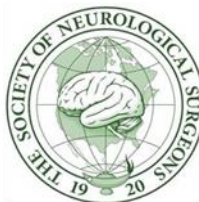


Comments of the
Society of Neurological Surgeons
American Board of Neurological Surgery
American Association of Neurological Surgeons
Congress of Neurological Surgeons

to the
Accreditation Council for Graduate Medical Education
on the subject of
ACGME Review of Resident Duty
Hours Policy

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Executive Summary

1) Your organization's formal position on the current ACGME resident duty hour requirements, including impact analysis, from your organization's perspective, on costs and impact of implementation.

Summary Statement:

Mastery of the knowledge and skills required to manage expertly the extensive and wide-ranging list of neurosurgical disorders requires many years of commitment and intensive experience.

Neurosurgical practice is unlike many other medical specialties. Neurosurgical procedures are long — lasting an average of four hours, but often more than eight to ten hours — and the learning episodes — from presentation, through evaluation, surgical treatment, and immediate postoperative care — can be very long. To obtain the most educational value from these learning episodes, and to best serve their patients, residents must be able to participate in each phase of the learning episode. These learning episodes frequently cross the “shift” boundaries set up by work hour restrictions.

Studies and surveys demonstrate a number of deleterious effects from duty hour restrictions, including:

- A reduction in the overall hours of surgical experience
- Use of midlevel practitioners to assume educationally valuable activities
- Reduction of time in elective operations
- Compromises in the continuity of care
- Reduced research and conference time

Studies also demonstrate that more medical errors in neurosurgery derive from transfers of clinical responsibility (“handoffs”) than from fatigue.

Current duty hour rules have led to the development of a “shift work” mentality and loss of commitment and professional responsibility to the patient.

Current duty hour rules often create moral dilemmas for residents. They must choose between commitment to their patients and the requirement to end their “shift.” If they keep their commitment to their patients and thereby violate duty hour restrictions, they face another moral dilemma of being untruthful about the duty hours violation or adversely affecting their training program.

Recommendations:

Allowing a more flexible schedule within the current 80-hour workweek system would help residents internalize the importance of the continuity of care, take personal responsibility for their patients and avoid the moral dilemmas of the present system thus realigning surgical education with professionalism.

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

Summary Statement:

Maximizing patient safety and resident education requires attention to supervision and fatigue management, not a restriction of duty hours and designated shifts. Supervision will vary according to the level of training, with junior residents requiring more immediate supervision than senior residents who are assuming a greater degree of autonomy and responsibility for patient care. The last year of resident training is a transition to practice year during which the resident develops the time management, clinical and operative skills to become an independent neurosurgical practitioner.

Recommendations:

Recommendations for graduated responsibility and work hours for neurosurgical training:

PGY 1: Residents are learning to take care of the neurosurgical patient before and after surgery in the neurocritical care unit and on the neurosurgical wards. They are closely supervised by more experienced residents, fellows and faculty members during this time.

- 80 hours per week averaged over four weeks
- One day in seven off-duty averaged over four weeks
- 10 hours off between duty shifts
- In-house call (24-hour shift) may be followed by up to 10 hours to permit the resident to participate in the operating room, participate in didactic activities and maintain continuity of care.

PGY 2-4: Residents gain increasing surgical responsibility, and while taking in-house call, are the "first contact" for patient care. Residents are supervised by more experienced residents, fellows and faculty members during this time.

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

PGY 3-7: Residents in the final years of education may stay on duty or return to the hospital with fewer than eight hours free of duty under the fellowship circumstances:

- Required continuity of care for severely ill or unstable patients
- Required continuity of care for a complex patient with whom the resident has been involved
- Events of exceptional educational value
- Humanistic attention to the needs of a patient or family

PGY 5: Residents in a supervisory role, usually not taking call in-house. By definition, these individuals are not the "first contact" for patient care. One or more of these years may be devoted

to focused, subspecialty practice and/or research in neurosurgery. Residents are supervised by more experienced Chief Residents, fellows and faculty members during this time.

- 88 hours/week averaged over four weeks
- One day in seven off-duty averaged over four weeks

PGY 6: Chief Resident (this may occur in either the 6th or 7th year of training). Assumes responsibility for managing the neurosurgical service, organizing conferences and supervising less experienced residents. The last year of training is a transition to practice year in which the resident develops the clinical and operative skills to become an independent neurosurgical practitioner. The resident is given greater autonomy but continues to be supervised by faculty members during this year.

- One day in seven off-duty averaged over four weeks

PGY 7: Focused training in a neurosurgical subspecialty and/or research (this may occur in either the 6th or 7th year of training). Assumes greater autonomy in managing the subspecialty neurosurgical patients and supervising less experienced residents. The last year of training is a transition to practice year in which the resident develops the clinical and operative skills to become an independent neurosurgical practitioner. The resident is given greater autonomy but continues to be supervised by faculty members during this year.

- One day in seven off-duty averaged over four weeks

3) Your organization's formal recommendations regarding standards governing key aspects of the Learning Environment, and justification (wherever possible) for these recommendations with evidence.

Summary Statement:

A well-trained, safe neurosurgeon must:

- Obtain technical and clinical mastery, which requires many hours to achieve. Effective duty hour standards must not limit essential operative and peri-operative experience. Steadily increasing, supervised responsibility throughout residency training, leading to the transition to independent practice, is essential to create safe neurosurgeons.
- Develop professionalism and surgical ownership. Patients expect their surgeons will be available to care for them throughout their surgical encounter and duty hour restrictions must not interfere with this, especially in the post graduate years six and seven.
- Learn how to recognize and manage fatigue. Fatigue is a fact of life in a surgical career. It cannot be avoided but can be identified and managed through the development of strong professional skills that require mentorship and practice during training to be effectively implemented during independent practice.
- At present, neurosurgical training takes, at least, seven years. Further duty hour restrictions would require extending clinical training even longer. Students will not be willing to train for ever longer periods of time and the recruitment of high quality, talented medical students to neurosurgery would be compromised.

Recommendations:

The standards governing key aspects of the Learning Environment should take into account unique aspects of neurosurgical practice. Duty hour standards should conform to the fact that:

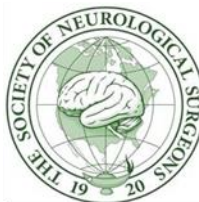
- Neurosurgical operations are long and technically demanding. The average operating time of four hours doubles that of other fields.
- The scope and breadth of neurosurgical disease requires a diverse set of surgical and clinical skills, with very long learning episodes that cannot readily be compressed into a single "shift."
- Neurosurgeons lack meaningful counterparts in other specialties to provide similar care in their absence.
- The diversity of clinical conditions demands that each resident gain exposure to the entire range of pre-operative, operative and post-operative care for all conditions.
- Neurosurgeons have substantial outpatient practices, inpatient practices and need to staff emergency departments and trauma centers. All of these skills need to be learned during residency.

4) Your organization's willingness to participate, if invited, in a Resident Duty Hours in the Learning and Working Environment Congress, to be held in March 2016 in Chicago Illinois. The attendees of this Congress will be configured to provide the ACGME with the breadth of perspectives across the medical community as it embarks on review and revision of the requirements addressing resident duty hours and the learning and working environment.

Neurosurgical organizations will enthusiastically participate in the Resident Duty Hours and the Learning Environment Congress in Chicago in March. Representatives from each of the neurosurgical organizations below would like to participate:

Society of Neurological Surgeons
American Board of Neurological Surgery
American Association of Neurological Surgeons (AANS)
Congress of Neurological Surgeons (CNS)
AANS/CNS Washington Committee

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.



January 14, 2016

Thomas J. Nasca, MD, MACP
Chief Executive Officer
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SUBJECT: ACGME Review of Resident Duty Hours Policy

Dear Dr. Nasca,

On behalf of the Society of Neurological Surgeons, American Board of Neurological Surgery, American Association of Neurological Surgeons, and Congress of Neurological Surgeons, we thank you for the opportunity to provide you with our views on resident duty hour standards for neurology. In response to your letter dated Dec. 21, 2015, this document represents organized neurology's position on this topic. Our specialty looks forward to participating in the ACGME process to evaluate this important issue. Our responses to your inquiries are outlined below:

Introduction and Background

Over the last several decades, the individual apprenticeship model of graduate medical education has been replaced by a team-based approach. Although there is much benefit that may accrue from a team-based approach, adverse consequences for patient care and resident education may also occur. Work hour restrictions represent one such negative consequence. The 1984 Libby Zion case provided the anecdotal impetus for reducing resident work hours. Political pressure funded and led to the publication of the Institute of Medicine (IOM) report "To Err is Human," which contributed to the establishment of the 80-hour work week by the Accreditation Council for Graduate Medical Education (ACGME). The concepts that fatigued in-house officers places patients' safety at risk and inhibits education of residents was also the driving force behind the Institute of Medicine's subsequent recommendation to restrict further and regulate resident work hours. Many previous authors have noted it ironic that in a field where data-driven decision making is lauded as the gold standard, this approach has not been rigorously applied to graduate medical education. **[See, Appendix]**

The 2003 work hours regulations designed by the ACGME, and those proposed by the 2008 IOM report, were assumed to improve patient safety and resident education regardless of specialty. Our hypothesis, initially stated in 2009, was, that for neurology, further work hour restrictions would adversely affect resident education without improving patient safety. Stated another way, we were very concerned that we would be putting future patients at risk without reducing the risk to our present patients. We believe that most of the data that have been generated since our 2009 report support our concerns. **[See, Appendix]**

Discussion

There are many ways to approach the issue of how we can most efficiently and safely provide patient care and high-quality graduate medical education in neurosurgery. The IOM recommendations focused on the effects of sleep deprivation, using available sleep literature to support their proposed regulations. We suggested that this proposal failed to consider the educational and patient safety trade-offs inherent in more stringent work hour restrictions. While benefits may accrue to having more rested residents is good, a substantial reduction in clinical and operative experience, fewer educational conferences and less resident research time would have substantial adverse effects on resident training. We highlighted areas where we believed the negative impact of further work hour restrictions would outweigh any benefit. As noted above, we believe that the data that have been collected since our 2009 report tend to support our concerns. **[See, Appendix]**

The training required to manage multiple nervous system problems includes emergent surgical interventions for trauma and vascular diseases, urgent intervention in many forms of brain tumors and more elective approaches to disorders such as peripheral nerve disorders, epilepsy, movement disorders, degenerative spine disease and pain. What each of these disorders has in common, however, is that surgical intervention is often dependent on detecting a change in the patient's neurological status over time. That change may be dramatic and sudden — such as a stroke or hemorrhage — or may be slow with subtle neurological changes. Regardless, during early years of training, residents must be 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 ever more challenging surgical interventions. The resident must learn to recognize and diagnose neurosurgical disease, make an appropriate decision to intervene, perform the invasive procedure and care for the patient following the procedure. It would be professionally destructive for a resident to engage in a procedure where he or she assumes a significant role in surgery without completing the operation or treating that patient's postoperative complication because it falls at a time after his or her "shift" is over. 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 surgeon and patient. Public and patient expectations are incompatible with the practice of neurosurgeons as shift workers.

