation of any new modifications should result in minimal to no cost to programs and should distinguish between onsite hospital work and that which is off site or not under a program's direct control. As dermatologists, we wish to emphasize that one size will not fit all and that the individual specialty RRC's should be given some leeway to interpret the rules. Thank you for soliciting our input.

Sincerely,

Thomas D. Horn

Randall K. Roenigk, MD
President

Thomas D. Horn, MD
Associate Executive Director

/mma
cc: Antoinette F. Hood, MD
Stephen B. Webster, MD

April 2009

Dear Dr. Nasca:

As an active member of the ACGME CRCR (Council of Review Committee Residents) and Resident Member of the Family Medicine RRC, I have been asked to present the position of Family Medicine residents on the IOM Report "Resident Duty Hours: Enhancing Sleep, Supervision, and Safety."

Background

After numerous discussions with resident leaders in our specialty as well as Family Medicine residents without official leadership positions, I have concluded that there is no single position on this issue that truly encompasses everyone's opinion. Our discipline by its natures encompasses an incredibly broad spectrum of residents training in diverse settings: from rural settings to urban; from university-based to community-based programs; from small to large programs; from inpatient-heavy programs to programs with more emphasis on the ambulatory setting; from "opposed" programs (in institutions with several residency programs of other specialties) to "unopposed programs" (where Family Medicine is the only specialty training at that institution); and on and on.

Current Duty Hours Standards

That being said, the general consensus among these diverse residents is to agree with the current duty hours standards. Limiting work hours is a positive concept and protecting residents from abusive work conditions is critical in preserving both resident safety and patient safety. Furthermore, as Family Physicians, we are role models for our patients. We constantly dispense advice on leading healthy lives and admonish patients for engaging in activities detrimental to their health: smoking, being sedentary, eating fatty foods, and, working too many hours without taking time to manage stress. It seems inappropriate to dispense such advice to patients but not to abide by those values ourselves. To that end, attaining a work-life balance is a desirable goal; it would be helped by limiting the number of hours that residents work. Although residents of this opinion may disagree with the methodology and even the specific conclusions drawn in the IOM report, they agree generally that living a healthy life is vital to being a physician and role model for our patients. Residents also stated that rejecting the IOM report out of hand sends an implicit message that as doctors we are unwilling to adapt to a changing society and that we prefer to uphold a paternalistic view that we know what is best for our patients, regardless of how we live our own lives.

Specifically regarding patient safety, some residents feel that there are already too many errors in resident care of patients. Taking care of ourselves by limiting work hours is a key first step in good patient care. Many residents think being more refreshed would allow them both to learn better as well as to provide better and safer patient care.

Other residents think limiting resident work hours is a good idea in general, but that the IOM recommendations take this idea to the extreme. In addition, many point out that these recommendations are not realistic to implement under the current structure. Many point out that the projected annual $1.7 billion required to implement new work schedules is funding that, even if it were available, would be far better used in many other ways, for instance, direct patient care for our indigent patients, enacting electronic medical records, or enhancing resident education.

Caution Against Haste

Regardless of their feelings about the appropriate number of hours to work, most residents caution against a hasty change in work hour regulations. Although teaching and evaluating skills in patient safety is a critically important goal of residency training, it remains unclear whether, at this particular juncture in 2009, reducing resident work hours without making other changes to graduate medical education is an appropriate method of, as the title of the IOM report claims, enhancing resident sleep, increasing trainee supervision, or even improving patient safety. Many feel strongly that an immediate change in work hour rules would be premature, as the original 2003 duty hour restrictions have neither been sufficiently studied nor have been fully complied with by all programs. It seems premature to implement even stricter regulations when the initial set of rules has not yet been evaluated.

In fact, there could be serious ripple effects of such haste. There is great concern among Family Medicine residents that rashly adopting even more limited duty hour regulations will be detrimental to many of our smaller programs. In locations where residents cover not only all patients of their Family Medicine Center, but also all inpatient services of the nearby hospital, reducing their work hours would necessitate either hiring physician extenders, using faculty to cover (both of which could be financially devastating) enacting a educationally-impoverished night float system, or, catastrophically, closing programs entirely. In this dire age of inadequate access to health care in this country, particularly access to primary care, closing Family Medicine programs would be disastrous not only for trainees, but also for their patients. We need to train more primary care physicians, not fewer. From moral, logical, and financial standpoints, primary care should be the foundation of our health care system. Even now we lack sufficient primary care physicians to provide all patients with adequate health care. Stricter work hour restrictions might not allow residents sufficient training to practice in our complex system. Worse, by expanding residency from 3 years to 4 years as a necessary outcome of fewer experience-hours per year, we may actually decrease the number of medical students choosing the field and thus decrease the number of physicians training in Family Medicine.

Additionally, the discipline of Family Medicine rests on the concept of evidence-based medicine. The method of training Family Medicine physicians (i.e., residency) should likewise be evidence-based. Clearly there needs to be a balance between allotting sufficient hours for training competent doctors and allowing trainees adequate rest and personal time. That "line in the sand" is currently arbitrarily set [at 80 hours per week, 10 hours between shifts, et al.], rather than being based in evidence. If that line ought to be shifted, determination of the correct balance should be attained scientifically. To that end, the 2003 Duty Hours ought to be fully studied before making changes.

Four Issues Regarding the Learning Environment and Patient Safety
Without studying the effects of the current work hour regulations, it is unclear that further changes to duty hours will actually have the desired effect of increasing patient safety. Many residents feel that it is imprudent to change duty hours without addressing several other issues that are directly related to patient safety: (1) supervision of residents, (2) handoffs, (3) assessment of resident competency prior to autonomy, (4) continuity of care.

(1) Regarding supervision, it seems to many residents anecdotally that errors in patient care (whether of omission or commission) occur far more frequently due to lack of supervision rather than to resident fatigue or excessive duty hours. Attending physician review of patient notes and direct supervision of procedures are two examples that can be significantly improved.

(2) Regarding handoffs, they are much like death and taxes: inevitable. Any shift – regardless of length – will eventually end in a handoff. Common sense dictates that the shorter a shift, the more handoffs in a week. Similarly, one day off each week without averaging means that weekend rounding is accomplished by two different residents – one on Saturday and one on Sunday – thereby decreasing patient continuity and increasing handoffs. Regardless of whether duty hours change or remain the same, residents absolutely must learn how to accomplish a handoff effectively (whether inpatient or outpatient) using oral communication skills, written formats, and electronic records. Faculty (who themselves were not necessarily trained in these skills when they were residents and therefore might need to learn) must teach residents these skills and then evaluate residents' ability to perform them effectively. As we move toward complex, multidisciplinary care where communication among physicians is paramount, performing effective and safe handoffs is a key critical skill of 21st century medicine. As family physicians, we have significant experience at this type of communication; we spend a great deal of time and energy coordinating care among physicians and other health care providers on a patient care team. We arrange consults and communicate with those consultants frequently, and we "cover" each other's primary care patients when the primary care physician is on an away rotation or otherwise unavailable. Becoming experts at transferring patient information is a key skill for us in the modern era and critically important for not only maintaining patient safety, but also improving efficiency of care and cost-effectiveness of care.

(3) Regarding evaluations, compromised patient safety occurs when residents perform procedures, prescribe medications, or manage illnesses that they are not competent to perform independently. Simply assuming that residents are ready to write orders, prescribe medications, perform procedures, or make medical decisions because they have logged a certain amount of time in training is not adequate; strict evaluation of residents' actual ability to perform various skills should occur before they do so

independently. Allowing only those residents who have attained competency to perform certain skills would prevent a large number of errors and dramatically improve patient safety.

(4) Finally, a core value of Family Medicine is continuity of care. Errors decrease and patient safety increases when the same physician cares for the same patient, even at various points in time and in various locations. System-wide efforts to increase continuity of care in both the ambulatory and inpatient settings would improve both resident education and patient safety.

None of these four issues is addressed adequately in the IOM report. Many Family Medicine residents feel it is impossible to address Duty Hours in isolation without making these concomitant improvements to residency education and the learning environment which would, in turn, enhance patient safety.

As a side issue, there is an objection to the infantilization of residents. Decreeing that residents need more sleep implies that doctors-in-training, who are charged with the massive responsibility of taking care of ill patients, cannot make judgments for themselves about their own ability to do their job. Furthermore, regarding external moonlighting, there were major objections to controlling residents' off-duty time. Residents found it objectionable to regulate what residents may and may not do in free time. In their off-duty time, could residents not work at Starbucks, travel, visit family or friends, or breastfeed their children at night? With mounting medical school tuition and concomitant mounting resident debt, many trainees need to work extra hours to sustain themselves and their families and to pay off enormous debt. This is particularly true in Family Medicine, where primary care reimbursement is woefully inadequate. Whereas programs and the ACGME can [and should!] dictate how residents spend their on-duty time, it is beyond their scope to stipulate how they may spend their off-hours.

Summary

In summary, most residents feel that the 2003 work hour restrictions were a positive change to graduate medical education. At this juncture, some feel we should further limit work hours, while some prefer to stay at the current limits, but most agree that though the general idea of preserving resident well-being has a positive impact on patient care, the particular conclusions drawn by the IOM should not be enacted prematurely. Premature enactment includes implementing new work hour restrictions without addressing other key issues likely to increase patient safety: increasing supervision, formalizing evaluation of competence, providing high-quality training in handoff /transition of care skills, and enhancing continuity of care.

Future Discussion

Resident leaders in Family Medicine would be willing to participate in a Resident Duty Hours and the Learning Environment Congress.

Other Recommendations

In order to counteract the lay press's recent focus on a possibly false causality drawn between resident hours and patient danger, we recommend a public relations campaign emphasizing the superb care offered by residents, the duplication and transparency associated with teaching institutions, and the commitment of residency programs across the country to the core values of comprehensive care, coordinated care, electronic record-keeping, up-to-date technologies in medical care, and high standards of patient care. If the media have managed to put the ACGME in a negative light, claiming that as a profession we cannot regulate ourselves, we must react with a positive message. If we fail to advocate for ourselves as a profession, no one will do it for us.

Conclusion

Given that the public media and the IOM have brought the issues of patient safety and resident work hours to the spotlight, we feel that the GME community ought to seize this moment in GME history and take the opportunity to improve residency training. Even if we do not agree with every detail of the IOM report and are concerned that hasty change is not warranted, we agree that the current system is not ideal. In this new century, the whole structure of residency may need to change. Perhaps residents will no longer be the main hospital workforce, "residing" in the hospital 24 hours a day, working around the clock largely without supervision. Rather, residents of the 21st century may be junior physicians who work a limited number of hours per week and engage in medical education activities the rest of the time. In the current system, residents often spend hours in the hospital (or clinic) that are not productive or educationally valuable; it would behoove both residents and their patients to re-structure residents' time to make the hours worked more educationally-rich. Rather than using residents as an inexpensive work-force, physician extenders (PA's and nurse practitioners) can be used to do some of the non-educational work currently done by residents, leaving residents the freedom to spend their [more limited] hours per week doing actual cognitive and clinical work. As adult, self-directed learners, residents can also read on their own time to increase individual medical knowledge.

So although the ACGME of its own volition may not have chosen this particular year to address duty hours, given that the issue has essentially been forced (by the public, by the press, and now by the IOM), we should take the opportunity not to make small incremental adjustments to residency schedules to fit the IOM recommendations, but instead to re-design residency entirely – for the benefit of young physicians and their patients of the future.

Thank you for your consideration of the resident perspective, and thank you for your investment in resident education today, which is ultimately an investment in patient care of tomorrow.

Deborah Erlich, MD
RRC for Family Medicine, Resident Representative
Family Medicine Resident at Cambridge Health Alliance, Massachusetts

AMERICAN SOCIETY OF HEMATOLOGY
1900 M Street, NW, Suite 200, Washington, DC 20036 ph 202.776.0544 fax 202.776.0545 e-mail ASH@hematology.org

April 30, 2009

Thomas J. Nasca, MD
Chief Executive Officer
Accreditation Council for Graduate Medical Education
515 North State Street, Suite 2000
Chicago, IL 60654

Dear Dr. Nasca,

The American Society of Hematology (ASH) appreciates this opportunity to provide input regarding the Accreditation Council for Graduate Medical Education's (ACGME) review of Resident Duty Hours and Learning Environment Standards. We are encouraged by the proposed review and would welcome the opportunity to be involved as the process moves forward.

ASH represents over 11,000 U.S. clinicians and scientists committed to the study and treatment of blood and blood-related diseases. ASH also has over 1,200 Associate Members, hematologists-in-training who are directly impacted by the policies of the ACGME. Training program directors for hematology training programs, combined hematology/oncology training programs, and hematology-related training programs (e.g. Pediatric Hematology/Oncology, transfusion medicine, and hematopathology) are represented by ASH's Committee on Training Programs.

Implementation of the 2003 ACGME regulations forced many training programs to redesign their curricula, clinical rotation structure, and approach to providing medical care to patients around the clock. Although not typically a direct problem for hematology-related fellowship programs, the implemented changes in the delivery of patient care have often led to significant indirect effects on our hematology-related training programs. In addition, compliance with these duty-hour restrictions has been quite difficult for some programs and for some specialties.

As you know, in the face of increasing concerns voiced by the public and by health-care workers, as well as increased media attention regarding patient safety and the role of fatigue and sleep deprivation, in 2007 the U.S. Congress asked the Institute of Medicine (IOM) "to evaluate current evidence on the topic and to develop strategies to optimize work schedules and other activities." The IOM report, released in December 2008, makes several recommendations that expand on the current ACGME regulations.

The ACGME's 2003 duty-hour policies and the IOM's new recommendations have created a number of significant concerns for training programs and teaching hospitals. We urge the thoughtful review and consideration of these concerns as the duty hours standards are finalized:

- The quality and relevance of the published methods and data that were reviewed have not achieved critical acceptance. There has been disagreement as to the selection, interpretation, and quality of the studies performed in an attempt to address the effects of sleep and fatigue. We urge the ACGME to ensure that any decisions about the implementation or change of duty hour regulations be based on well-designed, relevant clinical research. If these data do not exist, then we encourage the ACGME (and other stakeholders) to support the conduct of such research.

- The accumulation of requirements reduces the flexibility of the training programs to meet educational imperatives while responding to local or regional conditions. This abundance of regulations makes innovative approaches difficult, particularly for programs with a complex skill set, such as internal medicine.

- Program directors (and others) have consistently expressed concern that the current (and assumed to be modified) duty-hour regulations have been implemented without any assessment of the possible effects of these changes on the areas examined by the IOM report (impact on trainee quality of life and safety, impact on trainee workload, impact on education, and impact on patient safety). There is acknowledgment that "unintended consequences" have arisen and will continue to arise. The IOM does recommend that *flexibility be included in duty-hour policies in an attempt to minimize the negative impact that might occur as a result of duty-hour restrictions,* but it also acknowledged that it was not charged to look into the downstream effects of the recommendations. We urge the ACGME to modify current (and any future) duty hour policies to include flexibility in how these duty hour restrictions are implemented. Individual programs should be allowed to determine how best to incorporate these policies into their curriculum in order to optimize their fellows' education and well being (as well as patient safety). Every situation cannot be anticipated and codified; overly prescriptive requirements may make compliance with the spirit of the standard needlessly difficult.

  In addition to flexibility we seek stability in the ACGME standards. If changes are implemented, consider allowing at least a two year period before making additional changes; this will allow program to make changes in a thoughtful way and allow evaluation of the impact of those changes without intervening variables.

- The true financial costs of complying with the IOM's recommendations will be many orders of magnitude greater than initial estimates. Having more trainees in a program might be a solution, but doing that would require adjusting the current caps on training positions in place since 1996. The current stresses on graduate medical education and on the physician workforce can be seen as an unexpected consequence of the 1996 caps on training positions and funding provided for these trainees by the Centers for Medicare and Medicaid Services and other third-party payers. In addition, with anticipated physician workforce shortages, it is not clear whether there will be enough qualified physicians to fill these needs even if there were funding for them. We are already seeing a shift to using physician assistants and nurse practitioners in the delivery of health care in the United States without a clear understanding of the long-term implications on patient care and safety.

- As duty hour restrictions have increased, there has been a recognized increase in daily clinical responsibilities for the teaching attending physician. This is adversely affecting the professional attitudes of many of the teaching faculty and may affect retention and recruitment of academic faculty; thus contributing to the specialties' workforce problems.

- The impact of further duty hour restrictions on the education of trainees is not known. Concern has been raised that further restrictions on House Officer duty hours may necessitate some specialties' needing to extend the required length of training in order to make up for the lost clinical and educational opportunities that will occur as a result of shorter work schedules. There is already concern that 2003 standards have challenged ACGME and specialty board certification requirements. This would have obvious financial, patient care and institutional consequences and would likely provide further disincentive to trainees who are considering the pursuit of research-based careers, exactly the type of physicians who are vital to the growth of hematology–related fields (as well as to other specialties).

We are dedicated to providing excellent care for our patients and effective, high-quality training for our residents, fellows and students. The matters of patient safety and trainees' sleep and fatigue are certainly deserving of attention, as patients' well-being and trainee education are crucial elements in today's health care continuum. However, significant changes to patient care and training environments must be thought out in advance and must not happen without collaborative communication with and involvement of the many stakeholders, including program directors, trainees, and patients. Change should not consist of precipitous actions made in response to emotionally charged comments from politicians or news media. Any changes should be data-driven and must optimize trainee education and patient safety. How any mandated changes will be paid for, not just monetarily but also with human resources, must also be considered. Much needs to be taken into account before any further regulations are imposed upon trainees and their training programs.

We strongly encourage the ACGME to move cautiously and to allow appropriate time to consider all of the items of concern discussed above. This may likely require the conduct of specific surveys and other clinical research studies in order to answer specific questions about sleep and fatigue. In our opinion, it is best to make any decisions based on high quality data and not because it "sounds good."

The plan laid out in your letter of February 16, 2009 would suggest that the ACGME has taken many of these concerns into consideration. We hope you will share the substance of these deliberations and the means by which a decision was reached when weighing the "pros & cons" of possible actions. We look forward to providing collaborative contact as you formalize the process and the changes.

Please contact Karen Kayoumi, ASH Senior Manager for Training and Evaluation, at 202-552-4939 or kkayoumi@hematology.org for any additional information.

Sincerely,

Nancy Berliner

Nancy Berliner, MD
President

ASCO®
American Society of Clinical Oncology

April 28, 2009

Thomas J. Nasca, MD
Chief Executive Officer
Accreditation Council for Graduate Medical Education
515 North State Street
Chicago, Illinois 60654

Dear Dr. Nasca:

On behalf of the American Society of Clinical Oncology (ASCO), thank you for the opportunity to respond to recommendations contained in the December 2008 Institute of Medicine (IOM) Recommendations on Resident Duty Hours: Enhancing Sleep, Supervision, and Safety and the current ACGME Resident Duty Hours Standards. Our feedback pertains mainly to oncology and combined hematology and oncology fellowship programs, though we also support many of the general points previously articulated by the Alliance for Academic Internal Medicine (AAIM).

ASCO shares, without reservation, the concern and commitment to superior medical training and outstanding patient care. Representing more than 27,000 members from all oncology disciplines, including training program directors, ASCO has a long history of involvement in the education of fellows in medical oncology, hematology, radiation oncology and surgical oncology. For example, ASCO has provided nearly $14 million for more than 350 Young Investigator Awards in support of fellows' research training, conducts training sessions and provides educational aids for program directors in medical oncology and hematology to comply with ACGME requirements, and created and runs the annual Medical Oncology In-Training Exam that supports training program directors in developing benchmarks for their educational programs, among many other activities. It is with this experience and commitment in mind that we share the following comments concerning the IOM recommendations.

While we certainly share the interest of the IOM and others in improving medical training and protecting patient safety, we do not believe that the recommended changes have been sufficiently studied to suggest that these changes would lead to improved patient care. In fact, we have some concerns that the recommended changes may be detrimental to patient care. Our comments center on patient care, the oncology workforce and the financial implications.

Patient Care

ASCO fully supports recommendations that result in an improvement in patient care. However, these recommendations should be validated by evidence before being made mandatory. Specifically, requirements relating to shift length, moonlighting

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and mandatory time off have not been proven to ameliorate trainee fatigue. Furthermore, little to no data currently exists that suggest the 2003 ACGME duty hour restrictions have improved patient safety.[1] In fact, we are concerned that increasing patient "hand offs" or transitions of care risk increasing error rates and decreasing the quality of patient care. ASCO urges the ACGME to delay making the IOM recommendations mandatory until further study on these issues is undertaken.

Impact on the Oncology Workforce

In March 2007, the *Journal of Oncology Practice* published an article by Erikson et al[2] that reported the results of an ASCO survey on the supply of and demand for oncology services through the year 2010. A follow-up article stated that:

> The study found that the United States will likely face a 48% increase in demand for oncologist services by 2020 – in large part because of the expected 81% increase in cancer survivorship and the 48% increase in cancer incidence caused by the aging of the population. The anticipated 14% increase in the number of oncologists over that same time period will not meet the growing demand. Thus, there is likely to be a shortfall of 2,550 to 4,080 oncologists – roughly one fourth to one third of the 2005 supply.[3]

If the patient load of fellows decreases at a time when the demand is increasing it has the potential to exacerbate the mismatch between demand for services and availability of trained oncology professionals and overburdens an already strained workload for oncologists. We ask that ACGME take into account workforce shortage issues as decisions are made on trainee duty hours to ensure that quality of patient care is not jeopardized and fellow patient care responsibilities are not further compressed.

As a side comment, the IOM recommendations note that fellows must have faculty supervision, but whether this supervision needs to be in-house is unclear. In-house supervision seems unnecessary for physicians who are already board-certified in Internal Medicine and are fully capable of caring for medical issues that arise in the middle of the night. This requirement needs further elucidation, particularly for oncology training programs.

Financial Implications

ASCO is concerned with the financial implications of the recommendations. The current economic climate is a difficult one in which to propose adding $1.7 billion per year to the cost of medical care. While it is commendable for the IOM to suggest that various stakeholders should financially support these recommendations, until this support is formalized, ASCO will have serious concerns about the financial viability of these recommendations. Indeed, without financial support, there is the danger that new requirements may divert scarce financial resources from efforts (such as adding trainee slots) necessary to ease workforce shortages in oncology and other specialty areas. In oncology specifically, this problem will only intensify as the need for oncology services continues to increase. Obtaining financial support is therefore a major determinant to the success of these recommendations, and should be considered accordingly in these deliberations.

Feedback on Specific IOM Recommendations

In addition to these general comments, we feel that the current ACGME limit to the 80 hour work week is reasonable and should be continued in the new program requirements. We would like to provide some additional feedback on several specific IOM recommendations.

1. In-house call duties limited to no more than every third night without averaging is reasonable, and should be feasible for oncology training programs to adopt with few issues.
2. Ten-hour minimum time off between regular shifts makes it very difficult to develop rational coverage schedules. The primary reason for such a requirement is to monitor fatigue and burnout, which are best left to the individual programs to assess.
3. Limiting the frequency of night shifts to a maximum of four consecutive nights may be unnecessary. Studies from other fields where people work night shifts show that once working several nights consecutively, the error and other problem rates decrease to the same rate as day shift workers. The errors occur during the transition between day and night shifts, not the frequency of night shifts.[4]
4. An increase in mandatory time off to one day per week, or four days per month, including one 48 hour period per month, will make scheduling very difficult for both small and large programs, and it is unclear if this will achieve the intended goal of preventing burnout and fatigue.
5. An increase in moonlight restrictions will be complicated to monitor or regulate, and will add a significant burden to programs and fellows alike. Many fellows utilize moonlighting to supplement their salaries outside of their duties as a fellow. Besides the greater concern that fellow salaries are such that moonlighting is necessary for many, the issue here is prevalence of fatigue. If fatigue is not an issue, moonlighting should not be restricted.
6. Reducing the maximum shift length to 16 hours is problematic. As noted earlier in this letter, the primary concern is that it will lead to more transitions of care, which is a major source of errors. This needs to be considered very cautiously.
7. Overall, these greater limitations on work hours also may create a number of issues with professionalism of fellows:
    a. It may ask physicians to decide between doing what is right for the patient (e.g. staying too long in hospital to talk to a patient's family) versus complying with hour restrictions.
    b. Most physicians will at times willingly violate these rules to do what is best for their patient. This presents a second dilemma: whether to report their duty hour violations and get their program in

trouble or misrepresent their actual duty hours. Neither is a positive scenario.

c. Requiring strict work hour limitations does not allow for the level of flexibility and professionalism required in subspecialty training and may result in unintended consequences. For example, a fellow who is not overly busy may refuse an admission because the patient came in one minute after proscribed cut off time for admissions.

In summary, we appreciate the ACGME's invitation for comment before adopting the IOM recommendations in the 2010 Medical Oncology and Hematology/Oncology Program Requirements. As detailed in this letter, we urge further study of the benefit of these recommendations in light of their cost and their potential adverse effects on patient care and on the oncology workforce. In the interim, ASCO agrees wholeheartedly that it is critical to monitor fatigue and performance of trainees, and we are working with our program directors to achieve this goal.

Thank you for the opportunity to provide feedback on these recommendations. We look forward to continued participation in and support for efforts to increase the quality of patient care and trainee education.

Sincerely,

Richard Schilsky MD

Richard L. Schilsky, MD
President
American Society of Clinical Oncology

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[1] Volpp KG and Landrigan CP. Building Physician Work Hour Regulations from First Principles and Best Evidence. JAMA. 2008; 300(10): 1197-1199.

[2] Erikson et al. Future supply and demand for oncologists: Challenges to assuring access to oncology services. J Oncol Pract. 2007; 3(2):79-86.

[3] Future supply and demand for oncologists. J Oncol Pract. 2008 Nov; 4(6): 300-302

[4] Lamond M, Dorrian J, Burgess H, et al. Adaptation of performance during a week of simulated night work. Ergonomics. 2004 Feb 5; 47 (2): 154-165.

May 1, 2009

Thomas J. Nasca, M.D., MACP
Chief Executive Officer
Accreditation Council for Graduate Medical Education
515 North State Street
Suite 2000
Chicago, IL 60654

Dear Dr. Nasca:

I am writing in response to your request for a statement regarding resident duty hours. This response includes comments from several organizations involved in medical genetics, including the Medical Genetics RRC, the Medical Genetics Program Directors Association, the Association of Professors of Human and Medical Genetics, and the American College of Medical Genetics.

As Medical Genetics Residency programs do not require in-house call, the majority of the IOM recommendations for resident duty hours do not affect our training programs. The only recommendation that would adversely affect both our training programs and trainees is the loss of ability to average over one month to achieve one day off in seven without any duty requirements. Medical Genetics residency programs are generally small programs with a small number of residents who are called upon for consultative care. Our residents prefer to cover an entire weekend of call in addition to their weekly duties once or twice each month. This allows them to have more full weekends off without duties. This call typically occurs at home, and may not result in any calls or need to come to the hospital; hence it is rarely, if ever, onerous. This is allowable in the current system, since programs can average call over one month and ensure that residents have on average one day per week without duties. The new recommendations would require programs to have residents split weekends. This would result in the residents having fewer full weekends without duties, and, more importantly, would result in more hand-offs and adversely affect continuity of care and education. If this recommendation is adopted, we would respectfully request that there be consideration given to development of specialty-specific requirements to allow training programs with home call that is rarely, if ever, onerous, to be allowed to average over one month. The same would apply if restrictions are placed on home call in the future. Even in the larger and busier Medical Genetics Residency programs, tracking of duty hours reveals that residents rarely work more than 50 hours per week and have an average of 12 hours between duty shifts. It is therefore evident that further modifications to the current duty hour structure are not necessary to ensure adequate time off.

Although the other recommendations that concern in-house call do not affect our residents directly, they do affect both our residents and clinical faculty indirectly on the inpatient units. Medical geneticists generally function as consultants and members of patient care teams in hospitals. As with any other specialty, when asked to consult on a patient, it is imperative to speak to someone caring for the patient who "knows" the patient best and who can ensure that our recommendations are understood and enacted. This is important for both patient care and education. As a result of current duty hour restrictions, it has become increasingly difficult to find the appropriate person to speak with when consulting on a patient, although most specialists have adjusted to the current system. Adopting a system that will result in a further increase in the number of hand-offs will ultimately adversely affect both patient care and education for not only our medical genetics residents but the residents caring for the patients that we see.

Thank you very much for the opportunity to express our views on this important matter.

Sincerely,

Bruce Korf

Bruce R. Korf, M.D., Ph.D.
Chair, Medical Genetics RRC
President, American College of Medical Genetics

Mira Irons

Mira Irons, M.D.
Chair, Medical Genetics Program Directors Association

Anthony Wynshaw-Boris, M.D., Ph.D.
President, Association of Professors of Human and Medical Genetics

ACGME

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March 24, 2009

Thomas J. Nasca, MD, MACP
Chief Executive Officer
Accreditation Council for Graduate Medical Education
515 N State Street
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Chicago, IL 60654

Dear Dr. Nasca,

The Neurology Residency Review Committee (NRRC) appreciates the opportunity to provide the Accreditation Council for Graduate Medical Education (ACGME) feedback regarding the proposed changes to resident work duty hours recommended by the Institute of Medicine (IOM). The NRRC feels strongly that these recommendations, if adopted, would have serious negative consequences to neurology resident education and patient safety and endorses the letter submitted March 2, 2009 by the American Academy of Neurology (AAN) Graduate Education Subcommittee (GES) and Consortium of Neurology Program Directors (CNPD) and the American Board of Psychiatry and Neurology (ABPN) (see attached).

The NRRC is in total agreement with all the specifics stated within this letter from the AAN and ABPN. The NRRC also requests that the ACGME not adopt the IOM recommendations unless unequivocal evidence from well-designed and controlled studies in health care settings (not proxies) can prove these changes result in significant improvements in the safety of patients without sacrificing the educational integrity of residency training programs, and financial support is provided to allow for transition to a mandatory night float system.

We look forward to hearing from you. Please contact Lynne Meyer, PhD, MPH, Executive Director for the NRRC, via email at lmeyer@acgme.org or via phone at (312) 755-5006.

Sincerely,

Ronald Kanner, MD, FAAN, FACP
Chair
Neurology Residency Review Committee

Attachment (March 2, 2009 AAN letter to Dr. Nasca)

cc: John W. Engstrom, MD, NRRC Chair-Elect

Terrence L. Cascino, MD, NRRC Member
Brett Kissela, MD, NRRC Member
Patricia Crumrine, MD, NRRC Member
Robert Pascuzzi, MD, NRRC Member
Jose Carrillo, MD, NRRC Resident Member
Larry Faulkner, MD, NRRC Ex-Officio, ABPN
Catherine Rydell, NRRC Ex-Officio, AAN
Jeanne K. Heard, MD, PhD, Senior Vice President, ACGME Department of Accreditation Committees
Larry D. Sulton, PhD., NRRC Senior Executive Director
Lynne Meyer, PhD, MPH, NRRC Executive Director

SNM
Advancing Molecular Imaging and Therapy

April 14, 2009

Thomas J. Nasca, M.D., MACP
Chief Executive Officer
Accreditation Council for Graduate Medical Education
515 N. State St. Suite 2000
Chicago, IL 60654

Dear Dr. Nasca,

Nuclear Medicine is a small but exciting specialty. There are currently 56 ACGME-accredited Nuclear Medicine residency programs, all of which are located within academic institutions. Many of these programs are very small, with only one resident per year, and many have only one to three residents in the entire program. The average daily volume of nuclear medicine studies is relatively small, especially when compared to the average daily workload in a diagnostic radiology department. To address the Institute of Medicine (IOM) Report on Resident Duty Hours issued in December, 2008, the Nuclear Medicine Program Directors (NMPDs) were recently surveyed regarding two items that may have potential impact on training programs. 35 of 56 NMPDs responded to this survey, which addressed the following:

1) Would the proposed IOM recommendation of mandatory time off duty of one day (24 hours) in seven days without averaging affect your program (inclusive of day work and call duties, which are typically taken from home)?

43% reported that this would adversely impact their training program. For a Nuclear Medicine resident, call is typically taken from home for a week at a time, from Monday to Sunday. The main impact of the IOM's proposal would be that the residents would have to be assigned call from Sunday to Saturday in order to meet the requirement that a resident have 1 day off per week. If the IOM's proposal became effective, the residents would not be able to cover an entire weekend, with the associated loss in continuity of patient care. The other alternative would be to have the resident take a week day off, which would adversely affect the educational experience. A further NMPD concern was the gradual but continual erosion of a resident's learning opportunity and responsibility, some of which can only be obtained by being "on call".

2) Would the internal and external moonlighting policy affect your program? Only 8% of the respondents raised a concern on this matter.

SNM Position on the 2008 IOM Report of Resident Duty Hours:

1. Duty hours, as defined by the IOM report, are not onerous in Nuclear Medicine programs. Although one day off per week without averaging can be implemented, it would not serve to mitigate resident fatigue due to the nonexistence of extensive duty hours in Nuclear Medicine programs. Most residents work only 50-60 hours per week. This ruling would actually detract from the resident's learning environment.

The NMPDs anticipate minimal to no financial impact to implement the IOM's proposed mandatory time off ruling.

For programs such as Nuclear Medicine with non-extensive duty hours, we request that averaging of one day off in seven be allowed. This issue is germane to Nuclear Medicine.

2. With respect to the proposed monitoring of resident duty hours, there is grave concern regarding the involvement of outside regulators for this task, particularly of governmental oversight with unannounced ACGME site visits and the use of a "zero tolerance" compliance model. Implementing this would undoubtedly further encourage the underreporting of duty hours and would jeopardize a program's accreditation status of which there are only 56 in our specialty. This issue, however, is germane to all training programs.

ACGME Duty Hours Standards: The current ACGME Resident Duty Hours Standards implemented in 2003 are acceptable to the SNM.

SNM is willing to participate in a Resident Duty Hours and Learning Environment Congress in June, 2009 in Chicago. Dr. Darlene Metter will attend on behalf of SNM.

Respectfully submitted on behalf of SNM,

Michael M. Graham

Michael M. Graham, PhD, MD
President-elect, SNM
Past Chair ACGME Nuclear Medicine Residency Review Committee
Past President, SNM Academic Council

Bennett S. Greenspan, MD FACNP

Bennett S. Greenspan, MD, MS, FACNP, FACR
President, SNM Academic Council

Darlene Metter MD

Darlene F. Metter, MD, FACR
Chair, Nuclear Medicine Program Directors
Chair, ACGME Nuclear Medicine Residency Review Committee
Vice Chair, Council of Review Committees

Joanna R Fair, MD, PhD

Joanna R. Fair, MD, PhD
Resident Member, ACGME Nuclear Medicine Residency Review Committee
Member, ACGME Council of Review Committee Residents

The American Board of Nuclear Medicine

A Member Board of the American Board of Medical Specialties

February 16, 2009

Thomas J. Nasca, M.D., MACP
Chief Executive Officer
Accreditation Council for Graduate Medical Education
515 North State Street
Suite 2000
Chicago, IL 60654

Dr. Nasca:

I am responding to your letter dated 02/12/09 in which you asked the ABNM to submit a formal position paper on the Institute of Medicine (IOM) Report on Resident Duty Hours issued in December, 2008. Because the impact on nuclear medicine training will be minor, I will be brief.

For nuclear medicine, the main impact of the most recent IOM report on Report on Resident Duty Hours would be that residents who take call from home would have to be assigned call from Sunday to Saturday (instead of Monday to Sunday) in order to meet the requirement that a resident have 1 day off per week with no averaging. This change in duty hours would have minimal financial impact on residency training. Meeting the rest of the IOM's recommendations should not be a problem and should not impact training.

Because this is a minor issue for nuclear medicine, the ABNM does not plan on participating in the Resident Duty Hours and the Learning Environment Congress, to be held in June, 2009 in Chicago Illinois.

Please let me know if you have any additional questions.

Sincerely,

Henry D. Royal, M.D.

HDR/mw

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AMERICAN COLLEGE OF
OCCUPATIONAL AND
ENVIRONMENTAL MEDICINE

February 27, 2009

Thomas J. Nasca, MD
Chief Executive Officer
Accredidation Council for Graduate Medical Education
515 North State Street, Suite 2000
Chicago, IL 60654

Dear Doctor Nasca:

Thank you for your letter of February 19, 2009 requesting input from the American College of Occupational and Environmental Medicine (ACOEM) concerning Resident Duty Hours and Standards.

ACOEM has not developed independent positions on these matters as occupational medicine residents are generally not employed in the hospital setting. As a member of the American Medical Association (AMA) House of Delegates, ACOEM endorses the AMA positions in these matters and typically supports its relevant policy proposals.

Clearly these issues are critical to the future of medicine in the United States and we commend the ACGME for continuing to explore these issues through the National Congress on Resident Duty Hours. ACOEM would be willing to participate in the June 2009 Chicago meeting, at your pleasure.

Thank you again for contacting us.

Sincerely,

Barry S. Eisenberg, CAE
Executive Director

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Association of University Professors of Ophthalmology

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February 20, 2009

Thomas J. Nasca, M.D., MACP
Chief Executive Officer
Accreditation Council for Graduate Medical Education
515 North State Street
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Chicago, Illinois 60654

RE: IOM Report on Resident Duty Hours

Dear Dr. Nasca:

Thank you for your letter requesting a formal position paper to the ACGME from the Association of University Professors of Ophthalmology. Attached is a letter to the American College of Surgeons which summarizes the position of the Association of University Professors of Ophthalmology and the Residency Program Directors in Ophthalmology on this matter.

Sincerely,

Bartly J. Mondino

Bartly J. Mondino, M.D.
Executive Vice President, AUPO

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February 12, 2009

Thomas R. Russell, M.D., F.A.C.S
Executive Director
American College of Surgeons
633 N. St. Clair Street
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Dear Dr. Russell:

Thank you for your inquiry about the Institute of Medicine's (IOM) recent report entitled, "Resident Duty Hours: Enhancing Sleep, Supervision, and Safety." In response to this report, I have requested feedback from all Ophthalmology Residency Program Directors throughout the United States. I have incorporated their feedback into this letter and am responding for the Program Directors as well as the Association of University Professors of Ophthalmology (AUPO).

As you know, Ophthalmology training programs are primarily ambulatory care training programs, often with at-home call. Patient care and resident education are inherently different in this setting compared with the typical inpatient environment. Due to these factors and the nature of Ophthalmology, our specialty is rarely in violation of the current duty hours requirements and is almost never considered a field where residents are overworked and chronically fatigued. Enacting the IOM duty hour recommendations will merely reduce the trainee's availability for educational, clinical, surgical, and research experiences, while reducing the quality and continuity of patient care.

The major change of five hours of uninterrupted sleep between 10:00 pm and 8:00 am would have the most affect on our specialty; however, it is unclear whether the five hours of uninterrupted sleep would apply to an at-home-call resident. If that is the case, many programs would have to split call to give the five hour free time to each resident. This doubles the number of nights of call each resident would be obligated to take and will significantly complicate the transfer of patient care. While these changes may improve the already good quality of life of Ophthalmology residents, it may necessitate the extension or expansion of our residency training programs, requiring significant additional funding. Residents learn about a disease process by following a patient through an entire course of events. This rule would make it impossible to have residents follow-through on patient care from the previous night. In turn, this decreases the educational value of the consults and increases the potential for hand-off related errors. Most importantly, it will damage the patient-physician relationship and fracture the continuity of care.

A study done at Washington University in 2006 (Ophthalmology 2006;113:889-90) showed that, even when our residents took in-house call, they got an average of five hours per sleep a night. Interestingly, residents slept on average five hours per night on call, but on average six hours a night not on call. Perhaps the chronic sleep deprivation in this population is not a result of being on call. Ideally, further sleep studies could be undertaken to document resident sleep patterns prior to the implementation of new duty rules as the problem may be in the behavior patterns of residents during time off, not during time on.

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The second major concern is the recommendation to increase the number of days residents must have off each month from four to five, with one 48-hour period off per month. Several Ophthalmology programs allow residents to operate on Friday and see their post-operative patients on Saturday morning which requires approximately one to two hours of time. If this rule takes effect, then a different resident would have to see the one-day post-op patients or the programs would have to cancel Friday surgical days. This would seriously impact resident education and patient care.

Occasionally, programs have invited lectures or specific meetings on Saturdays to enable local ophthalmologists to participate and accommodate speakers. This could no longer occur and would diminish the resident learning experiences by not having access to these distinguished guests.