Following the initial work hour restrictions, hospitals responded by providing support staff in the form of physician assistants and nurse practitioners, better ancillary services, and better digital imaging systems. Organized neurosurgery has been working on curriculum development to improve competency-based training, enrolling fellowships into resident training programs and improving the quality of resident education. We have worked closely with the ACGME to develop the Next Accreditation System (NAS) and to refine the Neurosurgical Milestones. We believe in collecting reliable data, analyzing it carefully and feeding it back to individual program directors as the best way to improve resident education and ensure the safety of patients now and in the future. We are convinced that focusing on restricting work hours, rather than on adequate supervision, quality improvement, and fatigue recognition and management is misguided.

We recommend that the ACGME follow its present plan of conducting randomized studies that will allow us to analyze the impact of work hour restrictions. We further recommend that the ACGME recognize that one size will not fit all residency training programs. It will be essential to allow flexibility in work hour restrictions to accommodate the differences among specialties. Shift work is a training model, which is anathema to what we — and the American public — expect of neurosurgeons. Those who choose the field of neurological surgery do so with an understanding of the challenges that lie before them. Altering our training system to create neurosurgeons who may lack the necessary skills to care for their future

patients is unwise. Until we have irrefutable evidence to the contrary, we are obliged to adhere to the long-tested principles of neurosurgical training — responsibility, professionalism, and dedication.

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 strongly oppose a role for the Centers for Medicare and Medicare Services (CMS), the Joint Commission or other entities in this area. Only the ACGME has the requisite knowledge, infrastructure and experience.

Responses to Questions Posed by Dec. 21 Letter

The following discussion responds to the specific questions posed in your recent letter.

1) Your organization's formal position on the current ACGME resident duty hour requirements, 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 must have had sufficient training to manage expertly and execute a series of diagnostic and therapeutic decisions. Training must include taking a detailed history; interpreting the salient points of the history; performing a neurological examination; generating a differential diagnosis list; ordering and interpreting appropriate diagnostic studies (e.g. MRI, CT, angiography, EEG, EMG, nerve conduction studies, CSF analysis, clinical laboratory studies and others); and reaching a preliminary diagnosis. To accomplish this, a neurosurgeon must have knowledge of the myriad neurological disorders — surgical and non-surgical — affecting the brain, spinal cord, and peripheral nerves, their clinical manifestations, and their imaging or other diagnostic testing characteristics. At this point, the neurosurgeon must make a recommendation to the patients regarding management. This requires detailed knowledge of the medical and surgical options for treatment, their expected benefits, limitations, and associated risks. The neurosurgeon must have experience with the natural history of a broad range of disorders, decide if neurosurgical treatment is indicated, and if so be able to select the optimal operation, plan the procedure, and expertly perform the surgery.

The surgical intervention requires motor skills, precise knowledge of neuroanatomy and neurophysiology, experience and practice in executing many different surgical procedures and the experience and knowledge needed to deal with a wide range of contingencies that may occur during surgery. The neurosurgeon must have the stamina to maintain concentration and peak performance for operations that often take many hours. After surgery, the neurosurgeon must be able to provide expert postoperative care, including the capacity to diagnose and manage the full range of potential complications. These essential skills are required for disorders within many categories of neurosurgical disease, including, but not limited to, brain trauma; spine and peripheral nerve trauma; degenerative disease of the spine; nerve entrapment syndromes; brain tumors; spinal cord tumors; peripheral nerve tumors; metastatic tumors to the brain and spine; pituitary tumors; central nervous system infections; cerebrovascular disease, including ischemic and hemorrhagic stroke; intracranial aneurysms; vascular malformations; hydrocephalus; epilepsy; Parkinson's disease and other movement disorders; pain syndromes etc. This list is not inclusive. The surgical intervention may be

using an open surgical procedure, stereotactic placement of stimulating electrodes, an endovascular procedure, use of focused radiation or ultrasound or stereotactically directed laser ablation. This list is also not inclusive. New treatment modalities and new indications occur on a regular basis.

Following the neurosurgical procedure, the neurosurgeon must be able to manage the patient in the neurocritical care unit or the neurosurgical ward. This requires the ability to anticipate, recognize and treat a myriad of possible post-operative complications that may involve all organ systems in addition to the nervous system.

Mastery of the knowledge and skills required to manage expertly this extensive and wide-ranging list of disorders, from presentation through recovery, requires years of commitment and intensive experience. When work hour restrictions were introduced there was considerable concern that decreased experience would compromise the training of neurosurgical residents. The effects of the present restrictions have been studied by examining the cumulative number of hours in surgery during neurosurgical residency and by surveys of neurosurgical residents and neurosurgical program directors. The results of these studies and surveys indicate that there has been a reduction in the overall hours of surgical experience, the need to employ advanced practice clinicians (physician assistants and nurse practitioners) to assume some clinical activities of educational value, reduction of time in elective operations, interruption in the continuity of care and altered conference schedules. The studies and surveys also suggest that more medical errors in neurosurgery derive from transfers of clinical responsibility ("handoffs") than from fatigue.

Because it is hard to quantify, there is limited information on what we believe is the most concerning aspect of the effects of work hour restrictions — the development of a "shift work" mentality and the loss of the sense of professional responsibility and complete dedication to the patient. This problem derives not from the overall limitation of hours in the resident work week but rather from the inflexibility of the current restrictions regarding continuous work hours.

Several features of neurosurgical practice are different from many other disciplines. For example, neurosurgical emergencies are common, they often occur at night, and they often require an evaluation of changes in the patients' neurological status serially over a period of time. For optimal patient care and as a vital part of resident education, these serial evaluations are best performed by the same individual. As previously noted, neurosurgical cases last an average of four hours, and many take considerably longer — often eight hours or more. The self-discipline and stamina needed to maintain intense concentration and retain peak motor and intellectual performance over many hours — critically important features of a safe neurosurgical practice — are learned by experience. If residents must leave the operating room in the middle of a case or leave their patients during an important event in the neurocritical care unit or on the ward, they lose much of the educational value of the learning episode. More importantly, they may not develop an essential component of neurosurgical training — taking personal responsibility for their patient's care as long as their patient needs them. It is this "shift work" mentality that is our greatest concern. Increased flexibility in the distribution of the work hours within the 80-hour weekly limit would help residents recognize the importance of continuity of taking personal responsibility for their patients.

Summary

It is the position of organized neurosurgery that the implementation of 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 that will enhance patient safety, improve resident education and thus enhance the safety of future neurosurgical patients as well.

2) 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 ensuring the safety of today's patients, optimal supervision and education of our resident trainees, the health of our residents and continued access to well trained and responsible neurosurgeons in the future. We believe that duty hour restrictions must be more flexible and that they must vary according to the level of training. Accordingly, we strongly recommend the following dimensions for resident training in neurological surgery:

PGY 1: Residents are learning to take care of the neurosurgical patient before and after surgery in the neurocritical care unit and on the neurosurgical wards. They are closely supervised by more experienced residents, fellows and faculty members during this time.

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

PGY 2-4: Residents gain increasing surgical responsibility and while taking in-house call are the "first contact" for patient care. Residents are supervised by more experienced residents, fellows and faculty members during this time.

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

PGY 3-7: Residents in the final years of education may stay on duty or return to the hospital with fewer than eight hours free of duty under the fellowship circumstances:

- Required continuity of care for severely ill or unstable patients
- Required continuity of care for a complex patient with whom the resident has been involved
- Events of exceptional educational value
- Humanistic attention to the needs of a patient or family

PGY 5: Residents in a supervisory role, usually not taking call in-house. By definition, these individuals are not the "first contact" for patient care. One or more of these years may be devoted to focused, subspecialty practice and/or research in neurosurgery. Residents are supervised by more experienced Chief Residents, fellows and faculty members during this time.

- 88 hours/week averaged over four weeks
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PGY 6: Chief Resident (this may occur in either the 6th or 7th year of training). Assumes responsibility for managing the neurosurgical service, organizing conferences and supervising less experienced residents. The last year of training is a transition to practice year in which the resident develops the clinical and operative skills to become an independent neurosurgical practitioner. The resident is given greater autonomy but continues to be supervised by faculty members during this year.

- One day in seven off-duty averaged over four weeks

PGY 7: Focused training in a neurosurgical subspecialty and/or research (this may occur in either the 6th or 7th year of training). Assumes greater autonomy in managing the subspecialty neurosurgical patients and supervising less experienced residents. The last year of training is a transition to practice year in which the resident develops the clinical and operative skills to become an independent neurosurgical practitioner. The resident is given greater autonomy but continues to be supervised by faculty members during this year.

- One day in seven off-duty averaged over four weeks

The nature of these dimensions increases the flexibility for house staff and program directors to modify a daily schedule to maximize the educational experience. We recognize that this is a demanding schedule. Neurosurgery is a demanding profession with the highest of stakes.

3) Your organization's formal recommendations regarding standards governing key aspects of the Learning Environment, and justification (wherever possible) for these recommendations with evidence.

Standards Governing the Learning Environment

Standards governing the learning environment 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

Surgery involves an extraordinary level of trust on the part of our patients. The surgeon-patient agreement carries an implicit understanding that the surgeon will be present to see the patient through their experience. The culture of ownership and doing what a patient's care demands as long as necessary are essential features of neurosurgical training. When duty hour restrictions

interfere with a patient care task, physicians-in-training face a conflict between regulatory compliance and their dedication to their patients.

Graduated and Supervised Responsibility

One hundred years of neurosurgical education rests on the culture of graduated, supervised responsibility. The subsequent discussion explores the neurosurgical learning environment.

Neurosurgical residency training differs from many other specialties. For example, the hierarchical approach of surgical training limits the responsibility of junior residents in medical decision making. Senior and chief level neurosurgical residents are involved in all aspects of patient care while supervising the care of more junior residents. Review of the junior and chief neurosurgical resident responsibilities will elaborate this critical difference. These important differences may explain the differing impact of existing duty hour standards on medical and surgical resident well-being. **[See, Appendix]**

Regarding technical skills development and medical decision making, the first postgraduate year focuses on perioperative management of neurosurgical patients — ranging from surgical indications to critical care — as foundational knowledge for neurosurgical training. Related neurosciences including pathology, radiology and neurology augment this early patient care experience. During the PGY 2-4 years, procedural skills involve the stepwise mastery of patient positioning, operative opening, meticulous hemostasis and efficient wound closure as essential prerequisites for any successful surgical procedure. As residents progress through these years they do more and more of the surgical procedures under close supervision.

Finally, supervised 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 residents' responsibilities are straightforward. First, reliable reporting of information to more senior residents and faculty members demands impeccable honesty at all times. Second, when given responsibility for carrying out a clinical assignment, the junior resident must complete the task and provide an accurate account to more senior residents and faculty members. Finally, junior residents must know their limitations and exercise a low threshold for requesting help from more senior members of the neurosurgical team.

The senior and chief residency years in neurosurgery further develops the culture of responsibility and surgical ownership fundamental to successful neurosurgical care. In the neurosurgical culture of delegated, graduated and supervised responsibility the senior and chief residents and the neurosurgical faculty members must be supportive and available. Senior and chief neurosurgical residents participate throughout a patient's surgical encounter. They develop technical proficiency in surgical procedures and direct the perioperative care. The chief resident is being prepared for the rigors of independent practice at a time when the support of the neurosurgical faculty members remains available. Duty hour regulations must not interfere with this critical transition to practice. In addition to the development of technical skills and professionalism, supervision by the chief resident mitigates against the transfer of care errors that impact patient safety.