Lastly, the IOM recommendation for greater supervision of residents by "experienced" physicians is concerning. Certainly, all Ophthalmology programs have faculty available at all times for supervision as needed. It would be an inefficient use of faculty and fellows to require them to take in-house call or even to see every after hour's patient at the time of presentation, even if the problem is not emergent. If a senior resident is considered an "experienced physician" than this creates a major scheduling challenge that would probably require float rotations to account for required post-call absences. Programs do not have the resources to build float rotations, nor are they efficient use of personnel due to the low volume at night.

Other concerns raised by Ophthalmology Program Directors were that the implementation of these recommendations may drive faculty away from academic medical centers because the work load will fall to faculty physicians who are already overworked and underpaid. Finally, changes such as these do our residents a great disservice by giving them an unrealistic idea of life after residency.

While these recommendations may have good intentions in programs that are well-known for long work hours, applying them to all of medicine, particularly to Ophthalmology, which is primarily an outpatient based specialty, seems counter-productive and could have serious adverse effects on both resident education and patient care. A differentiation in duty hours should be made for inpatient based training programs versus outpatient based training programs and for home-call versus on-site or in-hospital call.

We believe that most of our Ophthalmology programs are well within the current duty hour requirements and do not feel that our residents are chronically fatigued or lack appropriate supervision, even after hours. Therefore, we would like to ask that any recommendations be defined specifically to our circumstances or allow for fine tuning of the requirements on a specialty specific basis.

Sincerely yours,

Maria M. Aaron, MD
Associate Professor of Ophthalmology
Residency Program Director
Emory University School of Medicine

MMA/T^2

American Board of Ophthalmology

Founded in 1916

Martha J. Farber, M.D., Chair
Albany, NY

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Martin Wand, M.D., Vice-Chair
Farmington, CT

April 29, 2009

Thomas J. Nasca, M.D., MACP
Chief Executive Officer
Accreditation Council for Graduate Medical Education
515 North State Street, Suite 2000
Chicago, IL 60610

Dear Dr. Nasca:

The American Board of Ophthalmology (ABOp) appreciates the opportunity to review and provide a response to the December 2008 Institute of Medicine (IOM) Report on Resident Duty Hours. As a founding member of the American Board of Medical Specialties (ABMS), the ABOp has collaborated with and supports the recommendations of the American Board of Surgery (ABS) on this issue. In addition, we have some specific comments relative to the impact of the proposed changes on training programs for Ophthalmology.

First and foremost, the proposed changes are not supported by existing data. In addition, the proposed changes do not take into account the significant differences in training programs by specialty. Surgical disciplines have unique educational and patient care challenges imposed by trauma which can occur at any time. Although some disciplines such as General Surgery, Orthopedics, Neurological Surgery and Cardiothoracic Surgery may be impacted to a greater degree than other surgical specialties.

The 80 hour work week, inclusive of moonlighting, if permitted is appropriate. However, each specialty should have the flexibility to establish guidelines within the 80 hour week as determined by the specialty specific Residency Review Committee (RRC). Some specific concerns for Ophthalmology training programs are as follows:

1. Five hour sleep required each day.
Significant learning takes place during "after hours" non-elective surgery. Such non-elective activity, by definition, cannot be scheduled. Mandating arbitrary time off would disrupt the following day's operative and clinic schedules interfering with both patient care and learning.

2. Definition of "on call."
"On call" has different meanings in different institutions depending upon clinical demand. Some programs permit taking call from home and could assign residents to call for several consecutive days. Such a call schedule would not be permitted under the proposed rules even though residents taking call at home might receive more sleep than required.

3. Sixteen hours continuous duty followed by 5 hours sleep then 9 hours transitional/educational activity.

This arbitrary rule would require that a resident on duty beginning at 8 AM would discontinue clinical activity at 12 AM, regardless of the level of activity, requiring another resident to provide coverage at midnight. This could require smaller training to hire additional physicians to provide coverage independent of the clinical need or educational value.

The purpose of a training program is to confer competence in the "real world." Emergencies and complicated medical problems requiring more than 16 consecutive hours of clinical activity occur with regularity. Continuity of care is critically important for the resolution of complex medical problems. It is mandatory that the management of complex problems be taught under supervision during training. The proposed rules artificially mandate disruption in the continuity of such care and are not in the best interest of patient safety or physician education.

In summary the American Board of Ophthalmology endorses the following recommendations:

1. Retention of the current 80 hour work week, including moonlighting activity.

2. Based upon the unique specialty demands, each RRC should determine the guidelines for clinical activity, education and rest within the 80 hour week and include this as a part of RRC oversight of training programs.

The ABOp is willing to participate, if invited, in a Resident Duty Hours and Learning Environment Congress to be held in June, 2009.

Sincerely yours,

John G. Clarkson, MD
Executive Director

AAOS
AMERICAN ACADEMY OF ORTHOPAEDIC SURGEONS
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April 16, 2009

Thomas J. Nasca, M.D., MACP
Chief Executive Officer
Accreditation Council for Graduate Medical Education.
515 North State Street, Suite 2000
Chicago, Illinois 60654

Dear. Dr. Nasca:

Thank you for your letter of February 19 to Karen L. Hackett asking the American Academy of Orthopaedic Surgeons (AAOS) to share its thoughts and concerns regarding the Institute of Medicine (IOM) Report and the Accreditation Council for Graduate Medical Education (ACGME) Resident Duty Hours Standards. The AAOS is a professional society that represents over 25,000 orthopaedic surgeons in the United States with the mission of serving our profession, championing the interests of patients and advancing the highest quality musculoskeletal health. Many of our members are not only actively involved in orthopaedic residency education, but also include all orthopaedic program directors and department chairs in the United States. The AAOS is the pre-eminent provider of musculoskeletal education to orthopaedic surgeons. In that context, we currently have 3,337 resident members and we consider providing educational programming to them to be a central part of our mission.

The issue of resident work hours has been a concern of the AAOS since our first position statement, "Limiting Resident Hours," was issued in 2003, as well as with subsequent revisions in 2008. Attached is our position statement, Limiting Resident Duty Hours. We have participated in the resident work hour debate since its inception because of the potential impact on the training of orthopaedic surgeons who will provide future orthopaedic care in the United States. In this light, we feel compelled to respond to the IOM report, "Resident Duty Hours: Enhancing Sleep Supervision and Safety." Simply stated, the AAOS feels that if the recommendations of the IOM report were adopted by the ACGME the result would be severely detrimental to the training of orthopaedic residents in the United States and ultimately to orthopaedic care. In 2003, the 80-hour work rules were adopted by the ACGME and were implemented for every residency program in this country. We believed then, as we do now, that these changes were beneficial for residents and patients. However, our "sense" that this has been a better approach has not yet been substantiated by data that support this conclusion. A systematic study of the effects of the 2003 work-hour rules has not yet been performed. In this context, upon what basis can further changes be mandated? In this era of evidence-based medicine, we need to look for evidence before changing the work hour rules again. To do so would be, at best, unscientific, and at worst, dangerous. A study of the impact of the 2003 work rules may indeed document the benefits of limiting work hours and suggest a positive alternative to the issues that were the focus of the IOM report.

Moreover, the impact of additional changes--in very practical terms--must not only be understood but should be addressed by specific plans. For example, the economic burden of the proposed changes is estimated to be $1.7 billion annually. This is an astounding additional cost given the current stress on graduate medical education funding. Where will these funds come from and at what costs to the current system? As the IOM report states, "without the necessary restructuring and resource allocation, attempts to implement the recommendations will fail to have the desired benefits and could even reduce patient safety."

The impact of reduced patient care experiences that will follow a further reduction in work hours has the potential to significantly compromise resident education. We don't yet have adequate studies showing how the reduced hours have impacted surgical and clinical experiences so cannot predict how much additional cuts would further impact patient care experiences. Assuming that these numbers are significant, any plan to reduce clinical training experience further should be accompanied by a plan to replace that experience either by increasing the duration of training or preferably by substituting techniques such as surgical simulation which have been shown to be educationally effective. However, there is a real cost to either approach which needs to be balanced objectively against and projected benefits of changing the work hours.

We have a last area of concern: We have no information about the impact of the 2003 work-hours reduction on how residents trained in the 80-hour work week system provide patient care when they complete residency training. In an effort to improve resident education during the three to seven years of training, we may indeed be compromising their approach to patient care over the next 30 years. As you know, in practice, work hours are not restricted. While we do not necessarily support this approach it is currently the norm, particularly in surgical specialties where there are significant emergency on-call responsibilities. We certainly hope the shorter work-hours proposal will not compromise future patient care, but once again we do not have sufficient information to answer this question.

There are many questions to be answered and we fully support a scientific approach that evaluates the impact of the previous changes before any additional changes are made. Any other approach would be unacceptable for our profession and our patients. We strongly urge the ACGME not to adopt any of the proposed changes contained in the Institute of Medicine report unless and until further study documents the need for change and certainly not until adequate funding mechanisms are solidly in place.

AAOS is willing and eager to participate in a Resident Duty Hours and Learning Environment Congress to be held in June 2009 in Chicago. We commend you on scheduling this Congress to continue the dialogue on this important topic. We look forward to receiving an invitation to attend.

Thank you for asking for our comments and please don't hesitate to contact us with any questions.

Sincerely,

JD Zuckerman MD

Joseph D. Zuckerman, MD
President

John J Callaghan

John J Callaghan, MD
First Vice-President

Daniel J. Berry, MD
Second Vice-President

E. Anthony Rankin, MD

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cc: Alan M. Levine, MD
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AAOS American Academy of Orthopaedic Surgeons
American Association of Orthopaedic Surgeons

Position Statement

Limiting Residents' Duty Hours

This Position Statement was developed as an educational tool based on the opinion of the authors. It is not a product of a systematic review. Readers are encouraged to consider the information presented and reach their own conclusions.

On July 1, 2003, the Accreditation Council for Graduate Medical Education (ACGME) implemented new duty standards that limit resident duty hours to a maximum of 80 hours a week as well as set other restrictions. These new standards affect all 7,800 residency programs in the United States, and those who fail to comply may face adverse action, including loss of accreditation. In addition, various states have adopted legislation or regulations that may differ from the ACGME standards.

The work environment of orthopaedic surgical residents is an area of major concern for the American Academy of Orthopaedic Surgeons (AAOS). The welfare of patients and the protection of a nurturing and effective training and educational experience for house staff are of paramount importance. Each residency program must ensure that the possible deleterious effects of resident fatigue do not compromise its educational objectives or safe and effective patient care. Studies should be encouraged and financially supported that clarify the effects of fatigue and continuity of care on resident education and safe patient management such that adjustments to duty hours and the work environment can be made in a rational and timely manner.

The American Academy of Orthopaedic Surgeons (AAOS) recognizes that residents are physicians in training and require an environment in which they achieve an education of the highest quality, while providing patients with safe and responsive care. Compliance with current ACGME duty hour standards and/or applicable state law is required.

At the completion of an orthopaedic surgical residency program, the AAOS believes that the orthopaedic resident must have acquired the knowledge and experience to care for patients with diverse musculoskeletal disorders and have developed those professional values and commitments necessary to sustain a career in orthopaedic surgery. The judgment and ability to recognize clinical patterns come from seeing and assisting in the management of a sufficient number of patients with musculoskeletal disorders. Providing residents with a thorough academic and clinical education must be balanced with the protection of residents' well being and outstanding patient care.

The Fiscal Impact on Residency Programs

Although the ACGME has reduced the number of hours residents are allowed to be on duty, the amount of work and educational activities continue to grow. The availability of specialty physician services, often provided by residents, is an issue at many hospitals, particularly in many smaller community or urban hospitals. Many hospitals are struggling to make alternative arrangements for this coverage through the use of physician extenders, competing for funds dedicated to other programs and capital expenditures. The new ACGME rules will potentially add considerable costs for academic medical centers already struggling with decreasing third party payments and reductions in government reimbursement for services. Without additional funding to hire physician extenders to fill the void created by the duty hour limitations, academic medical centers will be restricted in their ability to fulfill many of their mandates, including provision of care for the uninsured and bringing new and improved medical technology to the clinical arena.

With significant nursing shortages looming, limitations on the number of residents, and falling reimbursement rates, residents are subject to pressures to do more work in less time and with less assistance. A reduction in resident labor that is unaccompanied by a significant increase in Graduate Medical Education (GME) funding from Medicare and/or third-party payers may produce several unfortunate and unintended results, including an increase in the number of errors from a lack of continuity of care. The medical community and the federal government need to think creatively about the use of current workforce and explore other options for increasing the healthcare workforce in order to preserve safe and high quality care.

The AAOS believes that preserving continuity of care and patient safety must be achieved within the framework of an educational environment that also respects the resident's rest and quality of life.

However, without adequate and appropriate staffing and financial support, teaching institutions will not be able to successfully address their educational mission as well as their obligation to provide quality patient care.

Further there is a growing body of evidence that medical errors have not decreased significantly since the implementation of the current work hour restrictions. The AAOS believes that any further decrease in resident work-hours, similar to those in place in Europe and Canada, needs to be thoroughly evaluated in light of its potential impact on resident education and patient care.

December 2003. Revised September 2008 American Academy of Orthopaedic Surgeons

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Position Statement 1160

For additional information, contact Public Education and Media Relations Department at 847-384-4031.

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April 28, 2009

Thomas J. Nasca, MD, MACP
Chief Executive Officer
Accreditation Council for Graduate Medical Education
515 North State Street, Suite 2000
Chicago, Illinois 60654

Dear Dr. Nasca:

The American Board of Orthopaedic Surgery (ABOS) is, and has been, the recognized and accepted certifying body for the profession of orthopaedic surgery since 1934. A member board of the American Board of Medical Specialists (ABMS), the ABOS is an independent corporation whose volunteer directors are actively practicing orthopaedic surgeons elected from three sponsoring organizations, the American Orthopaedic Association (AOA), the American Academy of Orthopaedic Surgeons (AAOS) and the American Medical Association. The mission of the ABOS is to serve the American public and the medical profession by establishing educational standards for orthopaedic residents and by providing publicly accessible, ongoing evaluation of the qualifications, knowledge and skills of orthopaedic surgeons. The regulatory changes to resident work duty hours which have been proposed by the Institute of Medicine would directly and significantly impact the training of orthopaedic residents and, the resultant competence of orthopaedic surgeons trained in this new environment.

Since 1934, a number of changes in technique, organization and content have improved the orthopaedic education of trainees. Usually, these changes have been developed to address specific orthopaedic educational goals. As a result of this evolution in training, our current system reliably produces some of the world's best orthopaedic surgeons, and is highly sought by medical school graduates.

After carefully reviewing the IOM consensus committee report, "Resident Duty Hours: Enhancing Sleep, Supervision, and Safety", we agree with the committee that there are "simply too few data" to determine whether resident fatigue contributes to the occurrence or significance of medical error, and its role in patient safety. The 2003 duty hour restrictions were enacted in response to public concerns over a single high profile case, but without careful study of the inter-relationships between resident work hours, fatigue, medical error and adverse outcome. Unfortunately, our current understanding of these issues has not improved since the 2003 implementation. Unfortunately, it does not seem that any planned study of the effect was ever done. For example, it has never been determined that an increase in time away from the workplace has been used by the trainees to enhance rest or sleep. The effect of further restrictions in resident work hours, as it relates to patient safety, is unpredictable. However, there are realistic reasons to believe that these restrictions may actually increase risk to patients and have an adverse impact on surgical education. The new resident work schedules have necessarily thinned the ranks of resident physicians available to see patients. This leaves some orthopaedic teams potentially undermanned for the work that is required, particularly in our nation's trauma centers, and decreases the continuity of care, which is a crucial and somewhat fragile component of surgical education. Further, by increasing the number of patient "hand offs" that are required, work hour restrictions increase the probability that information crucial to patient care is lost, reduce the opportunity for resident-to resident supervision and teaching, and may reduce faculty oversight by increasing overall faculty workload.

Further, it is likely that additional restriction of resident duty hours would reduce resident experiences in patient evaluation, management and in surgical procedures, both in the inpatient and outpatient setting. The diminished exposures to these valuable educational opportunities will lead to a less complete and potentially less competent physician at the conclusion of traditional length training programs. Graduates of foreshortened training programs may have difficulty adjusting to the rigors of unsupervised practice at the conclusion of their residency program. While such a problem might be addressed by conversion from a system that defines training by time to a system that defines training by a specific number of experiences such a change would be dramatic and would cause disruption in the development of manpower in orthopaedic surgery. Such a radical change requires extensive study to establish the correct benchmarks prior to implementation. Change in the number of hours that residents are available to work will necessarily mean restructuring orthopaedic education. American orthopaedic surgery training programs currently produce well trained, high quality orthopaedic surgeons in a reliable manner. It seems unwise to make further substantial changes to that successful training system without adequate reason.

One unintended consequence of the 2003 resident duty hour's restriction is that it may limit residents' ability to participate in some important aspects of their education. After being on call, residents may be forced to miss a day of subspecialty education.

To our knowledge, this important unintended consequence in surgical training has not been satisfactorily addressed.

The personal characteristics required for the successful practice of different medical specialties varies. Some specialties require significant physical and emotional stamina which cannot be developed nor evaluated in an environment in which the trainee is never challenged. Modern orthopaedic residency programs allow residents to develop awareness of their personal limits, familiarity with the warning signs of excessive fatigue and to learn how to handle stress in a setting that has traditionally been protected with both resident and faculty support. If this aspect of training is removed, surgeons will have to learn these important lessons in practice on their own, with potentially damaging results. Trainees will not be able to evaluate whether they are a good fit for the rigors of an orthopaedic surgery career until completion of their training.

In addition to testing medical knowledge and surgical skill, the ABOS attempts to evaluate the candidate's character, ethics, and professionalism. The enforcement of a "shift-work" mentality by these strict duty hour regulations is antithetical to the development of physicians who place the patients' interests above their own. It sends the message that it is acceptable to "clock out" and go home when one is tired, no matter what the needs of the patient. This is incompatible with important core values of the medical profession.

In summary, we strongly recommend:

1. That the ACGME make no changes in the current resident duty hour restrictions until adequate study is performed to provide evidence that the proposed changes will improve safety of *all* patients, including those treated after the completion of residency training. This will require a careful evaluation of the effects of duty hour restrictions on physician competency.

2. That the ACGME sponsor and participate in research designed to carefully assess both the beneficial and unintended adverse consequences of the current resident duty restrictions.

3. The ACGME include active clinicians (Board certified practicing physicians), current residents and program directors in the aforementioned assessments. We believe that the panel composition is crucial to obtaining useful feedback on this issue. The inclusion of active practicing surgeons is necessary to understand the particular implications to surgical education, which are substantially different than for non-surgical specialties.

Sincerely yours,

John G. Seiler, III, MD
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Marybeth Ezaki, MD
Vice President

Harry N. Herkowitz, MD
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Randall E. Marcus, MD
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Elizabeth Eccleston

From: Debra Dooley
Sent: Friday, April 17, 2009 2:17 PM
To: Elizabeth Eccleston
Subject: FW: Opposition to Duty Hours Restriction
Follow Up Flag: Follow up
Flag Status: Red

From: Chris Donaldson, M.D. [mailto:ctdonaldson@hotmail.com]
Sent: Wednesday, April 15, 2009 1:12 PM
To: Thomas Nasca
Subject: Opposition to Duty Hours Restriction

Dr. Nasca-
As you are aware, leaders of the Orthopaedic Trauma Association (OTA) expressed their opposition to further duty hour restrictions imposed by the ACGME (The Orthopaedic Forum, *Journal of Bone and Joint Surgery*, March 2009). The OTA leadership cited "unintended and unexpected consequences" to result from additional restrictions that would: limit resident experience in patient care, increase economic burden, decrease patient safety and further stress an already critical manpower shortage in trauma centers nation-wide.

I agree with the OTA leadership's concerns with further duty hour restrictions. We, as residents and fellows trained under such restrictions, have benefitted by more balanced work-life schedules than our predecessors experienced. However, we have also dealt with the challenges such restrictions have created regarding patient safety with increased coverage and patient hand-offs, less resident-resident teaching experience as hour restrictions push residents from the hospital, and the decreased sense of accountability that "shift-work" mentality and duty-hour restrictions reinforce.

While I do not claim to have the solution, I understand that further restrictions would only worsen a flawed situation. I strongly encourage you to aggressively oppose further duty hour restrictions that are detrimental to both patient care and resident education.

Many regards,

Christopher T. Donaldson, MD
Orthopaedic Sports Medicine Fellow

Karla Wheeler

From: Melissa Dyan Lackland
Sent: Tuesday, March 24, 2009 9:46 AM
To: Karla Wheeler
Subject: FW: OTA-IOM

From: Thomas Nasca
Sent: Tuesday, March 24, 2009 9:37 AM
To: 'jbwdmd@aol.com'
Subject: RE: OTA-IOM

Dear Dr. DeTorre,

Thank you for your note. We must be of about the same age – and every third night call would be a real challenge for me, especially in as demanding a field as Orthopaedic Surgery (I am a Nephrologist, so I am familiar with middle of the night emergencies). One of the challenges for us all is the balance between meeting patient needs (which would go unmet if we worked fewer hours) and being sure that we are functioning at a proficient or higher level at all times. With the mounting physician shortage, this pressure is exacerbated. With the increasing knowledge in neurobiology, the trade-offs and need for balance is becoming more clearly identified.

This is the challenge of the practicing physician, and it is also the challenge that we have to face in training the next generation of physicians.

I will include your note in the information that the Task Force will receive.

Thanks again for your service to your patients, and the profession.

Tom Nasca

Thomas J. Nasca, MD, MACP
Chief Executive Officer
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From: jbwdmd@aol.com [mailto:jbwdmd@aol.com]
Sent: Tuesday, March 24, 2009 8:42 AM
To: Thomas Nasca
Subject: OTA-IOM

I think the OTA is totally off the mark on work hours report. I am in my 33 rd year of every third night call so I have paid my dues I believe. The neuro biologist have clearly shown the negative effects on learning and performance with fatigue. Airlines don't tolerate it and neither should we as consumers and providers. James B DeTorre MD FAOS

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March 1, 2009

Dr. Thomas Nasca, ACGME
Dr. Brian Burkey, Chair, Otolaryngology RRC
Otolaryngology RRC Members
c/o Patricia Levenberg
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Chicago, IL 60654

Dear Dr. Nasca, Dr. Burkey, and the members of the Otolaryngology RRC:

As the elected representatives of the Society of University Otolaryngologists-Otolaryngology Program Directors Organization (SUO-OPDO), we would like to respond to Dr. Nasca's recent communication, "An Open Letter to the GME Community" regarding further duty hour restrictions, and also to state our position in response to the Institute of Medicines (IOM) recent report "Resident Duty Hours: Enhancing Sleep, Supervision, and Safety."

We echo the position taken by the American College of Surgeons (ACS) in their 2008 document, "Position of the American College of Surgeons on Restrictions on Resident Work Hours presented to the Institute of Medicine Consensus Committee."

Our organization of Program Directors feel that no alteration in resident duty hours restrictions be pursued until the impact of the current duty hour restrictions on patient safety, medical education, and surgical proficiency are known and more fully understood. Furthermore, a well-designed, multi-institutional study evaluating the impact of further reduction in duty hours on resident training, medical education, and patient safety, among other issues, including defining specialty-specific outcomes measures, should be completed prior to the implementation of more duty hour restrictions. We also agree that the "cap" on GME positions funded by the Centers for Medicare and Medicaid Services be removed and that consideration be given to the exemption of PGY-5 residents from the duty hour limitations to more realistically prepare them for the transition to an competent, independent practitioner of Otolaryngology-Head and Neck Surgery who functions without real-world duty hour restrictions.

At present, there has been no publication of an evidence-based study that associates improved patient safety with restricted duty hours in surgical residents. There are also no evidence-based guidelines for optimal otolaryngology resident education to ensure that medical errors are avoided, patient safety is maximized, and teaching is effective. The Accreditation Council for Graduate Medical Education (ACGME) is still assessing the full impact of the implementation of the 2003 duty hour restrictions, and as yet, there are no peer-reviewed publications documenting improved patient safety, improved educational outcomes, or improved surgical outcomes as a result of these restrictions.

We do, however, have documentation of the adverse effects of restricted training hours published in the medical literature of Europe and the United Kingdom. The European Working Time Directive (EWTD) was initiated over a decade ago to protect clinical personnel against overwork for the benefit for patient care. As evaluated by the Association of Surgeons in Training (ASIT) at the Royal College of Surgeons (RCS) in England, the EWTD has been "severely detrimental" to surgical training, resulting in the inadequate preparation of surgical trainees. The reduction in duty hours has brought with it a reduction in index operative cases in a large study looking at surgical resident log books.[1,2] It is not unreasonable to assume that the same effect will occur in many otolaryngology programs if the IOM recommendations are implemented.

While we, too, wish to advance the goals of patient safety, reduced medical errors, and effective medical education, it would be premature, at this point in time, to proceed with further changes to duty hours without first understanding the impact of what has been wrought. As demonstrated by examples in the European literature, sometimes the result is the opposite of the intended effect. We must proceed cautiously and with full awareness of the consequences of further changes as we are training the future practitioners of Otolaryngology, practitioners who will someday care for us.

Sincerely,

Christine Franzese, M.D.
Chair, SUO-OPDO

Terry Tsue, M.D.
Vice-Chair, SUO-OPDO

Joel Goebel, M.D.
Secretary, SUO-OPDO

Anna Maria Pou, MD

Anna Pou, M.D.
Member-at-Large, SUO-OPDO

Chris McMains, M.D.
Member-at-Large, SUO-OPDO

Mark A Zacharek, MD

Mark Zacharek, M.D.
Member-at-Large, SUO-OPDO

References
1. Benes V. The European Working Time Directive and the effects on training of surgical specialists (doctors in training): a position paper of the surgical disciplines of the countries of the EU. Acta Neurochir (Wien). 2006 Nov;148 (11):1227-33
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AMERICAN ACADEMY OF
OTOLARYNGOLOGY–
HEAD AND NECK SURGERY

April 30, 2009

Thomas J. Nasca, MD, MACP
Chief Executive Officer
Accreditation Council for Graduate Medical Education
515 North State Street, Suite 200
Chicago, IL 60610

Dear Dr. Nasca,

In response to the request from ACGME for comment on the topic of the IOM report on resident duty hours and recommendations it contained, the American Academy of Otolaryngology—Head and Neck Surgery (AAO-HNS) has been in communication over the last eight weeks with the Society of University Otolaryngologists (SUO), the Association of Academic Departments of Otolaryngology (AADO), and our own leadership in academic medicine to consider the questions you posed. We have been copied on two responses to ACGME that have resulted from those discussions; one from SUO and one from AADO. These represent a consistent message of agreement with the desire for safer and more effective training programs as well as concern for some elements and potentially negative consequences of the proposed IOM recommendations.

The AAO-HNS endorses the statements and expressed concerns from SUO and AADO. We acknowledge the paucity of impact analyses or comparative studies of the effects of the current restrictions and policies on otolaryngology residency programs and believe that before further restrictions or actions are contemplated, additional study is warranted to evaluate current conditions and any measurable change from previous standards. This focus should address the differences between specialty residency training programs, since current data are not uniformly available for all programs and specialties. We are likewise concerned about the perceived increase or potential for errors due to handoffs in care that may be more severe for our specialty than errors previously due to resident fatigue. Additionally it is universally agreed that the full range of necessary training and exposure of residents to the clinical content required for comprehensive learning would be impossible with further restrictions in duty hours. Finally, we agree with the observations that the needs of specialties and their residency training programs are unique, not homogeneous. . What may be necessary for otolaryngology policy may not be appropriate for general surgery or internal medicine.

We support the recommendation that the Residency Review Committees, academic department leaders, program directors, and clinical faculty should be involved in providing direct input and implementable solutions to any continuing problems with training, patient safety, and key aspects of the learning environment.

We thank you for the opportunity to comment and look forward to more dialog. Thank you for addressing these critical issues and for soliciting the involvement of the specialty societies, training programs, and their organizations.

Sincerely,

David R. Nielsen MD

David R. Nielsen, MD
Executive Vice President and CEO

Cleveland Clinic

May 8, 2009

Thomas J. Nasca, MD, MACP
Chief Executive Officer
Accreditation Counsel for Graduate Medical Education
515 North State Street, Suite 2000
Chicago, IL 60654

RE: Invited Position Paper on the 2008 IOM Report from the Otolaryngology Residency Review Committee

Dear Dr. Nasca,

Thank you for allowing the Otolaryngology Residency Review Committee to provide input on resident duty hours and the learning environment within residency training. The Otolaryngology Residency Review Committee oversees about 120 ACGME-accredited programs and their program directors. This includes resident training programs in otolaryngology and fellowship training programs in pediatric otolaryngology and neurotology. As suggested in your letter, this response will concern the duty hour standards initiated in 2003, as well as the Institute of Medicine recommendations from December 2008. All of these responses are from an otolaryngology perspective , but they are certainly widely applicable to any surgical subspecialty training.

The current duty hour standards, initiated in 2003 by the ACGME, have clearly improved residents' quality of life, and helped create a more humane learning environment. By mandating standards, the ACGME virtually eliminated the abuse of the residents' learning environment by a small subset of programs. However, there is no data to suggest that the duty hour standards have improved patient care or systematically prevented resident errors. In otolaryngology, the duty hour standards have caused almost all programs to give up in-house call secondary to manpower considerations. This has caused residents to lose their "sense of ownership" of their patients and lessened residents' experience with acute airways which had been gained when they had been the first on the scene in an urgent situation. Duty hour standards have been met by almost all programs, and only two or three programs had applied for the 88 hour exception, and few programs in our field are ever cited for duty hours violations. There is no question however that the decreased resident work hours have increased the demand on faculty time and decreased the morale of those faculty and lessened their desire to teach, secondary to time constraints. It has also increased the use of physician extenders, such as nurse practitioners, sometimes at the expense of resident involvement in patient care.

It is in the above light that we will consider the recent Institute of Medicine recommendations concerning the resident learning environment. Many of these recommendations are reasonable, including providing safe transportation for residents, providing support for non-educational activities such as drawing blood, providing enhanced supervision and training for safety reporting and handoffs, providing increased GME funding for the above activities, minimizing moonlighting, as well as providing support for data collection and review of resident work hours and errors.

However, the specific IOM recommendations concerning work hour restrictions are significantly worrisome, and threaten the integrity of otolaryngology residency training. Specifically, the sixteen hour work rules will create the need to schedule resident work shifts in order to meet the regulations. Such changes will invariably create a shift work mentality, and fragment the resident experience in patient care. This will jeopardize the core surgical principles of patient ownership and continuity of care. The number of handoffs of patient care by the residents will invariably and significantly increase, and this itself will decrease the quality of patient care. Resident work hours will move from the most educational daytime activities to more work-related nighttime activities. Resident operative experience and volumes will significantly decrease, robbing the American medical system of highly skilled physicians in the long term. Further, the eighty hour limit is certainly acceptable for junior level residents, but such work hour restrictions may not be appropriate for those senior residents needing to begin the transition into independent practice in academic centers and in the community. While we understand that the sleep data is driving this, the sleep data does not take into account the unique surgical training models which are present across America. These models are of graduated training, with multiple layers of supervision and oversight by more senior residents, chief residents, and attendings. Such oversight will allow residents who are somewhat fatigued to provide care in a safe environment.

The IOM's recommendation for shared oversight of duty hours compliance by the ACGME and other organizations is also particularly worrisome. The presence of outside interests, other than the ACGME, will destroy the traditional and very functional model of professional self-regulation that has been employed by medicine, and allowed our patient care and education system to flourish in the past century.

We would recommend continued ACGME oversight of duty hour standards, with input from the Residency Review Committee and the local institutions into finding new methods of enhancing adherence to the duty hour standards currently in place. We would recommend the continuance of the eighty hour standard, with increasing requirements for adherence and increasing penalties for non-adherence. We would suggest the application of additional resources for applying the key concepts of adult learning to residency training programs, along with the use of novel models such as surgical simulators to allow for increased educational deficiency within the current time limits. The use of the electronic medical record and information technology should also be supported to facilitate safer patient care while advancing resident education in a more time efficient manner. We recommend the use of pilot projects and the collection of data on such projects to forge new educational paradigms to provide residents with increasingly complex concepts and techniques without incurring increased fatigue. Finally, we would recommend that residents be taught the concepts of professionalism, including the recognition of signs of fatigue, such that they can remove themselves from patient care appropriately when stretched beyond their limits.

In summary, there is little data to support the success of the current duty hours regulations and essentially no data to support the current recommendations from the Institute of Medicine. The application of these recent IOM recommendations would significantly damage resident training, and unintentionally hurt patient care. As well, the new recommendations would decrease the volume of adequately trained surgeons in the future, and thus harm patient care not only in the present but even more dramatically in the future. The burdens on smaller hospitals by the new recommendations may cause the closure of many programs, further decreasing patients' access to quality healthcare. Rather than creating a "one size fits all" model, the medical educational community will eventually need duty hour regulations that are flexible and fit the needs of resident education and safety as well as ensure safe patient care. The creation of such models will only be possible with further study, such as pilot programs with data collection, and the enhanced participation of the individual residency review committees, local institutions, and the ACGME. I appreciate the opportunity to formally reply and look forward to the continued discussion of the resident learning environment in the future.

Respectfully yours,

Brian Burkey, MD, FACS
Chair, Otolaryngology Residency Review Committee
Section Head, Section of Head & Neck Surgery and Oncology
Head and Neck Institute
Cleveland Clinic Foundation – Cleveland, OH

CC: Patricia Levenberg
Executive Director, Otolaryngology RRC
515 North State Street, Suite 2000
Chicago, IL 60654

The American Board of Pediatrics

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April 17, 2009

Thomas J. Nasca, MD
Chief Executive Officer
Accreditation Council for Graduate Medical Education
515 North State Street, Suite 2000
Chicago, IL 60654

Dear Tom:

Thank you for your letter of February 12, 2009, requesting a formal position paper on Resident Duty Hours. The American Board of Pediatrics (ABP) sets standards for its certification in general pediatrics and the pediatric medical subspecialties. We do not anticipate that the Board in any way will alter its standards required for eligibility for certification. The recent IOM report may or may not have implications for training programs and the ability of trainees within these programs to meet the competency standards set by our Board. Program Directors will be expected to continue to verify the same competencies as previously required by the ABP. As of now we feel there is no way to predict the impact of the IOM recommendations. Given the greater ability we currently have to assess training outcomes, we trust that we will quickly learn whether satisfactory adaptations are occurring. We believe that it is essential that the effect of the proposed changes on the requisite competencies and on patient care be evaluated as fully as possible.

Beyond the above, our Board has taken no position on the recent IOM recommendations. There are many aspects to the pros and cons related to these recommendations which can only be fully evaluated by careful prospective analysis of training outcomes. We certainly are willing and interested in participating in the Congress being planned for June 2009.

Sincerely,

James A Stockman III MD
President and Chief Executive Officer
American Board of Pediatrics
President and Chief Executive Officer
American Board of Pediatrics Foundation

ASSOCIATION OF MEDICAL SCHOOL PEDIATRIC DEPARTMENT CHAIRS, INC.

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April 28, 2009

Thomas J. Nasca, MD, MACP
Chief Executive Officer
Accreditation Council for Graduate Medical Education
515 North State Street, Suite 2000
Chicago, IL 60654

Dear Dr. Nasca:

At the annual meeting of the Association of Medical School Pediatric Department Chairs (AMSPDC) held in Savannah, Georgia March 6-9 of this year, the recommendations of the Institute of Medicine's subcommittee (Committee on Optimizing Graduate Medical Trainee (Resident) Hours and Work Schedule to Improve Patient Safety) on adjustments to ACGME duty-hour limits were discussed. The discussion occurred during the plenary session and included presentations by a panel of pediatric chairpersons followed by a robust discussion by chairs and other invited guests in the audience. At the conclusion of the session, a subcommittee was instructed to develop an official response to the proposed work rule changes on behalf of our Association and to submit this document to the Executive Committee of AMSPDC for endorsement as the official position of AMSPDC. The following comments are based on this action and represent the views of the AMSPDC membership:

The membership of AMSPDC believes that patient safety must be the most important and over-riding issue for all educational training programs. However, pediatric chairs expressed concern that patient safety after the implementation of the 2003 ACGME Duty-Hour Limits had not been studied adequately although it was acknowledged that data from industry as well as the medical profession (NEJM 351, 1829, 2004) supports limiting the number of consecutive hours a person is on duty. The Chairs believe that other elements of the 2003 ACGME Rules may actually be detrimental to patient safety. In addition, there are no data suggesting that resident education is improved and there is legitimate concern and some evidence that it may be negatively impacted in both the short and long term for trainees. Points of concern about the recommended modifications to the resident work rules were:

1) Limitation of work hours requires more frequent transfer of patient responsibility and hand offs to cross-covering residents which has been associated with an increase in preventable adverse events (Ann Int Med 121,886, 1994), We believe that the new recommendations by increasing the number and frequency of transfers of patient responsibility and the patient hand-offs, a process which is often flawed, particularly when attempting to pass responsibility for very sick and complex patients, may result in a reduction in patient safety and quality of care.

2) The frequent changes in resident responsibility undermine the development in the resident physician of the concept of a medical home with a responsible physician and may result in fragmentation of care and lack of continuity. If a "shift work" mentality develops as a result of the frequent changes in responsible physician, it will hamper the development of the concept of a medical home, and may make it difficult to encourage pediatricians to practice in rural communities where such work habits would be untenable.

3) The practice of resident rotations which are solely night duties as a result of the duty hour requirements limits the exposure to attending physicians for a number of programs that do not at present provide 24/7 attending coverage on in-patient services, thus limiting the educational opportunities for the resident.

Academic pediatric chairs strongly support a safe and supervised educational environment for residents and believe we can no longer allow resident educational experiences to be dictated by service needs. When the need to provide an educational experience to better train a future pediatrician (e.g. in mental health services, community pediatrics, etc) does not align with an inpatient service requirement, there must be an effort to separate education and service and only allow them to overlap when the missions are congruent. Yet this has not been the case in programs requiring more residents to staff inpatient services so as to adhere to duty hour requirements rather than provide these residents with the time to enhance their knowledge, skills, and professional competencies in other non-inpatient rotations. The cost of doing this is currently prohibitive, and will require us to change the models by which resident education is funded and structured. Further as clearly noted in the report of 2 December, there will be additional costs required to continue the level of patient care currently being provided if trainees are being asked to focus on educational needs that will uncouple them from being the major inpatient workforce.

The members of AMSPDC had unanimous concern about the source and amount of funding that would be required to replace resident providers under the new work hour recommendations. They also expressed concern for the potential loss of financial support by hospitals for resident education if we separated the service component from the educational experience. Given the fact that we are anticipating a significant shortage of physicians including pediatricians in this country in the next 20 years, anything, which might result in a reduction in funding for resident education, would have a very negative impact on our attempt to address this short fall.

We fear a future in which training programs cut back their numbers or eliminate their programs altogether because hospital administrators feel they are no longer cost-effective compared to the hiring of efficient mid-level providers to meet primary, secondary and tertiary care needs. What advantage a hospital system may gain in efficiency by not having to deal with the costs of residency duty hours and filling the gap of the uncovered hours would result in an overall loss to our health system by the reduction in pediatricians produced by these programs. This reduction in workforce would eventually most affect patients in areas that are underserved or with limited access to care, resulting in higher childhood morbidity and mortality due to lack of readily available pediatricians or pediatric subspecialists.

Lastly it was pointed out that we are in the process of exploring the composition of our current pediatric residency training components and expect them to be altered substantially as we attempt to better prepare our residents to provide care in the current and future environment. Meeting the new morbidities of the children of the twenty-first century would be further hampered if these training components were further compromised by duty hour restrictions preventing these important training innovations from being fiscally feasible and in turns resulting in pediatricians less well trained to deal with these morbidities.

The AMSPDC membership respects the concerns expressed by the IOM committee authoring the report but believes that the changes in the 2003 ACGME Duty-Hour Limits proposed by the IOM should not be implemented unless there are data which demonstrate that such changes would result in improved care and safety of pediatric patients. We further believe that the current models for resident education should be studied and evaluated and changes recommended based on data supporting an improvement in the quality and safety of patient care and enhanced education for the residents. At the same time, there needs to be discussion of how resident education can be funded if there is a new paradigm and how and with whom we can replace the service hours lost in a new model in ways that will not result in a further reduction in the pediatrician workforce necessary to meet the needs of children and their families.