Fatigue Management

Fatigue management at the individual resident level follows from a culture of graduated, supervised responsibility. Senior residents and faculty members carefully monitor the

performance of junior residents and make schedule adjustments to provide safe and effective patient care. Senior residents participate throughout a patient's episode of care 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 affecting the patient. The absence of data tying surgical patient safety to fatigue-related errors raises the concern that we are sacrificing the safety of future patients without improving the safety of our current patients.

One Size Does Not Fit All

We must take into account the vast variety of day-to-day tasks among medical specialties. Emergency medicine physicians, for example, independently have adopted a shift work approach to manage a relentless emergency department census and acknowledge the lesser importance of continuity of care in a specialty devoted to short, acute clinical interactions. Radiologists must manage fatigue in a manner different from surgical specialties. Neurosurgeons engage in active, physical tasks requiring extreme focus. Prolonged attention and the stakes involved require sustained focus and alertness — concepts familiar to any neurosurgeon, but 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. Neurosurgical residents must have significant exposure to each subspecialty area to function in independent practice. Neurosurgeons lack meaningful counterparts in other specialties to provide similar care in their absence. Operations tend to be long and technically demanding — the average operating time of four hours doubles that of other fields. The diversity of operations further requires that each resident gain an exposure to the broad range of expected post-operative recovery and the recognition of post-operative complications. In addition to the issues surrounding neurosurgical procedures and in-hospital care, neurosurgeons also have a tremendous elective and emergency outpatient practice. These aspects of neurosurgery demonstrate the demanding practice environment awaiting neurosurgical trainees. A successful neurosurgeon must be able to manage these diverse clinical responsibilities and the fatigue that will occur. The opportunity for the senior and chief neurosurgical residents to navigate patients through their entire episode of care is essential to training safe neurosurgeons.

- 4) Your organization's willingness to participate, if invited, in a Resident Duty Hours in the Learning and Working Environment Congress, to be held in March 2016 in Chicago Illinois. The attendees of this Congress will be configured to provide the ACGME with the breadth of perspectives across the medical community as it embarks on review and revision of the requirements addressing resident duty hours and the learning and working environment.**

Neurosurgical organizations will enthusiastically participate in the Resident Duty Hours and the Learning Environment Congress in Chicago in March. Representatives from each of the neurosurgical organizations below would like to participate:

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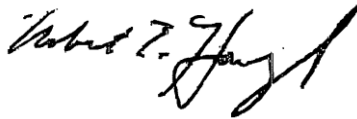
AANS/CNS Washington Committee

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.

Conclusion

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

Respectfully submitted,



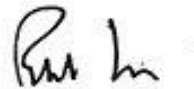
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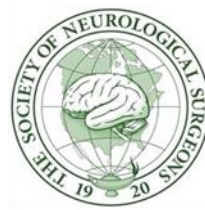


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Enclosure: Appendix

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Appendix

The following documents (attached) support the statements and recommendations presented herein:

1. Resident duty hour regulations: time for reassessment and revision.
2. On resident duty hour restrictions and neurosurgical training: review of the literature.
3. The effect of call on neurosurgery residents' skills: implications for policy regarding resident call periods.
4. Outcomes of Daytime Procedures Performed by Attending Surgeons after Night Work.
5. Comments of Organized Neurosurgery to the ACGME on the subject of Resident Duty Hours.



EDITORIAL

Resident duty hour regulations: time for reassessment and revision

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ABOUT 12 years ago the first national restrictions on the number of duty hours worked by residents in training were promulgated by the Accreditation Council for Graduate Medical Education (ACGME). We are now in a position to assess the impact of those regulations on the specialty of neurosurgery. It is important that we do this because the quality of and values held by future generations of American neurosurgeons are now being determined. What we are learning about these regulations (first implemented by the ACGME in 2003 and then revised in 2011) is very disappointing and a cause for concern among those interested in the quality of neurosurgical training in the US.

In the current issue of the *Journal of Neurosurgery*, Bina, Lemole, and Dumont² review and give their assessment of where we stand with regard to the duty hour regulations. In their succinct and comprehensive review they describe the impact of the regulations on fatigue, technical surgical training, and patient safety. To summarize their findings: the preponderance of evidence suggests that duty hour regulation has had no effect on patient safety and may in fact be harmful, and that residency training has probably been made worse by the regulations.

So almost 15 years after fundamental changes were made to the fabric of postgraduate medical education the question is “are we better off?” The answer to this question seems to be “no.” The rationale put forward by the sleep scientists who played a fundamental role in the adoption of the duty hour restrictions (DHR)—that if we restrict duty hours, patient safety would be improved—has not been validated by experience. Moreover, there is significant evidence that the quality of care has actually been diminished.¹

There is an overwhelming sentiment among experienced surgical educators that the quality of the surgical training environment has deteriorated in the wake of the DHR.¹ The American College of Surgeons, concerned about perceptions that the surgical trainee end product is not as good as it was, empaneled a working group to deal with the period of transition to independent surgical practice.⁵ Surgical residents express concern that their tech-

nical training may not be adequate and choose with increasing frequency to enroll in postresidency fellowships to augment their surgical experience.

The DHR and the resultant burden of “compliance” have taken a large toll on both residents and the dedicated educators who direct the residency programs. Residents who are concerned about the patients under their care and their families are frequently put in the position of having to leave their patients or needlessly sign out patient care responsibilities to colleagues who are not as familiar with their cases or invested in their care. My colleague notes that “... patients are reduced to a single box on a sign-out sheet, and ... the physicians on duty frantically refer to these sheets for even the most basic questions—‘I’m just cross-covering’” (David Limbrick, personal communication, 2015). Clearly transitions in care responsibilities must occur in complex hospital environments, but most practitioners believe that the endless churning of caregivers—mostly as a result of duty hour regulations—is excessive and detrimental to neurosurgical care and to patient well-being.³

For decades the best neurosurgical residents have taken pride in their progressively increasing surgical competence, with the realization that the more practical experience they accrue in intraoperative and perioperative patient management the better. Under the current DHR they must now leave the hospital, even when they realize that they could be sharpening their skills by doing another craniotomy for subdural hematoma or a spinal fracture reconstruction and stabilization. This has affected the culture of neurosurgical training programs and tends to devalue surgical technical competence.

In the 2011 regulations, accommodations were made for occasional exceptions to the restrictions in the case of a compelling educational benefit or for humanitarian support of a patient or family. In many academic centers, however, zealous Designated Institutional Officials (DIOs), who want to promote a “zero tolerance” policy of complete compliance, frown upon such exceptions because it is easier to have none than to explain a variance.

Millions of dollars are now being spent in our nation’s

academic medical centers to ensure compliance with the duty hour regulations. Complex software programs, additional personnel, and hours of paperwork and committee meetings are expended to feed the “duty hour compliance machine.” Program directors and coordinators spend hours devising complex block call schedules and continuously monitor the duty hour log software programs. All of these quantitative data can indicate complete compliance with the regulations. However, if a few residents fail to understand a question (for example, by using the word “sometimes” as opposed to “rarely”) they can submit “non-compliant” responses on the ACGME anonymous survey, triggering punitive actions by the ACGME. Under the new Next Accreditation System, the relative weight of the anonymous survey seems to have increased despite the fact that it is of questionable reliability.⁶ Systems may be carefully constructed to ensure compliance, but the motives of dedicated educators are called into question by the presumption of malevolence that is inherent in the anonymous survey mechanism. This pits busy program directors against residents and DIOs. For what? To ensure mindless compliance with rules whose fundamental rationale is now brought into question?

No thoughtful neurosurgeon would advocate a return to the crushing 120-hour work weeks that characterized neurosurgical training in the last century. Most neurosurgeons know that successful practitioners must, at an early age, learn to integrate and balance the professional and personal parts of their lives. This means setting reasonable limits on the hours they devote to their patients and to their continuing education. But rigid, bureaucratically complex rules applied in an atmosphere of punitive compliance are in conflict with such a process of rational work/life integration in a profession as complex and intense as neurosurgery.

Philip Howard, in his book *The Rule of Nobody*,⁴ describes how the prevalent, legalistic culture in the US today frequently creates complex regulations and detailed rules that prevent people on the ground from using their professional judgement to do the reasonable thing. He describes the pernicious effect this phenomenon has on those in our society who are responsible for accomplishing real things.

Think of any group activity in your life that works well—whether at the office, church, or Little League. In each one there will be people who do what’s right and sensible in the circumstances. Their record is probably not perfect, because they are human, but they achieve credibility not only by their skill but by their dedication to joint goals, and by the appropriate way in which they deal with others. The complexity of these types of moral traits can never be legislated but it is the glue holding together any healthy enterprise and society.

This is where we are now in the duty hour regulation area. We are slavishly struggling to comply with a set of complex regulations that often are in conflict with our professional responsibilities to our patients and that damage our training programs. Given that the much-anticipated improvement in patient safety has not occurred, the time has come to dramatically simplify the regulations, lessen the burden that they place on our residents and on neurosurgical educators, and let common sense prevail in postgraduate medical education. The only regulation should

be that residents should not work more than 80 or 88 hours a week, averaged over 4 weeks. The very disruptive policy of the 16-hour limit in Postgraduate Year 1 should be rescinded. This policy has significantly devalued the essential initial year of neurosurgical training, delaying the full incorporation of early stage residents into the team. The procedures of the ACGME should be changed to eliminate the punitive compliance mentality that dominates our daily interactions with our residents. We should teach our residents to thoughtfully integrate their professional and personal lives in the context of our demanding and complex specialty. In the formative residency training period of their lives, they should be able to vigorously pursue their surgical technical training, take care of their patients, and progressively amass that body of knowledge and experience that will sustain them for the remainder of their careers.

<http://thejns.org/doi/abs/10.3171/2015.4.JNS15574>

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Disclosure

Dr. Dacey has no financial conflicts of interest. He was a member of the ACGME Duty Hour Task Force, which was responsible for the 2011 Duty Hour Regulations.

Response

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We thank Dr. Dacey for his poignant, eloquent, and experienced editorial concerning our publication. As medicine in general and neurosurgery in particular navigates this sea change, we must be vigilant in evaluating Trojan Horse mandates. We truly appreciate seasoned voices and opinions like his.



On resident duty hour restrictions and neurosurgical training: review of the literature

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Within neurosurgery, the national mandate of the 2003 duty hour restrictions (DHR) by the Accreditation Council for Graduate Medical Education (ACGME) has been controversial. Ensuring the proper education and psychological well-being of residents while fulfilling the primary purpose of patient care has generated much debate. Most medical disciplines have developed strategies that address service needs while meeting educational goals. Additionally, there are numerous studies from those disciplines; however, they are not specifically relevant to the needs of a neurosurgical residency. The recent implementation of the 2011 DHR specifically aimed at limiting interns to 16-hour duty shifts has proven controversial and challenging across the nation for neurosurgical residencies—again bringing education and service needs into conflict.

In this report the current literature on DHR is reviewed, with special attention paid to neurosurgical residencies, discussing resident fatigue, technical training, and patient safety. Where appropriate, other specialty studies have been included. The authors believe that a one-size-fits-all approach to residency training mandated by the ACGME is not appropriate for the training of neurosurgical residents. In the authors' opinion, an arbitrary timeline designed to limit resident fatigue limits patient care and technical training, and has not improved patient safety.