We would be very pleased to discuss any of the issues we raise in this letter with you.

Sincerely yours,

Bonita Stanton

Bonita Stanton, MD
President, AMSPDC

cc. Gail McGuinness, MD, American Board of Pediatrics
Theodore Sectish, MD, FOPO
James Stockman, MD, ABP
Errol Alden, MD, AAP
Darrell G. Kirch, MD, AAMC
Lawrence McAndrews, NACHRI
Susan Guralnick, MD, APPD
Elena Fuentes-Afflick, MD, SPR
George Lister, MD, APS
Tina L. Cheng, MD, APA

AMERICAN BOARD OF
PHYSICAL MEDICINE AND
REHABILITATION

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April 28, 2009

Thomas J Nasca MD
Chief Executive Officer
ACGME
515 N State St Ste 2000
Chicago IL 60654-4322

Dear Dr Nasca:

Thank you for the opportunity to present the views of the American Board of Physical Medicine and Rehabilitation (ABPMR) on the current ACGME Resident Duty Hour Standards and the recommendations of the IOM Report on Resident Duty Hours issued in December 2008.

The attached table represents the perspective of the ABPMR. Thank you for allowing us to respond.

Sincerely,

Anthony M Tarvestad JD
Executive Director, ABPMR

cc: Dennis J Matthews MD, Chairman ABPMR

Attachment

AMT/sks

ACGME and IOM Duty Hours and ABPMR Position

	2003 ACGME Duty Hour Limits	ABPMR position	IOM recommendation	ABPMR Position
Maximum hours of work per week	80 hours, averaged over 4 weeks	Support	No change	
Maximum shift length	30 hours (admitting patients up to 24 hours, then 6 additional hours for transitional and educational activities)	Support	30 hours (admitting patients for up to 16 hours, plus 5-hour protected sleep period between 10 pm and 8 am with the remaining hours for transition and educational activities) 16 hours with no protected sleep period	This needs to be adjusted by specialty. The type of work done should be differentiated from work itself. Fatigue is a product of intensity as well as duration. In PM&R, patients are admitted during day-time work hours. Patients are not admitted in the middle of the night. Those residents on in-house night call are there to take care of patient issues that come up on the patients already there. The need for a five-hour nap is not based in science, and does not seem critical for PM&R because the night time duties are less demanding than for specialties that take admissions through the night. In fact, some residents may sleep through the night in house with no interruptions; yet it is impractical for the program to implement home call. For some programs it is more practical to have the residents sleep in house. In PM&R, a resident on in-house call would rarely work 16 continuous hours with no break. If a resident arrives at work at 8 am and has admissions until 5 or 6 pm, and then is in-house to care for existing patients, it is likely they will have time to rest. Smaller PM&R programs would be unable to supply two residents to be on call in each hospital each night. In-house call in PM&R is a service activity more than an educational one. To double the number of residents on call at night increases service at the expense of education.
Maximum in hospital on call frequency	Every third night on average	Support	Every third night no averaging	This standard needs to be adjusted by specialty. PM&R in house call is not as demanding as that of med/surg services. Some residents may choose to change call to allow more time off for a job interview, attend a meeting, or to schedule vacation. Taking call every other night twice a month is different than taking call Q2 or Q3 or Q4.

	2003 ACGME Duty Hour Limits	ABPMR position	IOM recommendation	ABPMR Position
Minimum time off between scheduled shifts	10 hours after shift length	Support	10 hours after day shift 12 hours after night shift 14 hours after any extended duty period of 30 hours and not return until 6 am of next day	Few if any PM&R programs have night shifts or night float.
Maximum frequency of in hospital night shifts	Not addressed		4 nights maximum; 48 hours after 3 or 4 nights of consecutive duty	If a program has residents taking in house night call for several days in a row, e.g., Monday through Thursday, the resident would need to be excused on Friday. PM&R is really a five day a week program with clinics and admissions Monday through Friday. Residents would be losing educational experiences. If the demands of in-house call are not significant, it means more hand-offs to distribute the call among more residents.
Mandatory time off duty	4 days per month 1 day (24 hours) off per week, averaged over 4 weeks	Support the averaging over 4 weeks.	5 days off per month 1 day off (24 hours) per week, no averaging One 48 hour period off per month	Support five days off per month and one 48 hour period per month. Disagree with need for one day off per week, especially in programs with home call. Many PM&R programs have call from home. In these programs one resident is on call over both days of the weekend. This reduces hand-offs and is safer for patients, rather than having a new resident take call on Sundays. The workload of this resident might be five 10-hour days from Monday through Friday, 3-6 hours of rounding on Saturday and in some programs Sunday, with night call from home. Night call from home is of varying duration by program, ranging from 2- 7 days at a time depending on workload. In such circumstances, the resident can work 12 days in a row, without compromising patient safety or jeopardizing their education. An acceptable change: one day off in seven averaged over two weeks. Faculty work five days per week, then take call over a whole weekend and come back to work for five more days. Having a different expectation for residents does not enhance training in professionalism; it puts the residents' needs ahead of the patients.

	2003 ACGME Duty Hour Limits	ABPMR position	IOM recommendation	ABPMR Position
Moonlighting	Internal moonlighting is counted against 80 hour weekly limit		Internal and external moonlighting is counted against 80 hour weekly limit All other duty hour limits apply to moonlighting in combination with scheduled work	External moonlighting needs to be defined. Is it just paid activity as a physician? We do support adding this to duty hours. But why might this have more impact on fatigue than other activities such as child care, extra-curricular activities or volunteerism?
Limit on hours for exceptions	88 hours for select programs with a sound educational rationale	Not in favor of any exceptions in PM&R programs	No change	
Emergency room limits	12 hour shift limit, at least an equivalent period of time off between shifts 60 hour work week with additional 12 hours for education	Does not apply	No change	

aaPM&R
American Academy of
Physical Medicine and Rehabilitation

Association of Academic Physiatrists

April 30, 2009

Thomas J. Nasca, M.D. MACP
Chief Executive Officer
Accreditation Council for Graduate Medical Education
515 North State Street, Suite 2000
Chicago, Illinois 60654

RE: Response to ACGME regarding Institute of Medicine Work Hour Recommendations

Dear Dr. Nasca:

We are delighted to be given the opportunity to respond to the ACGME with our comments regarding the new duty hours recommendations by the Institute of Medicine (IOM). This position paper represents the response from several of our national organizations representing the field of Physical Medicine and Rehabilitation. These organizations are committed to the principles of patient safety, excellence in education, and management of fatigue in residents during training. This response was prepared by representatives from the Association of Academic Physiatry (AAP) and the American Academy of Physical Medicine and Rehabilitation (AAPM&R), and included input from the Resident Physician Councils of both organizations, as well as the Residency and Fellowship Program Directors Council of the AAP.

Members of the field of PM&R are fully supportive of the ACGME Duty Hours Regulations, and the principles of patient safety and an optimized learning environment that they endorse. However, as pointed out in the IOM report, the data regarding effectiveness and safety of these interventions is not clear. We strongly believe that further study of the duty hours regulations should be undertaken, with an extensive analysis of the cost of implementation of the IOM Recommendations, before any other changes are made. The following table depicts specific issues pertaining to these changes.

	2003 ACGME Duty Hour Limits	PM&R Position	IOM Recommendation	Our Comments
Maximum hours of work per week	80 hours, averaged over 4 weeks	Support	No change	This is not typically an issue in our field, but should be monitored as currently done.
Maximum shift length	30 hours (admitting patients up to 24 hours, then 6 additional hours for transitional and educational activities)	Support in part; need to clarify nature of time on call.	30 hours (admitting patients for up to 16 hours, plus 5-hour protected sleep period between 10 pm and 8 am with the remaining hours for transition and educational activities) 16 hours with no protected sleep period	Needs to be adjusted based on specialty. Call for PM&R is not typically for admissions, but for providing coverage for inpatients only. A more comprehensive definition of "work" would be useful. For PM&R staying in house but not being called the entire night is clearly different from specialties where one may be called frequently. The IOM recommendation may be difficult for small programs, as it would require two residents every 24 hours to be on-call/work, thus limiting their educational experiences. This may not be possible, and may be extra resource intensive. Call is a service requirement; the more residents doing call, the less education those residents are receiving. "Night float" as a solution tends to be completely non-educational, thus exacerbating this issue.
Maximum in hospital on call frequency	Every third night on average	Oppose, should allow exceptions based on need.	Every third night no averaging	May be difficult to enforce in small programs. The ability to average may or may not be important, depending on the overall numbers of call nights per month, thus taking every other night call twice a month is different than a q2/q4 for the entire month. The impact of this on educational activities or continuity of care is less clear. May be that every other call is too fatiguing and it may be necessary to limit other night to more than 10 hours off; should be studied further.
Minimum time off between scheduled shifts	10 hours after shift length	Support	10 hours after day shift 12 hours after night shift 14 hours after any extended duty period of 30 hours and not return until 6 am of next day	Find recommendation reasonable.

Maximum frequency of in hospital night shifts	Not addressed	No specific comment.	4 nights maximum; 48 hours after 3 or 4 nights of consecutive duty	Support in part, with added flexibility
Mandatory time off duty	4 days per month 1 day (24 hours) off per week, averaged over 4 weeks	Support in part, with added flexibility	5 days off per month 1 day off (24 hours) per week, no averaging; One 48 hour period off per month	May be difficult to enforce in small programs. A suggested possibility is one day off per 7 averaged over 2 weeks, to allow for some flexibility, then the resident can have one weekend off in exchange for one weekend of work.
Moon-lighting	Internal moonlighting is counted against 80 hour weekly limit	Support	Internal and external moonlighting is counted against 80 hour weekly limit All other duty hour limits apply to moonlighting in combination with scheduled work	Comments on Moonlighting were received by attendings only. The consensus was that internal and external moonlighting should be further defined; any time where a resident is caring for patients should be regulated (regardless of site). However, some program directors thought that "external" moonlighting included volunteer activities or even child-care duties. It would not be practical (nor possible) to regulate all non-work activities that are not medically-related. Program directors should ensure residents are able to care for patients in all spheres, but especially during time at residency sites. The issue of regulating resident health (with regard to fatigue) and mental state transcends any work hours monitoring, and is one of the roles program directors serve in the best interest of those they mentor/supervise. Most residents do not moonlight, which may be why this issue was not raised by them.
Limit on hours for exceptions	88 hours for select programs with a sound educational rationale	Support	No change	
Emergency room limits	12 hour shift limit, at least an equivalent period of time off between shifts 60 hour work week with additional 12 hours for education	Not applicable for our field.	No change	Not applicable for our field.

Additional PM&R Residency Program and Fellowship Directors Response to the IOM Recommendations

The widespread concern centered on the reduction in professionalism due to the regulation of the work environment that de-emphasizes the importance of patient care. The most profound comments on this were received from residents, such as, "We are seeing a trend in the up and coming generations of laziness and unprofessionalism. Further reductions in work hours would discredit resident physicians altogether and would arguably make the transition from resident and attending switch from challenging to catastrophic." Other comments were: residency will need to be extended to achieve the same amount of training; the real work environment as an attending does not allow for limited work hours, excuses, and limitations on patients seen; if we are to make a difference in our healthcare system, we need to be portrayed as vital employees with viable work ethics; let's not forget what the residency period is: training to become an attending.

In general, residents were more disturbed about loss of patient continuity (issues with multiple hand-offs) and educational experiences. Moreover, mandatory and strict rules make scheduling (and its flexibility) more difficult. Some residents as indicated in the above quote raised concerns about transitioning from Resident to Attending being more difficult if residents are "too protected." It was pointed out that one of the roles of a resident is to learn (by reading) and this need gets less as one gets more experienced. Time for study is an important part of training and should be incorporated in the recommendations.

Attendings were more concerned about logistics of scheduling and covering clinical duties, as well as continuity of care. Some expressed concerns about the erosion of professionalism, but this was not an overwhelming concern of all, possibly because their perception is that the problem has not yet become too precipitous. They felt that without minimizing duty hours as an issue, the tasks involved should be differentiated from work itself. The fatigue issues relate primarily to work duration and intensity, and it would be ideal to have flexibility based on fatigue level. Some concerns were raised about who should be allowed to regulate physician's hours; the residents must be protected and could be vulnerable to too much service with no ability to protect themselves. They also expressed that they don't want government to take over all aspects of patient care.

Overall, we are pleased to have been given the opportunity to respond to the ACGME on this issue. Our organizations would be willing to send delegates to participate in a Resident Duty Hours and the Learning Environment Congress in June 2009.

Respectfully submitted by;

Susan Garstang, MD and John C. King, MD; Association of Academic Physiatrists
William Micheo, President; American Academy of Physical Medicine and Rehabilitation

ABPM®

The American Board of Preventive Medicine, Inc.®

A Member Board of The American Board of Medical Specialties

April 24, 2009

Thomas J. Nasca, M.D.
Chief Executive Officer
Accreditation Council for Graduate Medical Education
515 North State Street
Suite 2000
Chicago, IL 60654

Dear Dr. Nasca:

Thank you for the opportunity to present the views of the American Board of Preventive Medicine (ABPM) to the ACGME on the current ACGME Resident Duty Hour Standards and the recommendations of the IOM Report on Resident Duty Hours issued in December 2008. We will address each of the 5 points on which you requested our formal position.

1. *Your organization's formal position on the recommendations contained in the Institute of Medicine Report, including impact analysis, from your organization's perspective, on costs and impact of implementation.*

Residency training in Preventive Medicine occurs in a variety of settings, including rotations in managerial, administrative, and health department settings where almost all activities are carried out in the ordinary workday. Our clinical rotations are also carried out almost entirely in ambulatory settings. When we do inpatient work and training, it is almost always consultative in nature. As such we conclude that the impact of the IOM report on Preventive Medicine training would be negligible in terms of cost or impact of implementation.

2. *Your organization's formal position on the current ACGME Resident Duty Hours Standards including impact analysis, from your organization's perspective, on costs and impact of implementation.*

The ABPM supports the current ACGME Resident Duty Hours Standards. These standards have had virtually no adverse impact on Preventive Medicine residency training. To our knowledge, Preventive Medicine residencies have incurred essentially no violations of duty hours. The few apparent violations coming from resident surveys all turned out to be due to misunderstandings of the questions in the survey instrument. We have identified no adverse impact on costs or implementation of the current standards.

3. *Your organization's formal recommendations regarding dimensions of Resident Duty Hours standards, and justification (wherever possible) for this position with evidence.*

The ABPM supports statement in the letter to you from the ABMS concerning the dimensions of Resident Duty Hours standards:

- Count internal and external moonlighting against 80-hour weekly limit (However, we feel that external moonlighting is difficult to monitor and it is likely that many programs will respond by forbidding external moonlighting which may impact the workforce.)

4. *Your organization's formal recommendations regarding standards governing key aspects of the Learning Environment, and justification (wherever possible) for this position with evidence.*

The ABPM supports the points in the letter to you from the ABMS concerning the Learning Environment. These points are restated below:

- ACGME should ensure that programs provide timely, adequate, direct, onsite supervision for residents (We believe the supervision should be of high quality and provide timely feedback to the resident.)
- ACGME and residency programs should ensure the strength of their monitoring practices (We feel ACGME is the appropriate organization to monitor these practices, as they were established to do this and they have knowledge and experience with the residency programs. We do not feel that the Centers for Medicare and Medicaid Services or The Joint Commission are appropriate agencies to monitor or take an active oversight role.)
- Teaching hospitals should design, implement and institutionalize structured handover processes to ensure continuity of care and patient safety
- Graduate medical education – sponsoring institutions should fully involve residents in their safety reporting, learning and quality improvement systems, and this should become an important part of the resident's educational experience.

5. *Your organization's willingness to participate, if invited, in a Resident Duty Hours and the Learning Environment Congress, to be held in June, 2009 in Chicago Illinois.*

The ABPM would be very willing and interested in participating in a Resident Duty Hours and Learning Environment Congress. We believe that our specialty deals with directly relevant issues of fatigue, shift worker circadian rhythm, and prolonged aviation sorties through our expertise in Occupational Medicine and Aerospace Medicine. We would welcome the opportunity to share our expertise in these areas as part of this Congress.

We thank the ACGME for the opportunity to present our views on this important topic.

Sincerely,

James M. Vanderploeg M.D.

James M. Vanderploeg, MD, MPH
Executive Director
American Board of Preventive Medicine

Victor Reus, M.D.
Chair, Psychiatry RRC

Dear Victor:

The purpose of this letter is to provide you and the members of the Residency Review Committee in Psychiatry with input from the AADPRT membership, and recommendations from our organization's leadership, regarding the Institute of Medicine's recent report, "Resident Duty Hours: Enhancing Sleep, Supervision, and Safety." AADPRT supports evidence-based changes that would enhance patient safety, resident education, and resident well-being. We also recognize the need for the ACGME to be rapidly responsive to the issues and recommendations articulated in the IOM report.

In January, we surveyed our membership regarding the IOM recommendations. Our survey results highlight the widely variable effects that implementing the recommendations would have on psychiatry residency programs. Some changes, such as increased attention to the quality of patient care handovers, have broad support and could be readily implemented. Other changes could well have deleterious effects in many of our programs. Accordingly, we strongly recommend that the ACGME carefully study the impact of the proposed changes on selected, representative residency programs and partner with other organizations to ensure adequate funding, before putting into place specific, detailed program and institutional requirements. We also recommend maintaining as much flexibility as possible so that individual programs can accomplish over-riding goals in ways that best fit local circumstances and clinical care systems.

The Survey

In mid-January, we developed a survey which we sent to our membership, together with summary documents from the IOM report. With a one week turnaround time, we received responses from 109 of our members. Our survey was divided into four sections based upon the areas of recommendations in the report, as follows: 1. Duty Hours and Moonlighting, 2. Workload Adjustment, 3. Enhancing Supervision, and 4. Improving Handovers. This summary will be divided into these same sections as well.

Section 1. Duty Hours and Moonlighting

As shown in the attached summary of our survey results, only a minority of our members think that the recommended duty hour and moonlighting restrictions would improve the quality of patient care (25%) or improve resident education (24.1%) Most respondents (51.9%) think that they would improve resident health and well-being.

We asked our members to comment about which of the recommended changes would be most difficult to implement, which would be easiest, and what they see as the likely costs and benefits of these changes. We learned the following:

- While some of our respondents currently have relatively little resident on call in their programs and think that all of the recommended changes would be easy to implement, a substantial number of our respondents are concerned about implementing the new moonlighting requirements.
- Many of our respondents note that it would be particularly difficult to implement the new requirement limiting patient care to 16 consecutive hours, the requirement for mandated sleep for 5 hours thereafter, and the limitation of night float to four, rather than five, consecutive nights.
- The easiest requirements to implement would be the requirements regarding every third night on call and 48 consecutive hours off at least once monthly. There is varying opinion about how easy it would be to implement the recommendation regarding one day off per week without averaging over time.

We asked our members to comment on the likely costs and benefits of the proposed changes as well as for any other comments. Although it is difficult to summarize the many thoughtful and nuanced responses of our members, we can report that a significant minority of our respondents see the likely impact to be positive—better rested residents who are better able to learn and better able to provide care for patients. That having been said, more of our respondents voice a variety of concerns including the following:

- Concern about the need for more people to be on call in any 24 hour period and in any week-long period to meet these requirements. This would have its own consequences including the following:
    - It would also likely mean more frequent call for residents and, as such, a decline in resident satisfaction.
    - More residents on call overnight or on night float rotations would mean fewer residents available for classes, seminars, and conferences during the day. This will lead to a disruption in continuity of current teaching activities.
- Concern that smaller programs will not be able to meet the requirements and will be forced to close.
- Enormous concern about cost.
- Concern that these requirements will become an "unfunded mandate".
- Concern about the loss of continuity in care.
- Concern about limitation on opportunities for learning and fragmentation of the residents' clinical and classroom experiences
- Concern about adverse impact on residents' view of patient "ownership" and professionalism
- Concern that limitations on moonlighting would add to resident financial hardship

Section 2. Workload Adjustment

Although 45% of our respondents think the workload adjustments described in the report would improve the quality of care and 47.2% think these would improve resident education, only 13.8% or our respondents would like the Psychiatry RRC to specify "caps" in the number of patients treated on any given service or the number of patients evaluated on any given shift.

In many of their comments, our respondents discuss their endorsement of efforts to keep residents from being treated like "work horses". However, several of our respondents remind us that "scut work" is a part of all jobs, and that residency remains, among other things, a job as well as preparation for future jobs which will include "scut" as well. In keeping with the overwhelming opposition to "caps", many of our respondents are concerned that "one size fits all" caps do not take into account variability in patient acuity and clinical care settings, will inevitably be arbitrary and, as such, are likely to be deleterious.

Section 3. Enhancing Supervision

60.4% of our respondents think the recommended requirements regarding supervision would improve the quality of care and 63.2% think that they would improve resident education. 74.6% of our respondents think that it would be somewhat to very difficult to implement these changes in their programs.

In their comments, many of our respondents comment on the lack of clarity in the recommended requirement for in-house supervision. Many comment that if this is to be a staff physician, rather than a more senior resident, it will be very expensive and, for many systems, unaffordable. As noted, there is some difference of opinion about impact on patient care and on resident education. Regarding the latter, a number of respondents are concerned that the requirements would interfere with the development of autonomy in residents and in current efforts toward providing graded levels of responsibility.

Section 4. Improving Handovers

82.1% of our respondents think that recommended requirements in this area would improve patient care and 70.5% think they would improve resident education. 49.9% of our respondents think that it would be somewhat to very difficult to implement these changes in their programs.

The comments of many of our respondents reflect their support for these recommendations and the fact that many of our members have already implemented these changes. There is some concern about crafting new requirements in a way that leaves programs free to develop systems that work best for their specific systems and clinical needs.

General Comments

Our members were asked for any other comments regarding the report recommendations and a number of themes were prominent:

- Reiteration of concerns about cost and adverse impact on education.
- Concern that "shift work" will lead to (further) erosion in professionalism and the readiness of our residents to function independently post-residency.
- Concern that over-regulation will interfere with initiative, creativity and situation-specific adaptations in programs.
- Concern about whether the recommendations are, in fact, evidence-based in regard to resident well-being, patient safety, and resident education.
- Concern that the recommended implementation timetable is too short, the hope that the ACGME will work toward a consensus view on these difficult issues, and suggestions that no additional requirements be put into place before funding has been identified.

We hope that the results of our survey will be of help to you and other members of the RRC. Moreover, we strongly urge that a cautious, considered approach be taken, lest we risk causing unintended serious and potentially irreversible disruption in many excellent programs which are already committed to the goals of improving patient care, resident education, and resident health and well-being. Together with the membership of AADPRT, we look forward to working with you in the next months and years to continue to improve the education of our residents and, ultimately, the care provided to the patients we serve.

Sincerely yours,

William Greenberg, M.D.
Chair, AADPRT Taskforce on Resident Duty Hours
Director, Harvard Longwood Psychiatry Residency Program

Deborah Cowley, M.D
AADPRT President
Director, University of Washington Psychiatry Residency Program

AADPRT DUTY HOURS SURVEY
SUMMARY
January, 2009

1. DUTY HOURS

Do you think these recommendations, if implemented, would:

	Yes	No	No Opinion	#Responses
Improve the quality of patient care?	27 (25%)	72 (66.7%)	9 (8.3%)	108
Improve resident education?	26 (24.1%)	76 (70.4%)	6 (5.6%)	108
Improve resident health and well-being?	56 (51.9%)	40 (37%)	12 (11.1%)	108

2. WORKLOAD ADJUSTMENT

Do you think that these recommended changes would:

	Yes	No	No Opinion	#Responses
Improve the quality of care?	49 (45%)	53 (48.6%)	7 (6.4%)	109
Improve resident education?	51 (47.2%)	54 (50%)	3 (2.8%)	108

Would you like the Psychiatry RRC to specify "caps" in the number of patients treated on any given service or the number of patients evaluated on any given shift?

Yes	No	No Opinion	#Responses
15 (13.8%)	82 (75.2%)	12 (11%)	109

3. ENHANCING SUPERVISION

Do you think these changes would:

	Yes	No	No Opinion	#Responses
Improve the quality of care?	64 (60.4%)	36 (34%)	6 (5.7%)	106
Improve resident education?	67 (63.2%)	34 (32.1%)	5 (4.7%)	106

How difficult would it be for you to implement these changes in your program? (106 responses)

Very Difficult	45 (42.5%)
Difficult	16 (15.1%)
Somewhat Difficult	18 (17%)
Easy	16 (15.1%)
Very Easy	11 (10.4%)

4. IMPROVING HANDOVERS

Do you think these recommended changes would:

	Yes	**No**	**No Opinion**	**#Responses**
Improve the quality of care?	87 (82.1%)	11 (10.4%)	8 (7.5%)	106
Improve resident education?	74 (70.5%)	24 (22.9%)	7 (6.7%)	105

How difficult would it be for you to implement these changes in your program? (104 responses)

Very Difficult	2 (1.9%)
Difficult	12 (11.5%)
Somewhat Difficult	38 (36.5%)
Easy	37 (35.6%)
Very Easy	15 (14.4%)

The American Board of Plastic Surgery, Inc.®

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Founded 1937

April 29, 2009

Thomas J. Nasca, M.D.
Chief Executive Officer
Accreditation Council for Graduate Medical Education
515 North State Street
Chicago, IL 60610-4322

Re: Response to the Institute of Medicine report regarding Resident Work Hours

Dear Dr. Nasca,

I am responding to your letter of February 12, 2009 requesting comments of interested individuals or organizations in response to the report from the Institute of Medicine (IOM) addressing the topic of restriction of resident work hours.

The American Board of Plastic Surgery (ABPS) has discussed this topic with many of the entities within the specialty of plastic surgery, including the officers of the Association of Academic Chairmen of Plastic Surgery (AACPS), with members of the Residency Review Committee in Plastic Surgery, with representatives of other certifying boards at the American Board of Medical Specialties (ABMS), with the officers of the American College of Surgeons (ACS), and in detail with staff and directors of the American Board of Surgery (ABS).

The ABPS has had the opportunity to review the drafts, to address suggestions and to read the final comment that you will receive this week from the ABS. The ABPS is in full support of the detailed scholarly report from the ABS which should stand as one of the more complete opinions on this topic ever written by a surgical specialty group. It would be difficult for another organization to repeat the excellent work of the ABS, and such an effort would only serve to be redundant. Accordingly, I agreed, on behalf of the ABPS, to add my signature to the report from the ABS that will be forwarded to you.

We applaud your efforts and those of the Board of the ACGME to provide a serious response from organized academic medicine to the IOM.

With best regards, I am,

Very truly yours,

R. Barrett Noone MD.

R. Barrett Noone, M.D.
Executive Director

RBN/tmc

c: James M. Stuzin, M.D.
A.Michael Sadove, M.D.
Nicholas B. Vedder, M.D.
John W. Canady, M.D.
Frank L. Lewis, M.D.
Gabriel L. I. Bevilacqua
L. Scott Levin, M.D.

ARRO
Association of Residents in Radiation Oncology

4/13/2009

Thomas J. Nasca, M.D., MACP
Chief Executive Officer
Accreditation Council for Graduate Medical Education

Matthew Poppe, MD
Member, ACGME CRCR
Ex-Vice Chair, Association of Residents in Radiation Oncology

Re: Position paper on the IOM Report regarding resident duty hours.

The Executive Committee of Association of Resident in Radiation Oncology is a peer elected governing body of 6 members representing all US residents in ACGME approved training programs in radiation oncology. We have discussed the IOM report at our semi-annual meeting in March 2009 and have concluded the following:

In response to the requested positions:

- *Your organization's formal position on the recommendations contained in the Institute of Medicine Report, including impact analysis, from your organization's perspective, on costs and impact of implementation*

1) Our specialty is fortunate enough to not be affected directly by the 80 hour work week restrictions, to include: consecutive hours worked, time off between shifts and total weekly hours. Indirectly however, radiation oncology training will be affected by an increase in hand-offs and the reduction in available residents in medical oncology, gynecological oncology, neurology and urology.

2) Our training programs often utilize week long resident home-call, and would be adversely affected by restrictions on these hours. We understand there may be inappropriate use of home call in other fields, but this does not appear to be occurring in our field.

3) We fear the monitoring of external moonlighting as a breach on free liberty. What a resident does during his or her "off," time should be up to the discretion of the individual resident.

- *Your organization's formal position on the current ACGME Resident Duty Hours Standards including impact analysis, from your organization's perspective, on costs and impact of implementation.*
    - We feel the ACGME current Resident Duty Hours Standards are sufficient to delivery safe and effective healthcare, however, need closer monitoring and repercussion for violations.

- *Your organization's formal recommendations regarding dimensions of Resident Duty Hours standards, and justification (wherever possible) for this position with evidence.*
    - We make no formal recommendation here due to the fact that our specialty training does not currently run up against duty hour restrictions.

- *Your organization's formal recommendations regarding standards governing key aspects of the Learning Environment, and justification (wherever possible) for this position with evidence.*
    - We agree that the ideal learning environment allows residents to practice medicine in a safe and supervised environment. Residents should be allowed to get sufficient rest and sleep, however this must be balanced with the realities of our profession and reflect life as an attending. When unique (non-routine) training opportunities arise, residents should be allowed the opportunity to voluntary exceed duty hour limitations. When this occurs there should be sufficient justification, documentation and supervision to assure the absence of abuse and adequacy of supervision to minimize medical errors.

- *Your organization's willingness to participate, if invited, in a Resident Duty Hours and the Learning Environment Congress, to be held in June, 2009 in Chicago Illinois. This Congress will be configured to provide the ACGME leadership will the breadth of perspectives of the medical community as they embark on review and revision of the Resident Duty Hours and Learning Environment Standards*
    - We would be willing, if invited, to participate in a Resident Duty Hours and Learning Environment Congress this June.

We appreciate that the ACGME is diligently working on a formal response to the IOM Duty Hours report and understand the magnitude and diversity of opinion of this task. We feel that the ACGME will earnestly recommend what's best for medical training and keep the regulation of our profession internal. We appreciate the request for our input and will be happy to offer additional information as requested.

Sincerely,

Jonathan Straus, MD	(Rush University, Chicago, IL)
Matthew Poppe, MD	(RWJUH/CINJ New Brunwsick, NJ)
Siavash Jabbarri, MD	(UCSF, San Francisco, CA)
Casey Challot, MD	(Loyola University, Chicago, IL)
Linna Lin, MD	(Fox Chase Cancer Center, Philadelphia, PA)
Johnny Bernard, MD	(Mayo Clinic-Jacksonville, Jacksonville, FL)

Incoming Members:

Luqman Dad, MD	(Roswell Park Cancer Institute, Buffalo, NY)
Karen L. De Amorim Bernstein, MD	(Albert Einstein College, Bronx, NY)
Vinai Gondi, MD	(University of Wisconsin, Madison, WI)

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April 23, 2009

L.D. Britt, MD, FACS
Chair, Board of Regents
American College of Surgeons
633 North Saint Clair Street
Chicago, IL 60611-3211

Dear Dr. Britt:

I am writing this letter on behalf of the Board of Trustees of the Society for Surgery of the Alimentary Tract. At our most recent meeting, there was a vigorous discussion of the most recent the Institute of Medicine recommendations regarding resident work hours.

The Board was in full agreement in its concern about the possibility that these new guidelines might be implemented by the ACGME. It was the consensus that there is no evidence suggesting that the 2003 restrictions have had any positive impact on either quality of care or patient safety. In fact, there is continuing concern regarding their negative impact on continuity, a basic principle of surgical care, and on surgical education. In the absence of any evidence that the initial restrictions have had a positive impact and in the context of accumulating evidence that the may have damaged surgical training, the new recommendations seem to have little practical or scientific basis.

It is our understanding that the American College of Surgeons, representing the surgical community, is developing a response to the ACGME expressing these concerns. The Board of Trustees of the Society for Surgery of the Alimentary Tract is unanimous in its support of such a response.

Sincerely yours,

John C. Bowen, M.D.

John C. Bowen, MD
Chairman, Board of Trustees
The Society for Surgery Alimentary Tract

cc: Thomas J. Nasca, MD
CEO
ACGME
515 North State St.
Chicago, IL 60610

Thomas R. Russell, MD, FACS
Executive Director
American College of Surgeons
633 North Saint Clair Street
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April 30, 2009

Thomas J. Nasca, MD, MACP
Chief Executive Officer
Accreditation Council for Graduate Medical Education
515 North State Street, Suite 2000
Chicago, IL 60654

RE: Institute of Medicine recent resident work hour recommendations

Dear Dr. Nasca:

Frank Lewis, M.D., Executive Director, American Board of Surgery (ABS) has forwarded to you a very articulate and comprehensive document regarding the views of the ABS on the Institute of Medicine (IOM) recently recommended changes to resident work hour regulations. In this document Dr. Lewis extensively addresses the problems of lack of documentation for justifying the recommendations, the impact on resident training in Surgery and the ethical dilemmas forced on the residents during their training. The Pediatric Surgery Board is in agreement with these and all of the other concerns raised by Dr. Lewis in the ABS document.

I am writing as the Chairman of the Pediatric Surgery Board (PSB) of the ABS and my comments represent all of the members of the PSB. As you know, we are the Board that is charged with the ongoing assessment and certification of residents that are training in and have completed an ACGME-accredited Pediatric Surgery residency. Our specific responsibilities include defining the process and the criteria for certification of residents who have completed their training in Pediatric Surgery. Thus, it is the PSB that has the responsibility of assuring that the surgical care of premature infants through adolescents in those areas of surgical care encompassed within the field of general pediatric surgery (head and neck anomalies and masses, non-cardiac thoracic abnormalities, abdominal and urologic abnormalities, as well as soft tissue tumors) is performed by well trained pediatric surgeons practicing safe and high quality care. This broad scope of training is compacted into a two-year pediatric surgery residency that follows general surgery residency. Members of the PSB (as I am sure is the case for all of the specialty board members), take the responsibility of this certification process very seriously. The PSB is particularly concerned because the patient population for which our residents are training are infants and children. We must assure that those surgeons for whom we provide certification in Pediatric Surgery are indeed qualified to perform these complex surgical procedures as well as provide excellent pre- and postoperative care.

The process of becoming a pediatric surgeon is long and arduous. Beyond undergraduate education and medical school education (combined eight years) a residency in an ACGME accredited general surgery residency (5-7 years) is required. It is at this time that these individuals are eligible to be accepted into a two year pediatric surgery residency. The competition for the thirty-seven available pediatric surgery residency positions per year is intense. The quality of the individuals applying to these training programs is outstanding. Those individuals who are ultimately accepted into one of the training programs in Pediatric Surgery are highly motivated and qualified individuals. Their expectation at the end of their training is that they will have been exposed to, participated in and become competent in the very broad areas of care within the scope of Pediatric Surgery. Furthermore, it is anticipated by their program directors and faculty that indeed they have had this exposure and they have acquired a very large fund of knowledge and surgical experience to care for pediatric surgical patients and are competent to provide excellent care to infants and children in their selected place of practice. To facilitate these goals the training curriculum in Pediatric Surgery has been standardized and the standards set by the PSB for meeting and passing the certification process are high.

The PSB is very cognizant of the need to define appropriate work hours and to provide adequate rest and sleep time for residents training in Pediatric Surgery. It was difficult for the training programs in Pediatric Surgery to adapt to the work hour restrictions instituted in 2003. The reason is that the training programs are typically in freestanding children's hospitals without access to general surgery residents especially at the PGY-4 year or above. Thus, this limits the ability to supplement the call schedules of the pediatric surgery residents. However, the program directors were able to adapt but with difficulty. The obvious impact that the 2003 work hour restrictions have had is to diminish the exposure of pediatric surgery residents to complicated and unusual congenital and acquired anomalies in the neonatal and pediatric age groups. However, this has impacted on the quality of training and experience that the residents get over their 24 month training period. For example, a resident may be involved in 4-6 patients with an unusual surgical anomaly requiring specific emergent pediatric surgical expertise. It will be expected by the PSB that the resident will have appropriate experience in the management of that problem. Diminishing the exposure by 30% because of work hour restrictions would have a major impact on the residents acquired skills. There is no other method that can substitute for the knowledge and skills gained in their training other than direct patient involvement.

I have had one of the longest tenures in the evaluation and certification of residents following their training in Pediatric Surgery. I have noted over the past five years that the fund of knowledge and clinical expertise of the trainees has decreased. There are at least two reasons for this observation: (1) Decreased experience of general surgery residents because of the evolution of surgery specialty fellowships and work hour restrictions; and (2) The decrease in exposure of Pediatric Surgery residents to complex pediatric surgical problems particularly in the neonatal age group. This is particularly worrisome to me as well as all of the members of the PSB.

We are deeply concerned about the further restrictions that have been recommended in the IOM report. These new restrictions will further decrease the patient exposure of residents training in pediatric surgery and thus, result in a lower level of expertise. Furthermore, much of the surgical activity in general pediatric surgery is emergent such as a newborn infant with a life threatening congenital anomaly or a pediatric trauma patient with a life threatening injury. Pediatric surgeons must have the experience and background to handle these very complex patient care issues.

One solution might be to consider prolonging the training in Pediatric Surgery. However, the post-undergraduate education and training already is an additional 11-12 years resulting in the residents completing their training at 33-34 years of age. There would be little enthusiasm for further prolonging the training. The real and serious unintended consequence of this could be to discourage potential trainees from choosing a career in Pediatric Surgery and further decrease the workforce and access to care. . It should be pointed out that there are approximately 800 practicing pediatric surgeons for the entire United States. Currently, the demand exceeds the supply. Thus, a continuous input of well-qualified trainees is an absolute necessity to maintain not only an adequate workforce but it is equally important to maintain a quality of training for these pediatric surgeons. Because often they may be the <u>only</u> provider for a significant population base, their training must be thorough and "hands-on".

The members of the PSB are not only concerned about the specific impact of the recent IOM recommendations on education and training of pediatric surgeons but also on their assessment and certification. Although the 80 hour limit was preserved, many of the recommendations further compromise the pediatric surgery resident's ability to have access to critical patient care experiences. For an example, requiring the five hours of sleep during their night on call when they are already in the hospital could limit their access to a newborn infant born with one of the uncommon anomalies that would require emergent surgical intervention. This would also apply to pediatric trauma patients. Other recommended restrictions also decrease access to patient care-related educational opportunities.

Regarding the work hour restrictions currently in place, we would also strongly recommend that there be flexibility in the distribution of work hours within the eighty-hour work week restriction. The absence of flexibility in the application of work hour restrictions suggests that the training requirements for all medical/surgical specialties are uniform. Nothing could be further from the truth. As an obvious example compare the training in pediatric pathology to pediatric surgery.

In summary, the PSB strongly believes that the most recent IOM recommendations for resident work hour restriction changes are not appropriate for the advanced training of a pediatric surgeon. As noted in the ABS document, we also strongly question the basis for which the IOM recommendations were derived.

Sincerely,
Marshall Schwartz
Marshall Z. Schwartz, M.D.
Chairman, Pediatric Surgery Board

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A MEMBER BOARD OF THE AMERICAN
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May 1, 2009

Thomas J. Nasca, M.D.
Chief Executive Officer
Accreditation Council for Graduate Medical Education
515 North State Street, Suite 2000
Chicago, IL 60654-4322

Dear Dr. Nasca,

I would like to thank you on behalf of the American Board of Thoracic Surgery for the opportunity to present our views on the current recommendations of the IOM Report on Resident Duty Hours issued in December 2008.

We very much appreciate the balance between the public interest, patient safety and resident training and education. Duty hour standards as enacted in 2003 have provided a forum for ongoing discussion with a current paucity of literature indicating that this standard has resulted in an increase in patient safety. We believe that there should be further studies validating the current changes before applying new policies to the residency programs.

We have currently signed on to the response from the American Board of Surgery by Dr. Frank Lewis. We feel that this document scholarly addresses all of the pertinent issues involved in the Institute of Medicine report. Like the ABS, we are a specialty that conducts both elective and emergent operations. These new requirements would seriously limit the resident's education and training in emergency situations, crucial to the development of a cardiothoracic surgeon. Most importantly the recommendations by the Institute of Medicine in our opinion further provide a wedge between the resident and the patient in regards to continuity of care and further enhance the likelihood of "shift-type" rotations, leading to further erosion of the bond established between residents and their patients. We believe that patients would not be in favor of this type of relationship, whereby their primary surgeon is not allowed to follow them during their hospitalization. There should be flexibility in the current policies, as the care for patients is significantly different among specialties.