<http://thejns.org/doi/abs/10.3171/2015.3.JNS142796>

KEY WORDS resident education; duty hours; Accreditation Council for Graduate Medical Education; neurosurgery residency

WITHIN neurosurgery, the national mandate of the 2003 duty hour restrictions (DHR) by the Accreditation Council for Graduate Medical Education (ACGME) has been controversial at best. Ensuring the proper education, training, socialization, and psychological well-being of residents while fulfilling our primary purpose of patient care has generated an 11-year debate. Many of the formal medical disciplines have studied the effects that DHR have had on resident education and have developed strategies to address the often conflicting needs of education and service. These studies are, for the most part, cross-sectional studies at single institutions, and, although they provide insight into the controversy, they are not specifically relevant to the needs of a neurosurgical residency or a busy neurosurgical service. The recent implementation of the 2011 DHR specifically aimed at limiting interns to 16-hour duty shifts has proven to be more controversial and challenging across the nation for

neurosurgical residencies—again bringing education and service needs into conflict.

Each medical specialty is unique—although there is overlap in ideology and there is commonality in that all are composed of physicians. With this uniqueness come needs and demands that are not transposable across specialties. We believe that a one-size-fits-all approach to residency training mandated by the ACGME is not appropriate for the training of neurosurgical residents. In our opinion, an arbitrary and artificial timeline designed to limit resident fatigue limits patient care and technical training of neurosurgical residents, and has not improved patient safety. We will touch upon the topics of fatigue, technical training, and patient safety relative to the DHR as they specifically regard neurosurgical training, and review the literature relevant to these issues as they pertain to neurosurgical training, in the first review on this topic since the implementation of the 2011 DHR. Novel studies reviewed

ABBREVIATIONS ACGME = Accreditation Council for Graduate Medical Education; DHR = duty hour restrictions; OR = operating room.

ACCOMPANYING EDITORIAL DOI: 10.3171/2015.4.JNS15574.

SUBMITTED December 8, 2014. **ACCEPTED** March 12, 2015.

INCLUDE WHEN CITING Published online October 16, 2015; DOI: 10.3171/2015.3.JNS142796.

in this article are summarized in Table 1 (a review of studies pertaining to the DHR in nonneurosurgical specialties) and Table 2 (a review of studies pertaining to the DHR specific to neurosurgery training).

Fatigue

The underlying premise of resident work hour restriction is that new physicians, given sufficient time to rest, will make fewer errors because their thought processes will be clearer. This is based principally on mainstream media coverage of the unfortunate case of Libby Zion in 1984 and the implementation of the 1989 adoption of “405 (Bell) Regulations” in New York State due to growing and vocal public concern that fatigued residents were the major cause of medical errors in academic institutions. There is a fallacious assumption hidden in the argument that medical errors are caused by fatigue alone. Were that true, it should follow that reducing resident fatigue will decrease medical error; however, that has not been borne out in studies following the implementation of DHR.^{11,19,24,28,38,40} These concerns of fatigue being a major factor in errors came out of a variety of studies demonstrating the impact of fatigue on a variety of skills—cognition, technical skills, driving, and so on—tested in residential sleep laboratories; the extrapolation of the results of these studies to physicians is questionable.⁹ The reality is that medical errors that impact patients directly arise from a complex system—of which residents play only a part and in which fatigue plays a minor role.

With New York State serving as the first proving ground of DHR in the US, it serves as an early example of the failure of DHR to improve patient safety. In a 2005 study, well after the implementation of the nationwide restrictions by the ACGME, no significant reduction in medical errors was noted for surgical patients in New York State’s academic hospitals.³² This study in fact demonstrated an increase in some intraoperative complications, namely accidental puncture or laceration, and in postoperative complications such as deep venous thrombosis and pulmonary embolus. The authors conclude that DHR in their intended fatigue reduction strategy do not improve patient safety, but they do mention that with the imposition of DHR, a culture-wide awareness of complications and medical errors has come into common parlance and consciousness. Essentially, more eyes are watching.

This problem is not unique to New York State or the US. Duty hours for trainees in Europe have also been steadily reduced in the past 2 decades. In the United Kingdom and in Switzerland, the European Working Time Directive recommended a 50-hour weekly limit with some limited exceptions. In Canada, the National Steering Committee on Resident Duty Hours has made recommendations to avoid 24-hour periods of duty without sleep.⁴⁴ Despite these efforts, according to a Swiss study of surgical residents, although their performance on laboratory tasks improved after the reduced work hours, the end goal of improving patient safety did not materialize,⁵ and another study of postoperative care following the implementation of reduced work hours demonstrated an increase in the incidence of complications.²² This is of great concern and

it highlights the fact that DHR, despite best intentions, are not effectively addressing the issues of patient safety.

The 2011 updates to the 2003 DHR ACGME guidelines were intended to promote intern well-being and to decrease fatigue and burnout, with the ultimate goal of increasing patient safety; however, according to Antiel et al.,¹ the 2011 guidelines have not sufficiently addressed the continuing issue of resident fatigue, and neither have they addressed the attrition and burnout associated with surgical practice (for a discussion and study regarding the impact of intern DHR in nonsurgical specialties, see Sen et al.³⁸). In their study of 213 surgical interns (both categorical and preliminary) from 11 general surgery residencies in the US, they found that prior to starting their internship, a large majority of residents believed that the 2011 DHR would decrease their fatigue. At the end of their intern year, less than half, 44%, believed that the DHR reduced fatigue. This is an impressive change opposite to the intended direction. Not only did less than half of the surveyed interns believe that their fatigue was reduced, the majority perceived that their time in the operating room (OR) was decreased, whereas their time caring for patients in the hospital did not decrease as anticipated. This presents a problem unique to surgical training—one that is specifically relevant to neurosurgical training, given the complexities of neurosurgical patients and of neurosurgical operations—that of balancing the development of surgical skills with the fine-tuning of clinical reasoning.¹

Technique/Training

One of the original intentions of the ACGME in its initiation of DHR was to eliminate technical errors, which were presumed to be occurring as a result of fatigue.^{25,31,34} Also, there has been significant interest in the impact of fatigue on surgical skills. Much of the literature supporting a decrease in physical skill and ability cited by the ACGME in the initiation of DHR was based on studies conducted in nonsurgeons (military personnel and college-aged volunteers) in the self-promoted sleep science literature.^{2,9,15,31,43} Two studies of note tested the hypothesis of surgical technical errors occurring due to fatigue. This includes 1 study published prior to the DHR, which demonstrated only marginal reductions in surgical skills following a 24-hour call period in general surgery residents. A more recent, similar study of neurosurgery residents showed a marginal reduction in surgical skills in fatigued neurosurgical residents.^{14,16} Clearly the impact of fatigue on medical and technical error, in neurosurgery residents at least, is not as drastic as once feared, and these fatigue-related technical errors may have been traded for technical errors caused by lack of experience.

Fatigued or not, the neurosurgical trainee must master a variety of skills to complete training. Typical neurosurgical practice continues to evolve, with complex tasks including microsurgical and microendovascular skills that are not requisite in all surgical specialties. As neurosurgery advances, residents must master an increasing number of a wide variety of technical skills to practice independently; finding the time for this training in an already tight program timeline becomes increasingly difficult.

TABLE 1. Literature review of data-driven nonneurosurgical studies concerning the impact of DHR*

Authors & Year	Specialty	Summary	Focus	Positive or Negative for DHR
Wilkinson, 1963	Not medical	Sleep-deprivation experiments in US military	Fatigue, task ability	Positive
Haslam, 1982	Not medical	Effects of sleep loss on military performance	Fatigue, task ability	Positive
Asken & Raham, 1983	Surgery	Insufficient study to truly determine impact of sleep deprivation on resident performance	Fatigue, resident safety	Neutral
Samkoff & Jacques, 1991	All medical specialties	Resident sleep deprivation and performance	Fatigue, safety	Positive
Laine et al., 1993	Internal medicine	DHR may increase complication rates	Safety	Positive
Haynes et al., 1995	Surgery	Sleep deprivation does not statistically impact complication rates	Safety, fatigue	Negative
Howard et al., 2004	Internal medicine, ICU	DHR have no statistical impact on inpatient M&M for CHF, PNA, or AMI	Safety	Neutral
Landrigan et al., 2004	Internal medicine, ICU	DHR for interns have reduced serious medical errors in ICUs	Safety	Positive
Irani et al., 2005	Surgery	Perception among general surgery residents that DHR have not improved quality of care	Safety, fatigue	Negative
Poulose et al., 2005	All medical specialties	DHR in NY State did not improve surgical patient outcomes and are associated w/ increased DVT and accidental puncture	Safety	Negative
de Virgilio et al., 2006	Surgery	DHR do not adversely impact outcomes or education w/ adoption of novel schedule and increased operational costs	Training, safety	Neutral
Schneider et al., 2007	Surgery	DHR have not impacted general surgery residency in training examination scores w/ program reorganization	Training	Neutral
Occhino et al., 2011	Ob/Gyn	DHR have not impacted Ob/Gyn case volumes w/ novel schedule and patient handoffs	Training	Neutral
Businger et al., 2012	Surgery	DHR do not improve surgery patient safety in Switzerland	Safety, training	Negative
Kaderli et al., 2012	Surgery	Effects of 50-hr DHR in Switzerland	Safety, training	Negative
Typpo et al., 2012	Pediatrics	Impact of DHR on Pediatric ICU safety and practice patterns	Safety	Negative
Veazey Brooks & Bosk, 2012	Surgery	Impact of DHR on socialization of surgical residents	Fatigue, training	Negative
Antiel et al., 2013	Surgery	DHR have not addressed patient safety, resident fatigue, and burnout in general surgery residents	Fatigue, training, safety	Negative
Cooke et al., 2013	Psychiatry	Impact of DHR on psychiatry resident-in-training examination scores	Fatigue, training	Negative
Sen et al., 2013	Surgery	DHR have not impacted resident sleep or fatigue but have increased rate of self-reported medical errors	Fatigue, safety	Negative
Curtis et al., 2014	ENT	Impact of DHR on ENT case volumes	Training, safety	Neutral
Lindeman et al., 2014	Surgery	Impact of DHR on intern competence	Training, safety	Negative
Pepper et al., 2014	Internal medicine, ICU	DHR have led to fewer ICU transfers and to a significant decrease in in-training examination scores	Training, safety	Negative
Scally et al., 2014	Surgery	Novel rotation system implemented to preserve operative volumes in surgical residency	Training	Neutral
Silber et al., 2014	Internal medicine	DHR have had little significant negative impact on internal medicine in-training examination scores	Training	Neutral
Wu et al., 2014	All medical specialties	Impact of DHR on Canadian health care system	Training, safety	Negative

AMI = acute myocardial infarction; CHF = congestive heart failure; DVT = deep venous thrombosis; ENT = ear, nose, and throat; M&M = morbidity and mortality; Ob/Gyn = obstetrics and gynecology; PNA = pneumonia.

* Included are the studies reviewed that reported data about fatigue, safety, and training in medical and surgical specialties that are not neurosurgical in nature. In the last column, the data presented in each paper are classified as in support of (positive), neutral, or detracting from (negative) implementation of duty hours.