We sincerely appreciate all of the work that the Institute of Medicine put into their deliberations, but agree with Dr. Lewis and the American Board of Surgery that the current recommendations would be detrimental to resident education and would be a step backwards in the continuity of good patient care. We also appreciate the opportunity to comment on these recommendations.

Best regards,

William A. Baumgartner

William A. Baumgartner, MD
Executive Director

cc: Dr. Frank Lewis, American Board of Surgery
Patricia Watson

TSDA
Thoracic Surgery Directors Association
since 1978

May 1, 2009

Thomas J. Nasca, MD, MACP
Chief Executive Officer
Accreditation Council for Graduate Medical Education
515 N. State Street
Suite 2000
Chicago, IL 60654

Dear Dr. Nasca:

Thank you for inviting the Thoracic Surgery Directors Association (TSDA) for input on ACGME's review of its Resident Duty Hours Standards and Key Dimensions of the Learning Environment. We appreciate the opportunity to participate in this important discussion.

The Thoracic Surgery Directors Association represents residency programs in thoracic surgery and congenital heart surgery. TSDA members are on the front lines of the resident duty hours restrictions debate and can offer the practical knowledge and wisdom that come with experience. We are responsible for training the next generation of cardiothoracic surgeons, a responsibility we take very seriously. The care and quality of life of future generations of patients as well as residents must be factored into the equation.

TSDA leadership has reviewed and endorsed The Society of Thoracic Surgeons (STS) letter to ACGME on this topic (copy attached). We add our emphasis to the points made in that letter, including those regarding costs. The administrative costs required to implement further restrictions on resident duty hours would cripple the educational efforts of cardiothoracic surgery residency programs. Such a financial drain on already dwindling budgets would effectively eliminate many important initiatives and research projects. Perhaps most importantly, additional financial burdens would seriously compromise efforts to enhance the residents' education experience through the widespread adoption of simulators.

Also, as noted in the STS letter and elsewhere, there are no data indicating that the resident duty hour restrictions implemented in 2003 have reduced preventable adverse events or had any impact whatsoever on the quality of patient care. Indeed, academic medical institutions continue to be recognized as delivering the highest quality care.

TSDA takes this opportunity to offer to work with ACGME to develop and implement relevant research that would assess the range of implications of resident duty hour restrictions for patient care and resident education. Such research conducted with TSDA would provide important insights into the training of the most advanced residents at a time when most research has focused on PGY-1 and PGY-2 residents. A "one-size-fits-all" approach will not work for surgical specialty residency programs that are training the most advanced residents. Collecting and analyzing data is the only way to determine the best course of action for residents and for patients.

Finally, the work of K. Anders Ericsson and others has shown that sustained practice is the key element of developing expertise. We encourage a budding violinist or an athlete in training to practice as much as possible. Why would we then limit the amount of practice a surgical resident can do? Cardiothoracic surgery residents are training for one of the most challenging jobs in medicine. When our residents, among the best and brightest in medicine, want to stay on duty to follow up with a patient or to see or even do an important procedure, it is counterproductive to discourage such initiative. As has been said before -- one size *doesn't* fit all; surgery is different. And cardiothoracic surgery is unique. TSDA will be happy to work with ACGME to research the value and potential of resident duty hour restrictions. But further restriction of resident duty hours at this time – with no data on which to base those further restrictions - is not the answer.

TSDA appreciates the invitation participate in the ACGME's Resident Duty Hours and Learning Environment Congress, to be held June 11 and 12. TSDA representatives would also be happy to testify.

We look forward to hearing from you. Thank you again for inviting TSDA input to this important topic.

Sincerely,

John W Brown MD

John Calhoun

John W. Brown, MD
TSDA President

John H. Calhoun, MD
TSDA President Elect

Enclosure: STS Letter to ACGME

cc: TSDA Board of Directors
Nancy Gray Puckett, Executive Director

TSRA THORACIC SURGERY RESIDENTS ASSOCIATION
633 N. St. Clair Street · Chicago · IL · 60611

May 15, 2009

Thomas J. Nasca, MD, MACP
Chief Executive Officer
Accreditation Council for Graduate Medical Education
515 N. State Street
Suite 2000
Chicago, IL 60654

Dear Dr. Nasca:

The executive committee of the Thoracic Surgery Residents Association (TSRA) has had the opportunity to review the Institute of Medicine's report entitled "Resident Duty Hours: Enhancing Sleep, Supervision and Safety" and is appreciative of the opportunity to participate in our future.

The TSRA includes all ACGME accredited residents from 79 approved thoracic surgery residencies, 4 thoracic surgery integrated programs and 9 congenital cardiac surgery-training programs. Currently, each member of the TSRA has already had a minimum of six years of post-graduate training per resident and is one of the few remaining cohorts of residents that began their training prior to the initiation of the 80-hour workweek limitation.

As a group of professionals training in the field of cardiothoracic surgery, we are repeatedly conflicted by the ethical dilemma posed when patient care and family expectations collide with the limitation imposed by work hour restrictions. On the front lines of patient care, we are providers in a specialty where advanced critical care is required on even the most routine cases leading to strong emotional bonds between residents, patients and families. The relationships created are challenged when work hour restrictions prohibit us from providing continuity of care. Additionally, our education is impaired when the same complex patient care requires surgical intervention, either treating the primary pathological process or returning to the operating theater for an untoward postoperative event; yet the set limitations prohibit us from providing continuity of care and preclude us from benefitting from the invaluable learning opportunities.

We suggest that imposing additional work limitations would lead to less patient satisfaction and devalue the physician patient relationship. Moreover, resident education would be impaired leaving to chance that continuity of care would be maintained.

We support efforts that decrease patient adverse events, yet we challenge the notion that decreasing work hours beyond the initial limitations will obtain the desired outcome. In fact, three studies performed since implementation of the work hour restriction has shown no change in patient adverse events, despite the 80-hour limitation. Reducing resident hours further would lead to less consistent and non-continuous patient-physician interaction, further fragmenting patient care and potentially *increasing* the incidence of patient adverse effects. In an era where our public profile is diminishing and our professionalism challenged, additional limitations would continue to strain this boundary.

The TSRA is willing to participate in the Resident Duty Hours and the Learning Environment Congress proposed by ACGME. The Congress may benefit from senior level resident perspective at this important meeting and we welcome the opportunity to bring our experience and perspective to the forum.

Sincerely,

Bret Mettler, MD
President

American
Urological
Association

March 11, 2009

Thomas J. Nasca, M.D., MACP
Chief Executive Officer
Accreditation Council for Graduate Medical Education
515 North State Street
Suite 2000
Chicago, IL 60654

Dear Dr. Nasca:

Thank you for your letter of February 23, 2009 regarding your request to the American Urological Association (AUA) on our formal position on the current ACGME Resident Duty Hours Standards. Urology residents who are members of the AUA fall under the Candidate member category, which requires that they be enrolled in an ACGME-accredited urology training program in the United States, Canada or Mexico.

Upon consultation with our Section Secretaries/Membership Council, the AUA believes that the requirement for one day completely off of clinical duties per week rather than the current requirement of an average of one day completely off per week is problematic because it prohibits residents from taking weekend call and would also interfere with continuity of patient care. This proposed change would also mean that residents may not be able to have a full weekend off of all clinical care duties as the present system allows.

Therefore, in support of those urology residents who are AUA Candidate Members, the AUA continues to support the eighty hour work week.

Regards,

Robert Flanigan

Robert C. Flanigan, M.D.
Secretary
AUA Board of Directors

Headquarters

Michael T. Sheppard, CPA, CAE
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May 1, 2009

Thomas J. Nasca, M.D., MACP
Chief Executive Officer
Accreditation Council for Graduate Medical Education
515 North State Street, Suite 2000
Chicago, Illinois 60654

Dear Dr. Nasca,

We appreciate the opportunity to respond to the ACGME regarding the position of the Residency Review Committee for Urology on the matter of the 2008 IOM Report on Resident Duty Hours. Our Committee was represented at the ACGME Duty Hours Conference in March, and also has participated in the subsequent conference calls and discussions with the American College of Surgeons. The Urology RRC would welcome the opportunity to participate in a Resident Duty Hours and Learning Environment Congress this coming June, and in any other formal or informal discussions on this important topic.

The Urology RRC supports the current role of the ACGME in regulating resident work hours and the specific duty hour standards which are currently in place. We appreciate the thoughtful, data-driven approach applied by the IOM in assessing the impact of current duty hour standards, and in making the recommendations in the 2008 report. We agree with the perspective voiced at the recent ACGME conference and in other venues that many of the data utilized in the IOM report may not be directly applicable to the true working situations of residents on call. We support the view that much more data is needed through appropriately designed prospective studies of the impact of the current duty hour standards to appropriately modify the existing standards. Our committee would be willing leaders and participants in the design and performance of such studies.

While our Committee does not have independent data to inform the current discussion on the cost of implementation of the IOM recommendations, we do believe that such implementation would be very expensive and generally believe that the estimate of $1.7 billion is conservative.

Before addressing each IOM recommendation specifically, we do want to express a very relevant and general concern about the resident learning environment over which the ACGME could exercise greater control and which would directly impact on the duty hours discussion. This concern relates to the manner in which resident supervision is defined and overseen in resident training. The current definition of supervision is rather vague and allows widely varying interpretations as to physical presence, immediate availability, and potentially lack of true availability of faculty in supervising residents – particularly junior residents. The Joint Commission for Accreditation of Hospital Organizations and other bodies are increasing their expectations with regard to specifying exactly what residents at various levels of training may do without immediate physical supervision. This process is handled at the institutional and program levels through the creation of supervision policies and standards. Nevertheless, the system is quite "loose" in assuring that residents are supervised in a manner which maximally assures patient safety. Trainees at very junior levels do, in many cases, and in many practice and learning environments, function independently in exercising both judgment and decision-making, as well as technical skills. A more specific set of standards governing the manner in which trainees must be supervised by faculty (and by senior residents) would greatly alleviate the pressure on the duty hours discussion. This issue is highly relevant for surgical and other procedure-based specialties, but is also important for non-procedure-based fields in which interpretations of physical findings, and selection of medical therapies, can also have critical impacts on patient outcomes. We would welcome a broad discussion at the ACGME level to address the variability in supervision expectations and oversight within institutional, common, and program-specific requirements.

We will now address the specific IOM recommendations in sequence, and offer the position of the Urology RRC for each:

Maximum hours of work per week: We support maintaining the current standard of 80 hours per week, averaged over 8 weeks. It is our impression that this standard has been well-received by Urology Program Directors, and we are pleased that the IOM did not endeavor to further reduce this maximum.

Maximum shift length: While we recognize the data being applied to support the IOM recommendations to mandate a 5-hour protected sleep period, we do question the relevance of these data for residents in a surgical specialty who are actively engaged in operative tasks and other forms of "active" work. While we do not have data to the contrary, we believe that for our discipline and for surgical fields in general, the proposed protected sleep recommendation should not be implemented until this issue is addressed through prospective studies involving actual working surgical residents. This would be one of the most expensive and disruptive of the new recommendations. We do not support accepting this recommendation without data clearly showing its benefit in surgical specialties. We view this recommendation as highly problematic to implement and do not accept that a nights rest interrupted by infrequent calls results in a detrimental impact on patient care. In addition, this requirement will be especially difficult to implement in small residency programs such as urology where loss of a single resident because of this limit will significantly decrease the resident educational experience.

Maximum in-hospital on-call frequency: Many urology residency programs have home-call systems, so this standard would apply only to a subset of programs. We believe that eliminating the latitude to average the on-call frequency and comply with a strict every third night requirement is excessively restrictive, and unreasonably limits the judgment of the program director in assessing resident fatigue on a real-time basis with the expectation of making real-time adjustments in call coverage when the need arises. We all know that in-house call experiences range dramatically from busy, sleepless nights, to those during which adequate rest is obtained. In some cases, every third night call is not at all burdensome; in others, every forth night may be excessively frequent, depending on the actual call work activities. It is currently the job of the institution and the program director to oversee the quality of rest obtained during each call night and to take appropriate action. Enhancing the reporting requirements related to in-house call, rest and fatigue would be a better way of dealing with the natural variability in these parameters than would instituting this new restrictive standard.

Minimum time off between scheduled shifts: The current standard of a minimum of 10 hours after shift is adequate to assure rest between duty shifts, in our view. The proposed standard, which uses 10, 12, or 14-hour periods, depending on the shift worked, is too complicated and would be quite difficult to monitor in practice. We do not see the need based on the data presented to implement this recommendation. We do support the principle of not returning to work until at least 6am on the next day. This would enhance resident quality of life in various respects and is an appropriate expectation.

Maximum frequency of in-hospital night shifts: This recommendation regarding the consecutive night maximum appears to be based on legitimate data and accepted observations on circadian cycle responses, and could largely be implemented by modifications of resident call schedules without greatly increasing physician extender dependence. We support the 4 night maximum rule, but question the requirement for 48 hours off following the consecutive night shifts; 24 hours off would be adequate in most cases, with longer intervals off being left to the judgment of the program director and to institutional oversight.

Mandatory time off duty: We support increasing, to 5, the number of days off per month. This would avoid the problem of the challenge of calculating time off by week versus month, which is difficult for some programs depending on rotational and calendar practices. We do not support the elimination of the flexibility which the current standard provides with regard to averaging the days off over a 4 week period. Based on our discussions with residents, requiring one day off per week without averaging will adversely and significantly impact the residents' quality of life. The desire of residents to work for a weekend, and then have the next weekend fully off, is understandable, and does much to enhance the quality of personal time and family activities. In addition, this standard as proposed would apply to all residents, regardless of whether the call is in-house or from home. We have seen no data to indicate that when a resident takes a full weekend of call from home, they are in any way less able to function through the following week at a high level of competence and in a well-rested state. This weekend call system is, furthermore, similar to the call that many residents will encounter in their practice after residency. The issue depends, again, on the quality of the individual call episode, for which monitoring by the program director should occur. We oppose the implementation of the "1 day (24 hours) off per week, no averaging" recommendation for Urology, and would certainly oppose it for any program which allows call from home. We support specifying that at least one 48-hour period off per month should be provided.

Moonlighting: We support the principle of including both internal and external moonlighting as counting toward the 80-hour weekly limit. It is an artificial distinction to include one and not the other, and we believe this new standard will cause the program directors and institutions to more carefully oversee the work which trainees do as physicians, all of which adds up to affect fatigue and balance in life as a trainee.

Limit on hours for exceptions: We support the plan to have no change in this policy, for urology and for all training areas.

Emergency room limits: We support the plan to have no change in this policy, for urology and for all training areas.

There are several other areas which we would like to address, for which we believe there has not been adequate attention given in the IOM report. The first relates to what one might term the "home call loophole". The second relates to the use of daytime rest periods. The third relates to liberalizing the duty hour standards for senior and chief residents. All are highly relevant to the process of "transition to practice" and to what should be an additional goal of the work hour standards, which is the ultimate relevance of training standards and training paradigms to our lives as practicing physicians.

We also believe the revised duty hour standards should address several as yet unresolved issues, including:

- the well-recognized problem of the inaccuracy of self-report of resident work hours
- the IOM recommendations for outside agencies policing duty hour compliance
- and, the management of real-time exceptions for unique or especially valuable or uncommon clinical experiences

"Home call loophole": The current duty hour standards require that hours spent working while on home call be counted toward the 80 hour limit. The maximum shift length (30 hour rule) and the minimum time off after shift length (10 hour rule) do not apply, however, for residents on a home call system. This currently allows, for example, a resident to have been up half the night driving back and forth to the hospital, being exhausted the next day as a result, and having no protection with regard to the length of the following work day or the time off between shifts. In this setting, program directors and institutions are expected to have real-time fatigue monitoring systems in place which address resident fatigue and promote intervention when necessary.

Daytime rest periods: All of us in surgical practice deal with fatigue on a regular basis. There are no duty hour limits for practicing urologists, and we are expected to manage fatigue as a normal part of exercising professionalism. Practicing urologists who are fatigued have the option of delaying or working around scheduled activities and taking the time to get some daytime rest as needed. Hospitals often have facilities available for such a purpose. It may be valuable for the revised duty hour standards to consider how real working doctors manage these issues, and allow the institutional and program leadership to implement such processes, with appropriate documentation, as one approach to addressing the problems of resident fatigue and patient safety.

Liberalization of duty hour standards for senior and chief residents: As part of the transition to practice, we would recommend that the ACGME and IOM seriously consider relaxation of the duty hour standards for residents at the advanced phases of training and for post-residency fellows in certain situations. As these individuals are at the cusp of having to manage these challenges independently, creating a formal process to allow them to do so in a manner which provides support and mentoring may be very valuable, and may do much to help trainees develop the types of professional behaviors that we want to engender. This type of flexibility for senior and chief residents would support the basic training goal of encouraging progressive responsibility during residency.

The inaccuracy of self-report of resident work hours: As was reported during the recent ACGME duty hours program, this remains a significant and systematic problem. While it was appropriate for the ACGME not to mandate specific external monitoring functions such as punch cards or electronic attendance verification systems, it may be appropriate to revisit this issue and at least initiate research studies evaluating the feasibility and value of instituting processes not solely dependent on self-report.

Outside agencies policing duty hour compliance: We believe that the ACGME has performed admirably throughout this initial period of implementation of duty hour standards and monitoring compliance. Bringing CMS and JCAHO into this process may greatly change the flavor of assuring compliance - away from one focused on education and building professionalism, and towards a punitive and draconian policing structure. This should be given very careful consideration before acceptance; it may still be possible for this compliance function to be held fully within the ACGME's realm with improved reporting and monitoring processes.

Real-time exceptions for unique or especially valuable or uncommon clinical experiences: There is fear among program directors when facing such situations in which there is undisputed resident benefit and no risk to patient safety. The revised duty hour standards should be fully transparent in allowing these types of exceptions to occur, accompanied by appropriate documentation which would stand up to accreditation agency scrutiny. Denying critical and unique learning opportunities to residents is an unfortunate consequence of the current duty hour limits which arises within many programs. Mechanisms should be put into place to avoid this unintended consequence of the duty hour limits going forward.

Again, we appreciate the opportunity to contribute to this important discussion, and look forward to being active participants in this continuing dialog.

Respectfully submitted,

Residency Review Committee for Urology
Michael Koch, MD, Chair
Michael Coburn, MD, Vice-Chair

DENVER
HEALTH
Level One Care for ALL

Dr. Thomas Nasca
ACGME
515 N. State St., Suite 2000
Chicago, IL 60654

March 18, 2009

Dr. Nasca,

Please see the attached document for our response regarding the Institute of Medicine article titled *Revisiting Duty-Hour Limits – IOM Recommendations for Patient Safety and Resident Education.*

Feel free to contact me with any questions or concerns.

Sincerely,

Patricia A. Gabow, M.D.
Chief Executive Officer
Denver Health

RKAlbert
Richard Albert, M.D.
Medicine
Denver Health

HABatal
Holly Batal, M.D., Ph.D.
General Internal Medicine
Denver Health

David Brody
David Brody, M.D.
Managed Care
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Chris Carey, M.D.
OB/Gyn
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Richard Dart, M.D., Ph.D.
Rocky Mountain Poison
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Simon Hambidge, M.D., Ph.D.
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DENVER
HEALTH
Level One Care for ALL

Resident Duty Hours: Enhancing Sleep, Supervision and Safety.
Response to the Institute of Medicine *Resident Duty Hours: Enhancing Sleep, Supervision and Safety.*

As Chairs of the Clinical Services at a major urban public safety net institution we have significant concerns regarding the impact of the potential implementation of the IOM recommendations on residency training in a public hospital. Our concerns stem from lack of evidence that the changes suggested actually have a positive impact on patient care or education, the failure to consider the cost of such a change, the increased cost on continued training of residents in the safety net and the subsequent impact on access to care for the most vulnerable population.

Impact on patient care and education

The primary purpose of any residency training program is to prepare physicians in training to be independent practitioners. A component of is the ability to deliver safe care. A physician must be able to balance his or her own physical needs, including the need for sleep, with the needs of patients. Resident physicians must learn when they can and can not deliver safe care. They should not be required to work beyond the time that they can deliver safe care. Residents must have adequate rest and supervision in order to learn effectively and give safe care.