The DHR have forced neurosurgical residents to choose how to spend their weekly allotment of 80 work hours. Because patient care and safety must be prioritized, the result for most residents may mean a sacrifice in operative

experience. Studies demonstrate that with the decrease in time available to train—a maximum of 88 hours per week with the 10% exception—the area feared to suffer most is OR time,^{1,20,27,42} lengthening the time needed to meet the

TABLE 2. Literature review of data-driven, neurosurgery-specific studies concerning the impact of DHR*

Authors & Year	Summary	Focus	Positive or Negative for DHR
Jagannathan et al., 2009	DHR have led to decreased productivity from neurosurgery residents	Training	Negative
Babu et al., 2012	DHR have led to increased patient handoffs, which may contribute to increased medical error	Safety	Negative
Dacey, 2012	DHR have led to an increase in postop complications for neurosurgery patients	Safety	Negative
Dumont et al., 2012	Effects of DHR on M&M for meningioma in teaching vs nonteaching hospitals	Safety	Negative
Ganju et al., 2012	Post-call fatigue does not diminish neurosurgery resident skills at tasks	Fatigue	Negative
Hoh et al., 2012	DHR have led to increased complications and no change to M&M in neurosurgery patients	Safety	Negative
Babu et al., 2014	M&M and costs have increased for spine patients after implementation of the 2003 DHR	Safety	Negative
Dacey, 2014	DHR have not met goals of improved patient outcomes	Training, safety	Negative
Ragel et al., 2014	Night float system has eliminated duty hour violations for a neurosurgical training program	Fatigue	Neutral

* Included are the studies reviewed that reported data about fatigue, safety, and training from the neurosurgical literature. In the last column, the data presented in each paper are classified as in support of (positive), neutral, or detracting from (negative) implementation of duty hours.

10,000-hour rule for proficiency. This leads to the concern among surgical faculty that training programs under the new DHR are not providing sufficient technical training and that patient safety is another cost.⁴¹ This concern has not changed since 2003, when identical concerns were voiced by both attending and resident physicians regarding surgical training⁴² as are expressed now.⁴¹

Teaching technical skills with the 2011 DHR then becomes a balancing act as OR time and continuity of care are the first to be reduced when hours are restricted. Neurosurgery programs are implementing strategies to improve technical skill training within the confines of the DHR; many programs are including simulators as an integral portion of their training. A large percentage (83%) of US program director respondents believe that simulation, as fidelity and complexity increase,²³ will play a large role in training in the future, especially for preparation in complex cases and in early training.^{13,26,37} We believe that simulators are an excellent adjunct to surgical training, but cannot replace operative experience, which requires time that is diminishingly available to trainees as a result of the DHR.

The implementation of the 2011 DHR has required changing practice patterns and implementing unusual float systems to maintain intern operative case volumes that may limit quality care. There have been some studies published examining the operative case volumes for residents in surgical subspecialties,^{7,29} but these studies only examine operative volumes prior to the implementation of the 2011 DHR. In general surgery, there has been no overall decrease in the operative experience for junior and senior residents who started training prior to the 2011 changes; however, maintaining operative experience for interns was only feasible with the implementation of a novel call system.³⁵ The same has not been true for neurosurgical residents, excepting for programs adopting unusual night float systems,³³ which as a tradeoff may increase patient handoffs and so potentially compromise patient care. It seems that the predicted decrease in technical training due to the 2011 intern guidelines may not be borne out, but maintaining intern case volume has necessitated

new systems of duty hours (night float, naps) and increased use of midlevel providers,¹⁸ which reduces the exposure of residents to practice. These limitations are becoming evident as neurosurgical residents who started under the 2011 DHR are now maturing from junior resident status to senior status. There are no studies to date comparing the technical skills between the cohort of residents matriculating prior to the 2011 DHR and those matriculating after, but we suspect that such a study may display further limitations of training at least partially attributable to the DHR.

Other consequences of limited duty hours on neurosurgical training are becoming evident. Not only has there been an increase in handoffs,³ there has also been a decrease in educational time, indirectly measured by a decrease in mean scores on the American Board of Neurological Surgery self-assessment boards and by a decrease in the number of resident-presented abstracts at national meetings.²¹ Although there are limited data available on the impact of resident board performance and participation in research, other specialties have reported statistically significant decreases in training examination scores as well, including internal medicine.³⁰ In contrast to these findings, in some institutions there was no meaningful impact on mean board scores after the implementation of the 2003 DHR for internal medicine,³⁹ psychiatry,⁶ or general surgery;^{10,36} however, these were single-institution studies and did not examine national data.

Safety

A decade after the implementation of the DHR, there has been no clear decrease in the incidence of medical errors. A decrease in duty hours must, by definition, lead to an decrease in continuity of care and a commensurate increase in patient handoffs—a practice that is fraught with perils in and of itself. There is speculation that medical errors have increased secondary to the increased number of patient handoffs. In a study published in *Neurosurgery* in 2012, Dumont and colleagues¹¹ report an increase in complication rates for neurosurgical patients undergoing

craniotomy for meningioma collected from the National (formerly known as Nationwide) Inpatient Sample. Their data were collected from 2003, when DHR were instituted in teaching hospitals, and demonstrated that the increased rate of complications in teaching hospitals after the institution of DHR was not met with a commensurate increase in complications in nonteaching hospitals. The authors conclude that this increase in postoperative complications is probably due to a decrease in continuity of care in teaching hospitals due to an increased number of patient handoffs. Another study follows in the same vein for neurosurgical trauma patients,¹⁷ and a third for neurosurgical patients undergoing spinal procedures.⁴ It appears that the intent of the DHR is not having the desired effect.^{8,28}

Babu, Nahed, and Heary's 2012 study reported results from their survey of neurosurgical residents about patient handoffs.³ They found that at the 98 programs they surveyed, a majority of residents (64% of respondents) had little or no formal instruction in the format or mechanism of a patient handoff, highlighting the concerns about handoffs being fertile soil for communication errors and increased potential for sentinel events. They also report that multiple interruptions are frequent during handoffs (55% of respondents reported 3 or more interruptions) and that there is little formal feedback about handoffs (47% of respondents). Their study demonstrates that the current practice is insufficient. They go on to provide 4 best-practice suggestions for neurosurgery handoffs to minimize risks to patient safety: 1) specific identification of follow-up tasks; 2) formal handoff education training; 3) minimization of interruptions; and 4) clear, specifically delineated identification of neurosurgical management issues.

This is perhaps the crux of the failure of DHR for neurosurgical trainees: in our opinion, an arbitrary and artificial timeline designed to reduce resident fatigue actually limits quality patient care (by eliminating continuity of care), and it also limits technical training (by reducing the time available for operative experience). Additionally, these guidelines, which were intended to lessen fatigue and improve patient safety, have not, in our estimation, sufficiently done either.

Conclusions

For some specialties, both the 80-hour DHR and the 2011 DHR have been implemented with great success, with an increase in resident satisfaction and no impact on technical training. Unfortunately, this has not been true for neurosurgery training. The DHR were designed to reduce medical errors and improve patient safety in teaching hospitals by reducing resident fatigue. More than a decade after their sweeping implementation and 3 years after their first revision, this much-anticipated reduction in medical error has not borne out.²⁸ Several studies, as previously mentioned, even suggest that the opposite may in fact be true due to the unforeseen increase in patient handoffs from shift to shift.

Under the current guidelines, training neurosurgeons adequately for competent independent practice then becomes a significant concern. The training is rigorous and demanding and unlike the training required in other medical disciplines. Neurosurgery demands unusual skills, both

technical and cognitive, which are not easily obtained; Malcolm Gladwell's book *Outliers* popularized the idea of an estimated 10,000 hours of training to achieve expertise in a field, which he surmised from a study demonstrating that expertise is gained through a minimum hours deliberate practice ranging from at least 50 to 60 hours weekly.¹² Likewise, Dacey's 2012 article points to the military for models of stress inoculation and sleep deprivation while training individuals in highly specialized skills.⁹ He mentions the "emotional and psychomotor stamina" required of a neurosurgical resident and a practicing neurosurgeon to maintain efficacy at odd hours when meeting the needs of their patients. It seems better to inoculate residents to such stresses in the safety of a training program with sufficient backup, than to introduce these stresses when practicing alone after graduation.

So, neurosurgical residents are left with increased educational demands, increased patient and hospital needs, and fewer hours within which to perform these duties. The answers to these problems do not lie in allowing the course of neurosurgical training to be dictated externally. Neurosurgeons train neurosurgeons. We must find what is essential to the socialization, cognitive development, and skill training of neurosurgeons and focus our efforts there, all the while maintaining our dedication to our patients. We are not advocating a return to the historical physical residential standard of Cushing and Halsted. We need to be thoughtful about sweeping, unilateral regulatory mandates—federalism of this sort is bound to be fraught with difficulty.

There are several solutions to this problem: 1) abolishment of DHR and a return to unregulated resident duty hours; 2) continuing the current standard; 3) abolishing the 2011 Intern DHR; or 4) increasing restrictions and further reducing resident duty hours, as has occurred in Europe and elsewhere. The results of the current ACGME study comparing surgical and medical intern duty hours under the 2003 guidelines and the 2011 update with the medical errors reported in each period is much anticipated. It may provide some insight into how we should then proceed. Certainly, if organized neurosurgery were to act in unison and determine what constitutes safe and effective training for our residents and the care of our patients, a potentially productive split from the ACGME could develop.

Whatever the long-term solution to the problem of medical errors, implementation of the DHR has highlighted several things that are beneficial to academic medicine. It has identified the need for cohesive team communication, including accurate, supervised handoffs. It has provided a foil to the old model of residency without DHR and unlimited, unregulated work. It has highlighted the need for supervision and the responsibilities of faculty with their resident teams to ensure patient safety. It has given a louder voice to ancillary staff—nursing and other allied health professionals—in many things, but particularly in patient safety. It has forced graduate medical educators to examine closely what is necessary and sufficient in medical training and has caused them to remove that which is not essential. It has fed the drive for meaningful use of electronic medical records, medical alerts, and other safeguards. It has fertilized the seed of simulation as part of technical training. Most of all, the debate over DHR has

brought out many voices from many corners of our great profession to find the truth, which lies somewhere in the midst of all this noise. Adaptation is the key to survival in an ever-changing environment, and we are certain that the behemoth that is the academic medical establishment, including neurosurgical training, will adapt to whatever comes. To paraphrase Mr. Churchill, “You can always count on [physicians] to do the right thing – after they’ve tried everything else.”

For neurosurgical trainees, we believe that the importance of patient care, operative experience, and education (all time-consuming activities) outweighs the perceived risk of neurosurgical resident fatigue. We believe that the ACGME should be challenged to demonstrate the value of DHR for neurosurgical trainees and, in the absence of DHR, unique training parameters for neurosurgical training programs should be considered.

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Disclosure

Dr. Lemole is a consultant for BrainLab.

Author Contributions

Conception and design: Bina, Dumont. Acquisition of data: Bina. Drafting the article: Bina, Dumont. Critically revising the article: all authors. Study supervision: Dumont.

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The effect of call on neurosurgery residents' skills: implications for policy regarding resident call periods

Clinical article

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Object. Although fatigue and its effects on surgical proficiency have been an actively researched area, previous studies have not examined the effect of fatigue on neurosurgery residents specifically. This study aims to quantify the effect of fatigue on the psychomotor and cognitive skills of neurosurgery residents.

Methods. Seven neurosurgery residents performed a minimum of 3 and a maximum of 4 sessions of 6 surgical exercises precall and postcall. The simulation exercises were designed to measure a surgeon's cognitive abilities, such as memory and attention, while performing simulated surgical tasks and exercises that have been previously validated in several studies, including studies measuring the impact of fatigue on general surgery residents. Each exercise measured tool-movement smoothness, time elapsed, and cognitive errors. The change in surgical skills in pre-call and postcall conditions was assessed by means of an ANOVA, with $p < 0.05$ considered statistically significant.