We must consider the impact of work hour restrictions on resident learning, on preparation for independent practice and on patient safety. The Institute of Medicine has made specific recommendations for changes in resident work hours. We believe that implementation of these recommendations may have unintended consequences on resident education, patient safety, and preparation for independent practice. In the practice of medicine we have come to believe in the value of evidenced based care in which the evidence provided assesses both benefit and harm. This does not appear to be available for these recommendations.

In virtually all major teaching hospitals patient coverage must be provided on a continuous basis. To provide adequate experience and provide adequate patient care, in many disciplines residents must be available on a 24 hour basis. Residencies with this requirement predominately use either a "night float" system or an "extended duty" (call) system, or a combination of the two. Many residencies use a "night float" system during weekdays and an extended duty system on weekends. Many residencies have complex schedules built around hospital duty, clinic, and OR schedules; as well as scheduled didactic time. Many of these schedules are fixed by the day of the week. Operating room days are usually fixed by day of the week, and clinic schedules are built around a Monday-Friday schedule. Scheduled didactic time is usually tied to the weekly calendar. Current work hour requirements are tied to a weekly calendar. A resident work schedule must be adaptable to a weekly calendar to be implemented.

We attempted to examine the scheduling impact of specific recommendations of the IOM that are changes from 2003 ACGME policies on one specific service, Obstetrics and Gynecology to underscore the problem. Similar issues will occur on other services which require 24 hour coverage. The recommendation of concern are summarized on the attachment.

Cost impact and its consequences

It is our estimate that for this service alone twice the number of residents would be required. As you are aware, the cost of residents is covered in full or in part by GME payments. Denver Health is an organization in which the allocation for DME does not cover the cost per resident and we have exceeded our institutional cap for the number of residents. Therefore, as we add residents there is no mechanism to cover even part of the costs. For us resident education is approaching the point at which it is no longer cost effective to have residents in many disciplines. The members of the National

Association of Public Hospitals and Healthsystems represent approximately 2% of all hospitals and they train a disproportionate percentage of the US the housestaff. Because these hospitals are large and because they provide 1 in 4 emergency room visits, one in five obstetrical deliveries, and our often the trauma and burn centers, they afford trainees an excellent learning experience. They also provide an ethnically diverse population which is preparing this generation of physicians for America's growing diversity. These NAPH members provide 20% of America's uncompensated care and therefore, have limited ability to absorb the growing cost of training. Thus, any new mandates need to have a strong evidence base and the changes must have a clear, favorable cost benefit.

Failure to weigh costs and the potential to have critical institutions abandon the training mission would be irresponsible. Implementation of the IOM recommendations would have adverse effects on current resident education, health care costs, potentially on available training sites and access to care for underserved populations. We strongly recommend that the ACGME consider these factors when considering any changes in resident work hours.

- Scheduled continuous duty periods must not exceed 16 hours unless a 5-hour uninterrupted continuous sleep period is provided between 10 p.m. and 8 a.m. This period must be free from all work and call, and used by the resident for sleep in a safe and sleep-conducive environment. The 5-hour period for sleep must count toward total weekly duty hour limits. Following the protected sleep period, a resident may continue the extended duty period up to a total of 30 hours, including any previous work time and the sleep period.
- Residents should not admit new patients after 16 hours during an extended duty period.
- Extended duty periods (e.g., 30 hours that include a protected 5-hour sleep period) must not be more frequent than every third night with no averaging.
- After completing duty periods, residents must be allowed a continuous off-duty interval of
    - o A minimum of 10 hours following a daytime duty period that is not part of an extended duty period,
    - o A minimum of 12 hours following a night float or night shift work that is not part of an extended duty period, and
    - o A minimum of 14 hours following an extended duty period; and residents should not return to service earlier than 6 a.m. the next day.
- Night float or night shift duty must not exceed four consecutive nights and must be followed by a minimum of 48 continuous hours off duty after three or four consecutive nights.
- At least one 24-hour off-duty period must be provided per 7-day period without averaging; one additional (consecutive) 24-hour period off duty must be provided to ensure at least one continuous 48-hour period off duty per month.

Residencies use either a "night float" system or and "extended duty" system, or a hybrid of the two. We will examine the impact of the recommendations on these systems.

In an extended duty system, a resident could not work longer than 16 hours without a 5 hour rest period and could not admit new patients after 16 hours. Patients are admitted on a 24 hour basis. Implementation of this recommendation would require that two residents cover a call slot each night – one could admit patients for 16 hours (0700 -2300), then sleep for 5 hours (2300 – 0400) and then could care for patients again until 1300. It is not clear if the resident could accept care of hospital patients admitted by someone else, or if the resident would then need to perform other duties (such as clinic) the next morning.

At 2300, another resident or other non-resident provider would have to accept responsibility for admissions and care of patients. If it is another resident, that person would have to begin their shift in the evening in order to be able to admit patients for at least 16 hours. If a resident is to be able to admit patients until 0800 and cannot admit patients for longer than 16 hours, that person would have to begin work no earlier than 1600. That person would then be on a "night" shift and could not be on an extended duty shift.

Functionally, implementation of this requirement would eliminate the use of extended duty shifts, and force programs to adopt a "night float" system.

To implement the IOM recommendations in a night float system, residents would have to work no more than 4 nights followed by 48 hours off duty. Residents would have to have 12 hours off duty after a night float shift, limiting the night shift to 12 hours. This means that "handoffs" would have to occur every 12 hours. In order to give adequate time for hand-offs and meet the requirements for 12 hours off duty, the "handoffs" would have to occur during the "day" shifts hours. Thus the day shift would have to be 12 hours plus the time needed for handoffs. Because residents would have to have 10 hours off duty after a day shift, handoffs would have to be limited to no more than one hour in the morning and the evening.

For example, this means that if the night float resident works from 1900 – 0700, then hand-offs (or board rounds) would have to be scheduled at 0600 and 1900 to allow one hour for the handoff. This means that the "day" shift would be from 0600 to 2000, a total of 14 hours. The day shift would then have 10 hours off.

However, after 4 days the "night float" residents would have a 48 hour period in which they did not work. This means that other residents would have to cover the two nights not covered by the night floats. These would be a different two nights every week. As shown above, these could not be covered by an extended shift call.

Mechanisms required to meet the recommendations

1. Assign two residents to each night float rotation.

By assigning two residents to each night float rotation, one resident could work for 4 nights and another work for 3 nights. The resident who worked the 4 nights would then have 48 hours off, and could then be available for a "day shift" one day before repeating the week. The other resident would work 3 nights, be off 48 hours, and then be available for 2 "day shifts" the next week. The schedule is shown below:

Resident	Mon	Tues	Wed	Thurs	Fri	Sat	Sun
A	12 hr NF	12 hr NF	12 hr NF	12 hr NF	off	off	13 hr day
B	off	off	13 hr day	13 hr day	12 hr NF	12 hr NF	12 hr NF
C	13 hr day	13 hr day	Other duty	Other duty	13 hr day	13 hr day	

Resident A would work 61 hours and have 48 hours off. Resident B would work 62 hours and have 48 hours off. Both residents would have the required 12 hours off after a night shift and 10 hours off after a day shift. Resident C would work less than 80 hours per week if the other duty was less than 14 hours, have one day off per week and be available for other duty (clinic, operating room) two days per week.

Residents on such a schedule would be required to work both days and nights in the same week. Such "swing shifts" have been shown in industry to be associated with increased sleep disturbance and decreased productivity.

Compared to a traditional night float schedule with extended calls on the weekend, such a system requires that one additional resident be assigned to cover admissions each week. (See below)

Resident	Sun	Mon	Tues	Wed	Thurs	Fri	Sat
A	14 hour night float	14 hour night float	14 hour night float	14 hour night float	14 hour night float	off	off
B	11 hour day	11 hour day	11 hour day	11 hour day	11 hour day	24 hour	off
C	off	Other duty	Other duty	Other duty	Other duty	Other duty	24 hour

The net result of implementing that system will be that residents will be assigned to night call for more rotations, and time in clinic and other duty will be decreased. Fewer residents will be available for daytime duty.

2. Use extended shifts with no admissions after 16 hours.

As has been shown, it is virtually impossible to design a call system to cover admissions on a 24 hour basis using an "extended duty" system. It is only possible to do so by having residents assume duty at odd times – such as 1400 or 0300, or by using "swing shifts" where residents work some night shifts and some day shifts every week.

The only alternative to the "swing shift" approach would be to use non-resident providers to provide care from 2200-0800. Neither the providers nor the funds to pay them currently exists in public hospitals.

3. "Hybrid" systems".

It would be possible to assign a "night float" resident to be responsible for admissions between 2200 and 0800, with one or more other residents assigned to "extended duty" calls who did not admit patients between 2200 and 0800. Those residents could then care for patients when they were not sleeping, and could presumably assume care of patients when their sleep time was over. This would require that the care of patients be transferred at 2200, 0300, and 0800 (and presumably at approximately 1900), thus increasing the number of handoffs and the potential for error.

The net result of implementing the recommendations of the IOM will be to force residencies into a "night float" system AND to increase the number of residents assigned to night call. As a result, residents will spend more time on night duty and less time on day duty. Of necessity, daytime rotations will be decreased which is the time that is largely devoted to ambulatory care and education. Thus the net result on resident education will be to increase service over education and reduce outpatient experience.

Finally, we have published data to show that residents in different disciplines have markedly different work loads and hence different sleep hours during a shift. Therefore, it seems quite clear that one set of rules is an undesirable approach.

To the Members of the Accreditation Council of Graduate Medical Education:

In December of 2008, the Institute of Medicine issued a report entitled "Resident Duty Hours: Enhancing Sleep, Supervision, and Safety"[1] which recommends substantial changes in the current structure of resident work hours and supervision. Earlier this year, the ACGME initiated a call for comments about these recommendations. We hope that the following can help provide some insight into the experience of those who will be directly affected by any new changes. We, the Resident and Fellows Council of UCSF, are grateful for the chance to voice our impressions and concerns about the impact of these recommendations on our training, our health, and patient safety.

As you well know, in 2003, most physician training programs were forced to re-design their schedules to come into compliance with the ACGME regulations. As a whole, residents and fellows feel that the mandate of an 80-hour workweek is more humane than the prior unregulated work hours and has made a significant improvement in resident well-being. We recognize that the driving force behind both the 2003 duty hour changes and the new recommendations is patient safety. Unfortunately, on the basis of several studies[2], the 2008 Institute of Medicine report itself concludes that there is insufficient data to link a decrease in duty hours to a decrease in adverse events. There is also anecdotal and statistical evidence that the 80-hour workweek is not fully enforced. In general, we recommend that research be funded to study the impact of these recommendations before any more substantive changes are made to the system. Therefore, while we applaud the underlying goals of the new Institute of Medicine recommendations, we also have significant concerns about how they will affect patient safety, resident training, and resident well-being.

Below we discuss our thoughts regarding specific recommendations:

***Eighty Hour Workweek:* The eighty-hour work week has not been critically evaluated as the optimal training period, and increasing regulation may further complicate patient care.**
The Residents and Fellows Council (RFC) is concerned that four week averaging violates the intent of the rules, negates the safety benefit, and allows for maximization of resident utilization in a manner not conducive to patient care. Further, by averaging – complex systems are required to be put in place to enforce time restrictions inherent to each individual shift. Thus, it adds a layer of complexity and inflexibility relative to specific specialties. In our opinion, much of the additional regulation presented in the IOM report would be unnecessary if the 80 hour workweek was enforced weekly or over 2 week intervals with a capitation on the maximum work hours per week. A maximum limit to the number of hours allowed per week would help prevent those times when residents work 110 hours one week, but only 50 hours the next, thus averaging to 80 hours over the two week interval. A maximum ceiling of 90 hours for any given week, with averaging to 80 hours over 2 weeks would be one such alternative.

We would recommend further research into the optimal work-week for competent and humane residency training. While no resident or fellow is in favor of a return to the 120 hour workweek, there are significant concerns, particularly among the procedural-based residents, that even the 80 hour workweek may detrimentally affect the quality of residents and may result in inadequately trained independently practicing surgeons[3]. European studies have shown a reduction in quality of graduating surgeons with reduction in work hours[4]. It may turn out that different specialties require different work hour requirements but we do not feel there is currently enough information to make judgments about this issue.

***Maximum Shift Length:* The 5-hour rest period will further complicate resident work hours and will likely harm patient care through increased hand-offs.**
The IOM recommendations call for a 5-hour rest period during a 24 hour call period. Most programs utilize a 24 hour call team that admits and cares for patients for 24 hours, with 6 additional hours for follow-up education and handoffs (as per the 2003 recommendations). Within this construct, a 5 hour "nap" inherently requires at least 2 additional hand-offs, which have been cited as a cause of medical errors[5, 6]. There is also significant concern from residents and fellows that the 16 hour shift will affect continuity of learning, in addition to the obvious disruption in continuity of care. We would support changes that would reduce the number of handoffs. Rather than attempting to conform all specialties to the recommendation – the recommendations should be flexible enough for the inherent differences between specialties.

Having both a shift of 24 hours with 24 hours off or 12 hour shifts, and an option of 30 hour shifts with protected sleep time is a reasonable way to provide this flexibility.

Maximum Frequency of In-Hospital Night Shifts: **We strongly oppose the 4 night shift maximum recommended by the IOM and believe it is not conducive to either resident well-being or patient safety.**
The 16 hour shift, as discussed above, will be difficult to implement given the multiple handoffs involved and need for more staffing at night. The logical option, then, is a night shift schedule, already used by many programs. However, the IOM goes on specifically to recommend only 4 night shifts in a row. This recommendation does not appear to be evidence based. As with nurses and shift working truck drivers, switching shifts may prevent residents and fellows from acclimatizing to a particular schedule and thereby cause further sleep disturbances[7, 8]. Restricting the length allowed for night float appears to work against the residents. Working six 12 hour days is not unreasonable in our opinion. We support the 48 hour period off, but only when switching from a night rotation back to day. Restricting the shift to 12 hours may be reasonable, but will have the side effect of extending the day shift to 14 hours increasing the need for handoffs on many services. Again, we feel that limiting specific types of shifts is not necessary in most cases and strongly prefer that the weekly 80 hour limit be enforced with limited averaging. This maximizes flexibility while preserving a reasonable and safe work experience.

Additionally, the Resident and Fellow's Council submits that while shift restrictions may be beneficial – there are unintended side effects. Many sub-speciality attendings routinely work shifts longer than 16-24 hours. Physicians should experience and learn strategies to cope with long hours as residents, with supervision, rather than facing this challenge for the first time as an attending physician. Someday there may be limits on the hours attending physicians work – until then, it is the duty of training programs to prepare residents and fellows for the reality that awaits them.

Mandatory Time Off Duty/ Maximum In-Hospital On-Call Frequency: **The RFC is concerned that mandatory time off duty requirements may prevent residents and fellows from adequately participating in personal activities.**
The 2003 ACGME report states that, "adequate time for rest and personal activities must be provided." The new recommendations limit call shifts to every third night and implement a mandatory 48 hour off period once per month. Initially, this is certainly appealing; however we feel there is an unfortunate downside as well. One of the coping strategies residents and fellows use during training is visits to family and friends. The ability to attend "life" events, such as weddings and reunions, is critical to resident and fellows balancing the physical and psychological demands of working long hours. These events frequently take place outside the city of training. It is our fear that by mandating one day off in 7, not averaged over a month, may make it hard for residents and fellows to find time for these important personal activities. Allowing residents and fellows to arrange with their teams their time off duty helps us adequately balance our work-life with our personal life, a vital ability as we transition into independently practicing physicians.

Additionally, for programs that are heavily weighted to inpatient call, the mandatory shift limitations may completely eliminate weekends during which a resident could leave their place of training. For example, rather than beginning travel on a Friday evening resident may be forced to start their 48 hours post-call on Saturday morning in order to minimize the use of alternate coverage. This is not conducive to the intended goal of allowing residents and fellows a protected time for relaxation and the ability to attend life events.

***Moonlighting*:** **We agree with the IOM recommendations concerning moonlighting.**
Given the anecdotal report that most programs strongly discourage moonlighting and that most residents do not engage in this activity, we feel it is reasonable to make this change in counting both internal and external moonlighting hours towards the 80 hour workweek.

***Home Call*:** **The RFC recommends that the IOM and ACGME research and address the impact of home call on patients' safety and resident well-being.**

The Residents and Fellows Council feels that one of the most prevalent abuses of the current system is home call. Though this has been previously addressed in the original ACGME regulations, we were surprised and dismayed that this issue was not addressed in the IOM recommendations. It is common practice for residents and fellows to round in the AM, field pages all day and night from home, and then return to round the next day – repeating this cycle for days at a time. With the advent of computerized records and computerized ordering, it is quite feasible to work from home making advanced medical decisions. We question which is safer – repeated home call and attempting to perform as much patient care from home versus call every third night with a maximum 30 hour shift. The Resident and Fellow's Council requests that the ACGME recognize that institutions are using this workaround to avoid the letter and spirit of the current regulations and to specifically institute policies to address this problem. It is quite possible that programs will increase home call to comply with the newly proposed recommendations. This would be antithetical to the goals stated by the IOM and ACGME.

Training Length: **To ensure appropriate competency, many residents worry that increased regulation will require a lengthening of residency training.**
As stated in the new IOM report, "the principal aim of medical residency in the United States is to prepare recent medical school graduates to practice medicine independently." In general, it is our feeling that the 2003 ACGME recommendations are sufficient to allow residents and fellows to learn in a controlled setting. However, the addition of multiple new regulations that will not apply upon graduation from training does not ready us for the rigors of independent practice. The new recommendations significantly disrupt the work schedule and are unlike current practice in the broader medical community.

As an extension of this, there is real concern that residency training programs will have to be extended, with those programs already on the long end of the spectrum disproportionally affected. The average graduate from surgical residency is already 33 years old[9]. Data from our house staff surveys demonstrate that majority of residents do not contribute to retirement accounts or savings because they cannot afford to. Extension of residency programs not only decreases the number of years spent earning an attending salary, but also significantly affects our ability to responsibly plan for our families and retirement.

Supervision: **The RFC support the appropriate supervision of trainees, particularly early in training, to ensure adequate patient safety.**
We wholeheartedly agree that proper supervision is critical to safety and patient care. The Residents and Fellow's Council supports efforts and regulation to ensure appropriate supervision at all levels of residency, and in house supervision of interns. In addition, we would add that second year residents transitioning from preliminary or transitional years might also benefit from in house supervision dependent on responsibility.

Safety: **We applaud the IOM's commitment to resident and fellow safety.**
We fully support requiring hospitals to ensure all residents have access to free or reduced cost transportation after working extended shifts. In addition, the Council supports regulation aimed at enhancing personal safety where appropriate. Residents should not be placed in the position of walking to their car in a dark, distant lot while sleep deprived. We applaud the IOM for reaffirming resident and fellow safety.

Enforcement: **Enforcement continues to remain a concern among residents and fellows.**
The IOM report clearly delineated a list of ways to increase enforcement – and we support most of these including unannounced audits by regulatory agencies. We would caution that these agencies should be independent of both the training programs and payees, such as CMS, to avoid undue conflict of interests. We would ask for an independently operating third party that would not have any vested interest in the financial outcomes of the institutions but would instead be concerned with the primary aims of the ACGME: patient safety, resident training, and resident wellbeing.

Concluding Thoughts
In summary, we would like to thank the ACGME for this opportunity to voice our thoughts and concerns over the IOM recommendations. We feel that the spirit of the current regulations may be adequate to ensure patient safety and comprehensive resident training. It is our concern that the new IOM

recommendations fail to recognize that the current mandates are not yet fully followed. We agree that stronger program supervision may lead to better compliance. Complete compliance with current mandates may minimize the need for more rigid regulations. We strongly feel that enforcing the current regulations would accomplish many of the goals cited by the IOM while maintaining flexibility for departments, trainees, and medical centers. In our opinion, the addition of regulations prior to achieving sufficient compliance with the current system does very little to improve the current state of medical care; it restricts the ability of residents and fellows to participate in activities that help alleviate stress, and in the long run, may decrease preparedness for the demands of practice post-training. As well, we would strongly encourage improved data collection about the impact of these changes and improved funding into research on work hour changes.

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