Results. The neurosurgery residents did not show a statistically significant difference in their surgical skills between the pre- and postcall states ($p < 0.3$, $p < 0.4$, and $p < 0.2$ for movement smoothness, time elapsed, and cognitive errors, respectively). The mean decrement for all residents in the postcall condition was 13.1%.

Conclusions. Postcall fatigue is associated with a marginal decrease in proficiency during simulated surgery in neurosurgery residents. In a similar study, general surgery residents showed a statistically significant decrement of 27.3% in the postcall condition. The impact of fatigue on different specialties should be further investigated prior to implementation of a national physician work-hour policy. (DOI: 10.3171/2011.9.JNS101406)

KEY WORDS • Accreditation Council for Graduate Medical Education • work-hour restriction • neurosurgery resident

GRADUATE medical education was redefined in 2003 with the ACGME's implementation of work-hour restrictions. These restrictions imposed a "one size fits all" solution to the issues of resident fatigue and patient safety. Under these guidelines, work hours were limited to 80 hours per week, averaged over a period of 4 weeks. In December 2008, the Institute of Medicine released a report calling for further restrictions to be imposed, including mandatory rest time during residents' duty shifts. In response, in March 2009, the ACGME convened to critically review the impact of the work-hour restrictions on resident education and patient safety after 5 years of implementation. It was recognized that there is a paucity of data regarding the impact of work-hour restrictions on graduate medical training and patient care. In addition, it was acknowledged that there is tremendous

variation in residency training across the medical specialties; a work-hour restriction policy applied indiscriminately to all subspecialties is problematic. However, the report also pointed out that there was a lack of comparative data on the variations between specialties.

It is generally recognized that the various medical subspecialties have unique demands; practitioners must have unique abilities and skill sets to practice successfully. Neurological surgery is recognized as being a medical subspecialty in which timely care, delivered at any time of day or night, can often mean the difference between life and death, function and disability. No data exist regarding the effect of fatigue on the psychomotor and cognitive skills of neurosurgery residents. The onus is on medical practitioners to provide these data. It was our hypothesis that fatigue does not affect the psychomo-

Abbreviations used in this paper: ACGME = Accreditation Council for Graduate Medical Education; PGY = postgraduate year.

This article contains some figures that are displayed in color online but in black and white in the print edition.

Effect of call on neurosurgery residents' skills

tor and cognitive skills of medical practitioners equally. Specifically, we were interested in comparing, in a controlled manner, the impact of fatigue on the psychomotor and cognitive skills of neurosurgery and general surgery residents. Simulation environments provide a safe and effective means of measuring the impact of fatigue on skills. They have been employed in several studies, and it has been shown that performance in simulation correlates highly with intraoperative performance.⁸

In a meta-analysis of 19 studies conducted by Pilcher and Huffcutt,⁹ partial sleep deprivation (< 5 hours of sleep in a 24-hour period) was found to cause a significant impact on overall proficiency of residents. This study noted that cognitive skill (as measured through questionnaires, simple cognitive exercises, and so forth) is more deeply affected by fatigue than is psychomotor skill. In separate experiments, Grantcharov et al.⁵ and Taffinder et al.¹¹ examined the deterioration of laparoscopic skills in the fatigued condition as measured by the ProMIS surgical simulator (Haptica, Ltd.). In both of these studies, fatigued subjects demonstrated impeded accuracy and increased time span for completion of tasks. Neither study evaluated the effect of fatigue on neurosurgery residents; in addition, both of these studies isolated psychomotor proficiency as a measurement variable instead of recognizing the interrelatedness of psychomotor and cognitive proficiency.

Kahol et al.⁷ addressed this problem in a recent article; they were interested in developing, for surgeons, exercises and tools that require the use of psychomotor and cognitive skills simultaneously. In this study using a specially designed simulator to measure psychomotor and cognitive skills in general surgery residents, the authors developed an experiment that analyzed the effect of fatigue and sleep deprivation on trauma surgery and obstetric residents. Each participant was involved in 4 precall and 4 postcall sessions. Three exercises, chosen randomly from the 9 variations of the ring-transfer task, were performed in each session. The results showed a significant decrease in proficiency of performance in the postcall condition. In the postcall state, there was a 47% increase in cognitive errors across all exercises. However, the increase in errors was 56% in cognitively dominated exercises, showing that cognitive functioning is more significantly affected than psychomotor skills.

In this study, we employed the same apparatus and setup to test the impact of fatigue on neurosurgery residents. We recognized that the exercises do not in any way mimic actual neurosurgical procedures; at best, the measurement of cognitive and psychomotor skills is meant to parallel a measure of simulated surgical proficiency.

Methods

The study was conducted with the approval of Northwestern University's institutional review board. The study participants were 7 neurosurgery residents in different years of training, ranging from PGY2 to PGY5, in the Northwestern University Feinberg School of Medicine neurological surgery residency program. Written informed consent was obtained from each resident prior to

his or her participation. Baseline demographic data were collected from all 7 participants.

Simulation Exercises

We developed a series of virtual simulations that measured both psychomotor and cognitive skills in a controlled manner. A simulation was designed for the virtual ring-transfer task that is a part of a validated basic laparoscopic course using the ProMIS surgical simulator and FLS simulator (www.flsprogram.org). In the virtual ring-transfer task (Fig. 1), residents were tasked with grasping a series of "virtual" rings and placing each on randomly highlighted pegs on a board. The simulation was implemented using the Sensable haptic joystick, which allows for generation of 3 degrees of force feedback in response to events in the virtual environment. An OpenHL application programming interface was used to design the simulation. The simulation allows for measurement of the tool tip in the virtual environment. The basic task involves 10 rings. After the participant places a ring on a highlighted peg, another peg is randomly highlighted for the participant to put the ring on. This is repeated until all 10 rings are correctly placed. This basic ring-transfer task is a psychomotor task employed in many simulators to hone tool manipulation skills. A cognitive error is recorded every time the participant attempts to place a ring on the wrong peg (signifying error in judgment). It should be noted that the simulation does not allow placement of a ring on the wrong peg, and the participant is required to continue selecting pegs to put the ring on until the correct peg is chosen.

This basic validated laparoscopic exercise was modified to include cognitive variations. These cognitive variations were developed by employing neuropsychological methods that focus on developing tasks and exercises that measure cognitive abilities such as attention, visuospatial tracking, and intermodal transfer. Nine variations were designed, and these were described in detail by Kahol et al.,⁷ who validated the exercises as a tool to measure psychomotor and cognitive proficiency. Ring-transfer exercises are representative of laparoscopic tasks and are adequate for comparison of the performance of general surgeons and neurosurgeons.

Data Capture Tools and Proficiency Measurements

To assess fatigue levels of the participants, a questionnaire designed by Behrenz and Monga¹ was employed. Another questionnaire was developed for self-reporting of sleep obtained during call and the amount of caffeine consumption.

For measuring surgical proficiency, we employed a combination of time, cognitive errors, and tool movement. Tool-movement smoothness was measured on a scale of 0–1, with 0 indicating the least smoothness of movement and 1 the highest smoothness of movement. Tool movement, measured as movement of the tool tip in a virtual environment is a validated measure for surgical proficiency.⁴ In our simulations, tool-movement smoothness is determined by the simulator for an entire exercise. Senior surgeons tend to show a high degree of tool-movement

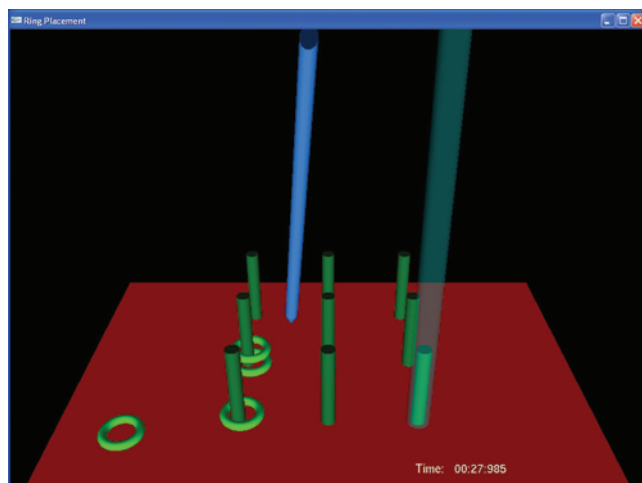


Fig. 1. Example of the virtual ring-transfer task. The highlighted peg is the one that the ring must be placed upon.

smoothness while novices tend to have lower values.¹⁰ In a simulation, the time required to complete a task is also recorded. The time elapsed can range from 0 to 300 seconds, but all raw data were normalized to a range of 0–1 and are thus reported as a percentage. Cognitive errors, defined as the number of times the ring was placed on the wrong peg, were also recorded for every type of exercise; once again, all raw data were normalized to a range of 0–1 and are thus reported as a percentage.

These 3 measures of proficiency (tool-movement smoothness, time elapsed, and cognitive errors) provided a broad framework for evaluation, and when coupled with fatigue and sleep-deprivation measures through the questionnaire, allow for holistic evaluation.

Experimental Protocol

We based our power analysis on previous studies of general surgeons. It was calculated that for a 2-tailed alpha of 0.05 with power of 80%, we needed a sample size of 5. For this study, we evaluated the pre- and postcall performance of 7 neurosurgeons.

For each participant, a session was defined as testing in the precall and corresponding postcall (sleep-deprived) state wherein “call” consisted of a 24-hour period of in-house call responsibilities. Participants completed a minimum of 3 and a maximum of 4 sessions. Only 1 session was allowed per week for each resident. Each testing session was preceded by the completion of the Behrenz questionnaire, which quantifies residents’ fatigue levels using self-reported assessments.

For each experiment, 3 exercises were randomly chosen from the 9 exercises available. Each exercise was repeated 2 times to counteract the warm-up effect in which the participant may perform suboptimally during the first exposure to a game. As with the previous methodology,⁷ the exercises in the precall condition and the postcall condition were not matched to account for a learning effect.

The designed software captured and stored the 3 proficiency measures. Fatigue ratings were captured through the questionnaire. Iterations of exercises performed pre-

call were compared with iterations of the exercises performed postcall. An ANOVA was employed to study the difference between precall and postcall performance on each of the 3 proficiency measures of surgical skills. These measures enabled comparison of the effect of sleep deprivation on the surgical skills of the residents. Differences with probability values less than 0.05 were accepted as statistically significant.

Results

A total of 7 residents from PGY2 to PGY5 participated in the study; all completed 3 or 4 sessions. A session was defined as performance of the exercises in both the pre- and postcall states, with a call consisting of a 24-hour period of in-house call responsibilities. In total, data from 26 sessions were obtained and analyzed. The specific breakdown of the sessions is as follows: 2 PGY2 residents completed 4 sessions each; 1 PGY3 resident completed 3 sessions; 2 PGY4 residents completed 4 sessions each; 1 PGY5 resident completed 3 sessions; and 1 PGY5 resident completed 4 sessions (Table 1).

Analysis failed to show any statistically significant difference in residents’ surgical skills between the pre- and postcall states. The mean values for movement smoothness, time elapsed, and cognitive errors in the precall condition were 0.56, 0.45, and 0.34, respectively; in the postcall condition, the respective values were 0.5, 0.39, and 0.41, respectively (Fig. 2). The difference between pre- and postcall performance was not found to be statistically significant ($p < 0.3$, $p < 0.4$, and $p < 0.2$ for movement smoothness, time elapsed, and cognitive errors, respectively).

Taking movement smoothness and cognitive errors together as a measure of surgical proficiency, the residents in the postcall state exhibited a decrease in performance of 13.1%. This decrement was not found to be statistically significant. In contrast, in a similar study performed in general surgery residents, a statistically significant decrement of 27.3% was found in the postcall state. We did not find a significant correlation between cognitive errors and caffeine consumption ($r = 0.45$); this points to a limited effect of stimulants on performance.

Discussion

The effect of sleep deprivation on physicians has been actively researched over the past 2 decades; a number of studies have investigated residents’ ability to perform under conditions of sleep deprivation. Multiple studies have examined residents across different fields, quantifying the effects of sleep deprivation on both cognitive and psychomotor abilities.^{2,3,5,6,9,11} However, there has been a dearth of studies investigating the impact of fatigue on neurosurgery residents.

In our study, when comparing neurosurgery residents’ skills in the pre- and postcall states, no significant difference was found in the parameters of movement smoothness, elapsed time, and cognitive errors made. Specifically, neurosurgery residents, in the postcall state, demonstrated a 10.7% decrease in movement smoothness

TABLE 1: Sessions completed by year of training

Participant No.	Year of Residency	Sessions Completed			
		1	2	3	4
1	PGY2	x	x	x	x
2	PGY2	x	x	x	x
3	PGY3	x	x	x	
4	PGY4	x	x	x	x
5	PGY4	x	x	x	x
6	PGY5	x	x	x	x
7	PGY5	x	x	x	

and a 20.6% increase in cognitive errors; this was not statistically significant. In a similar study,⁷ general surgery residents showed a statistically significant decrease of 42.4% in movement smoothness and a 46.5% increase in cognitive errors in the postcall state. The results support our hypothesis that sleep deprivation does not affect physicians equally or uniformly. It is recognized by the researchers that the exercises do not in any way mimic actual neurosurgical procedures; at best, what we offer is an extrapolation in regard to simulated surgical proficiency. It is entirely possible that these results have no correlation with actual surgical performance in sleep-deprived states. Future work involves developing exercises that are more neurosurgery specific in terms of technical execution. In addition, further work may address the effect of sleep deprivation on clinical decision making in neurosurgery.

Graduate medical education underwent a major transformation in 2003 with the institution of work-hour restrictions; a major criticism of the policy is that it applies a "one size fits all" solution to a diverse group. Medicine is a complex and diverse field, and the subspecialties can and will make unique demands on their practitioners. The Institute of Medicine and ACGME should recognize the great variation in the medical specialties and their practitioners. The impact of fatigue on different specialties should be clarified prior to further regulation of physician work hours nationally.

An important element to consider is also not just the number of hours in the call period, but the type of duties a resident may perform. It is important to consider that certain tasks may be harder to perform when fatigued while routine tasks can be performed with acceptable accuracy. This study did not investigate this question in detail, but future work will include experiments to investigate this research question.

Conclusions

The results of our pilot study reveal that postcall fatigue is associated with a marginal decrease in surgical proficiency in neurosurgery residents. In contrast, in a comparative study, general surgery residents showed a statistically significant decrement of 27.3% in the postcall condition. We believe that the impact of fatigue on dif-

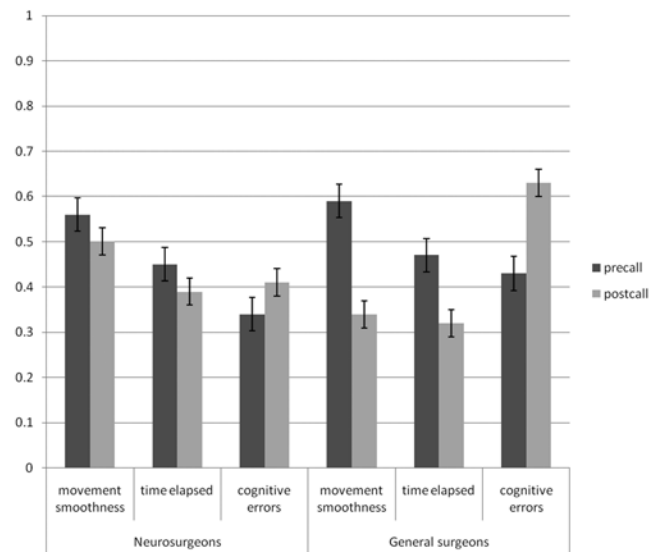


Fig. 2. Comparison of pre- and postcall performance in neurosurgeons and general surgeons.

ferent specialties should be further investigated prior to implementation of a national physician work-hour policy.

The recent recommendations by the ACGME were based on a significant amount of effort, planning, and coordination. However, a systemic problem in the process of coming up with duty-hour recommendations is that while agencies invest a significant amount of effort, planning, and coordination, the scarcity of data on the impact of fatigue hampers the overall outcome. In the current era of technological advances, including electronic medical records, radiofrequency identification tags (employed to measure systemic errors and workflow), and surgical simulation (shown to have a positive impact on medical education by measuring the impact of fatigue), we believe that the committee should recommend using technologies to gather data on various aspects of this policy in the future. Without a coordinated plan and a program to employ these technologies, future ACGME policy and recommendations will again be based on sparse and insufficient data. This is clearly unacceptable from a safety and cost-effectiveness perspective. Agencies such as the National Institutes of Health, the Agency for Healthcare Research and Quality, ACGME, and the medical specialty boards should facilitate data collection and analysis on a large scale to study graduate medical education policy. We have the necessary tools and technologies to study and improve graduate medical education until the next iteration of review is scheduled. Practitioners of medicine should become proactive rather than reactive in the investigation and implementation of measures that lead to decreased medical errors and increased patient safety.

Disclosure

The authors report no conflict of interest concerning the materials or methods used in this study or the findings specified in this paper.

Author contributions to the study and manuscript preparation include the following. Conception and design: all authors. Acqui-

sition of data: Lee, Simonian, Quinn. Analysis and interpretation of data: Kahol. Drafting the article: Ganju, Kahol, Simonian. Critically revising the article: Ganju, Kahol, Lee, Simonian, Batjer. Statistical analysis: Kahol. Administrative/technical/material support: Kahol, Quinn, Batjer. Study supervision: Ganju, Simonian.

Acknowledgments

The authors would like to thank Linda Savitskas and Michael Johnson for their assistance in technological support and manuscript preparation.

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Manuscript submitted August 20, 2010.

Accepted September 25, 2011.

Portions of this work were presented as an oral abstract at the American Association of Neurological Surgeons meeting in Philadelphia, May 4, 2010.

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Please include this information when citing this paper: published online December 2, 2011; DOI: 10.3171/2011.9.JNS101406.

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SPECIAL ARTICLE

Outcomes of Daytime Procedures Performed by Attending Surgeons after Night Work

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 Qi Li, M.Sc., Brian J. Murray, M.D., David Juurlink, M.D., Ph.D.,
 Erin Kennedy, M.D., Ph.D., Anna Gagliardi, Ph.D., Rinku Sutradhar, Ph.D.,
 and Nancy N. Baxter, M.D., Ph.D.

ABSTRACT

BACKGROUND

Sleep loss in attending physicians has an unclear effect on patient outcomes. In this study, we examined the effect of medical care provided by physicians after midnight on the outcomes of their scheduled elective procedures performed during the day.

METHODS

We conducted a population-based, retrospective, matched-cohort study in Ontario, Canada. Patients undergoing 1 of 12 elective daytime procedures performed by a physician who had treated patients from midnight to 7 a.m. were matched in a 1:1 ratio to patients undergoing the same procedure by the same physician on a day when the physician had not treated patients after midnight. Outcomes included death, readmission, complications, length of stay, and procedure duration. We used generalized estimating equations to compare outcomes between patient groups.

RESULTS

We included 38,978 patients, treated by 1448 physicians, in the study, of whom 40.6% were treated at an academic center. We found no significant difference in the primary outcome (death, readmission, or complication) between patients who underwent a daytime procedure performed by a physician who had provided patient care after midnight and those who underwent a procedure performed by a physician who had not treated patients after midnight (22.2% and 22.4%, respectively; $P=0.66$; adjusted odds ratio, 0.99; 95% confidence interval, 0.95 to 1.03). We also found no significant difference in outcomes after stratification for academic versus nonacademic center, physician's age, or type of procedure. Secondary analyses revealed no significant difference between patient groups in length of stay or procedure duration.

CONCLUSIONS

Overall, the risks of adverse outcomes of elective daytime procedures were similar whether or not the physician had provided medical services the previous night. (Funded by the University of Toronto Dean's Fund and others.)

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N Engl J Med 2015;373:845-53.

DOI: 10.1056/NEJMsa1415994

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THE EFFECT OF SLEEP DEPRIVATION AND fatigue on physician performance and patient outcomes has been of interest for many years. Acute sleep deprivation can impair mood, cognitive performance, and psychomotor function,¹⁻³ and its effects may be similar to those of alcohol exposure.^{4,5} The results of studies exploring clinical outcomes have been mixed, but a systematic review showed that a prolonged duration of sleeplessness, which would result from the provision of overnight medical care, significantly reduces clinical performance.¹

To date, most of the literature on sleep deprivation and performance has focused on medical trainees. This literature has contributed to the current duty-hour restrictions mandated in all North American residency training programs. However, few studies have examined the effects of sleep deprivation on the performance of attending physicians, and the results have been conflicting. In 2009, Rothschild et al. reported that their single-center study of surgeons and obstetricians showed an increased complication rate when procedures were performed by surgeons who had less than 6 hours of sleep opportunity.⁶ Although these results prompted calls for policy-level changes regarding potentially sleep-deprived surgeons,⁷ the findings have not been replicated by other groups.⁸⁻¹²

The published studies on this topic have had small samples and few events, resulting in limited statistical power. Moreover, these studies have generally been conducted in academic institutions, even though the majority of surgical procedures in North America are performed at non-academic hospitals, and the presence of trainees at academic hospitals may alter the relationship between sleep deprivation and performance on the part of attending physicians. The one study that included nonacademic hospitals focused on a single ambulatory procedure with a low complication rate.⁹ Thus, there is a gap in the literature on this topic. In the present study, we examined whether outcomes of elective procedures performed by physicians who were likely to be sleep-deprived because of overnight clinical work differed from the outcomes of procedures performed by the same physicians on a day when they had not provided overnight care.

METHODS

STUDY DESIGN

We conducted a population-based, retrospective, matched-cohort study in Ontario, Canada, using information from multiple linked health databases. The study population included all persons in the province who underwent 1 of 12 procedures (cholecystectomy, gastric bypass, colon resection, coronary-artery bypass grafting [CABG], coronary angioplasty, knee replacement, hip replacement, repair of a hip fracture, hysterectomy, spinal surgery, craniotomy, and lung resection) between January 1, 2007, and December 31, 2011. These procedures were chosen because they represent a broad array of common procedures in a variety of specialties. The study was approved by the Research Ethics Board at Sunnybrook Health Sciences Centre. The first two authors and the last author vouch for the validity of the data and analyses.

DATA SOURCES

Data linkage and analyses were conducted at the Institute for Clinical Evaluative Sciences (ICES), which houses population-level administrative health databases for the province of Ontario. All data sources (see the Supplementary Appendix, available with the full text of this article at NEJM.org) were linked with the use of encrypted unique patient identifiers. The data sources included specific fee codes that identify whether a given physician–patient interaction occurred between midnight and 7 a.m. (see the Supplementary Appendix). These fee codes are associated with remuneration and do not apply to routine medical care performed from midnight to 7 a.m. (e.g., early-morning rounds to check on a physician's inpatients).

STUDY PATIENTS

All patients undergoing one of the 12 index procedures as an elective, daytime procedure on a weekday during the study period were eligible for inclusion. Patients were assigned to the post-midnight group if they underwent an elective daytime procedure performed by a physician who had treated patients in the preceding overnight hours (midnight to 7 a.m.). We identified

overnight activity by means of specific fee codes (see the Supplementary Appendix). Patients were assigned to the control group if their treating physician had not worked clinically in the preceding overnight hours. Patients in the control group were matched in a 1:1 ratio with patients in the postmidnight group on the basis of the physician identifier, procedure type, and patient age (within a 5-year range). Thus, patients in each matched pair underwent the same elective procedure performed by the same physician. For each patient in the postmidnight group, a greedy-matching algorithm¹³ was used to select the control who most closely matched that patient in terms of the three matching factors. Since the study period encompassed only 5 years, controls were selected from the entire study period. If multiple possible controls were identified, one was randomly selected.

OUTCOMES

The primary outcome was a composite of death, complications, or readmission (to any hospital in the province) within 30 days, since all these measures reflect a complicated postprocedure course. Secondary outcomes were death within 30 days, complications within 30 days, readmission within 30 days, length of stay, and duration of surgery. Death, readmission, and length of stay were ascertained directly from the databases. Length of stay served as a proxy for in-hospital complications. Complications were identified with the use of a combination of diagnostic and procedural codes (see the Supplementary Appendix) that we had used previously to identify post-surgical complications in health databases.¹⁴ The duration of surgery was determined by means of a validated method¹⁵ that was based on the number of time units billed by the anesthesiologist. Procedures in which there was no fee code for concurrent anesthesiology were excluded from this analysis.

COVARIATES

Patient-specific variables included age, sex, socioeconomic status, and coexisting conditions. Socioeconomic status was approximated from the median neighborhood income, defined as a 6-level covariate (urban income quintiles 1 through

5 and rural income as a separate category). A rural neighborhood, defined as a community of no more than 10,000 people, was considered separately because neighborhood income is not an accurate representation of socioeconomic status in rural areas.¹⁶ Coexisting conditions were defined with the use of the Johns Hopkins Adjusted Diagnostic Groups (ADG) case-mix algorithm^{17,18} and categorized on the basis of ADG scores of 0 to 4, 5 or 6, 7 to 9, and 10 or higher (scores range from 0 to 34, with higher scores indicating more coexisting conditions). Physician-related variables that were recorded included age, sex, specialty, and years in practice.

STATISTICAL ANALYSIS

Descriptive statistics were calculated for the entire study population and stratified according to patient group (postmidnight group or control group). Between-group comparisons of baseline covariates were performed with the use of Student's *t*-test for continuous variables and the chi-square test for categorical variables. The association between the covariates and the primary outcome was examined by implementing a multivariable logistic-regression model, with the use of a generalized estimating equation (GEE) approach and an exchangeable 2-by-2 correlation matrix.¹⁹ Since matched patients were treated by the same physician, their outcomes may be correlated. The GEE approach was implemented to account for the clustering that may arise from matching persons to create pairs. We decided that it was important to account for clustering at the matched-pair level rather than just at the physician level. The primary exposure variable was postmidnight work by the attending physician (yes vs. no). Physician specialty and number of years in practice were excluded from multivariable models because of collinearity with procedure type and physician age, respectively. All other covariates were included in the model, and no variable selection was performed. Multivariable modeling for length of stay was performed with the use of Poisson regression and a GEE approach.

The primary analyses were performed on the entire study population. Three stratified analyses were planned a priori to determine whether

Table 1. Baseline Characteristics.*

Characteristic	Control Group (N=19,489)	Postmidnight Group (N=19,489)
Age of patient — yr	56.4±16.6	56.4±16.6
Female sex — no. (%)	11,987 (61.5)	11,992 (61.5)
ADG score — no. (%)		
0–4	4,573 (23.5)	4,588 (23.5)
5 or 6	5,160 (26.5)	5,186 (26.6)
7–9	6,169 (31.7)	6,007 (30.8)
≥10	3,587 (18.4)	3,708 (19.0)
Income quintile — no. (%)†		
Missing data	59 (0.3)	45 (0.2)
Rural	3,128 (16.1)	3,062 (15.7)
Urban, 1st quintile	3,117 (16.0)	3,203 (16.4)
Urban, 2nd quintile	3,357 (17.2)	3,327 (17.1)
Urban, 3rd quintile	3,239 (16.6)	3,237 (16.6)
Urban, 4th quintile	3,446 (17.7)	3,405 (17.5)
Urban, 5th quintile	3,143 (16.1)	3,210 (16.5)
No. of patients per physician		
Median (IQR)	6 (2–15)	6 (2–15)
90th percentile	33	33
Age of physician — yr	46.3±8.7	46.3±8.7
No. of years physician in practice	21.1±9.1	21.1±9.1

* Plus-minus values are means ±SD. There were no significant differences in baseline characteristics between the two study groups. There were 1448 physicians in the study. ADG denotes Adjusted Diagnostic Groups, and IQR interquartile range.

† Socioeconomic status of the patients was approximated from the median neighborhood income.

Table 2. Unadjusted Outcomes in the Study Cohort.

Variable	Control Group (N=19,489)	Postmidnight Group (N=19,489)
Primary outcome of death, readmission, or complication within 30 days — no. (%)	4362 (22.4)	4326 (22.2)
Death within 30 days — no. (%)	222 (1.1)	224 (1.1)
Readmission within 30 days — no. (%)	1385 (7.1)	1287 (6.6)
Complication within 30 days — no. (%)	3543 (18.2)	3527 (18.1)
No. of days in hospital — median (IQR)	3 (0–5)	3 (0–5)

the association between patient group and outcomes was modified by the type of hospital where the procedure was performed (academic

vs. nonacademic), by the type of procedure, or by the physician's age (<35 years, 35 to 40 years, 41 to 50 years, 51 to 60 years, or >60 years). The results of all a priori subgroup analyses are reported. In addition, a post hoc analysis was stratified according to the number of patient pairs for each study physician (top 10th percentile vs. bottom 90th percentile). A post hoc subgroup analysis was performed in which the postmidnight group was restricted to patients whose treating physician had performed procedures in two or more patients at night, as a surrogate for greater sleep loss. All statistical tests were two-sided, and P values of less than 0.05 were considered to indicate statistical significance. All analyses were conducted with the use of SAS software, version 9.3 (SAS Institute), at the Institute for Clinical Evaluative Sciences.

RESULTS

PATIENTS

Overall, 38,978 patients were included in the study (19,489 patients per group). These patients were treated by 1448 different physicians at 147 hospitals. The median number of patient pairs per physician was 6. Overall, physicians who treated patients from midnight to 7 a.m. performed a mean of 1.25 procedures (median, 1.00) during this time. The median number of years that the study physicians had been in practice (documented as the number of years since licensure) was 20, and 40.6% of procedures were performed at academic institutions. Baseline characteristics of the two patient cohorts were similar (Table 1).

OUTCOMES

The primary outcome (death, readmission, or complication) occurred in 22.2% of patients in the postmidnight group and 22.4% of those in the control group, with no significant difference between the two groups ($P=0.66$) (Table 2). Similarly, we found no significant between-group differences in crude rates of death (1.1% in the postmidnight group and in the control group, $P=0.92$), readmission (6.6% and 7.1%, respectively; $P=0.05$), or complications (18.1% and 18.2%, respectively; $P=0.83$). Adjusted analyses also showed no significant between-group differences in the primary outcome (adjusted odds ratio, 0.99; 95% confidence interval [CI],

0.95 to 1.03; $P=0.65$) (Table 3) or in readmission (adjusted odds ratio, 0.92; 95% CI, 0.85 to 1.00; $P=0.05$) or complications (adjusted odds ratio, 1.00; 95% CI, 0.95 to 1.04; $P=0.85$), when these outcomes were evaluated separately.

The median length of stay in each of the two groups was 3 days (interquartile range, 0 to 5; $P=0.84$). In an adjusted analysis, there remained no significant difference between the groups (adjusted odds ratio, 1.00; 95% CI, 0.94 to 1.06; $P=0.97$). The median duration of surgery was 2.6 hours (interquartile range, 1.9 to 3.6) in the postmidnight group and 2.6 hours (interquartile range, 1.9 to 3.7) in the control group, with no significant difference between the two groups overall ($P=0.40$) or after stratification according to procedure.

We found no significant effect modification when analyses were stratified according to hospital type (academic vs. nonacademic) (Fig. 1A). The adjusted odds ratio for the primary outcome of death, readmission, or complication was 1.00 (95% CI, 0.94 to 1.07; $P=0.97$) for academic institutions and 0.98 (95% CI, 0.92 to 1.04; $P=0.51$) for nonacademic institutions. Stratification according to the physician's age (Fig. 1B) and the specific procedure (Fig. 1C) also revealed no subgroups in which a significant difference was noted between the postmidnight and control groups, and the results were similar when the analysis was stratified according to the number of patient pairs for each physician.

When the postmidnight group was restricted to patients whose treating physician had performed two or more procedures at night (Table S2 in the Supplementary Appendix), the adjusted odds ratio for the primary composite outcome was 1.13 (95% CI, 0.99 to 1.27; $P=0.06$). For secondary outcomes, the adjusted odds ratios were as follows: death, 0.96 (95% CI, 0.56 to 1.67; $P=0.89$); readmission, 1.10 (95% CI, 0.89 to 1.36; $P=0.39$); complication, 1.14 (95% CI, 1.00 to 1.29; $P=0.05$); and length of stay, 1.04 (95% CI, 0.95 to 1.15; $P=0.39$).

DISCUSSION

Sleep deprivation and fatigue may have effects on physician performance. However, in this population-based study, we found no significant difference in short-term outcomes for patients

Table 3. Multivariable Analysis of Factors Associated with the Primary Outcome.

Variable	Odds Ratio (95% CI)
Care provided after midnight	0.99 (0.95–1.03)
Care not provided after midnight (reference)	1.00
Age of patient*	1.02 (1.02–1.02)
Sex of patient	
Female	0.47 (0.44–0.49)
Male (reference)	1.00
ADG score	
0–4	0.50 (0.46–0.54)
5 or 6	0.59 (0.55–0.63)
7–9	0.71 (0.66–0.76)
≥10 (reference)	1.00
Income	
Rural	1.16 (1.06–1.26)
Quintile 1	1.20 (1.10–1.31)
Quintile 2	1.09 (1.00–1.19)
Quintile 3	1.02 (0.93–1.11)
Quintile 4	0.98 (0.90–1.07)
Quintile 5 (reference)	1.00
Age of physician*	0.98 (0.98–0.99)

* The odds ratio is for each 1-year increase in age.

treated by a physician who had performed overnight clinical work, as compared with patients treated by the same physician but after a night when no clinical work had been performed. The results were consistent across a wide range of procedures and physician characteristics and in academic and nonacademic institutions.

Studies of physicians suggest that sleep deprivation may affect mood, cognition, and psychomotor function,^{1,3} but most studies have focused on medical trainees, and the results may differ for attending physicians. Using a laparoscopic simulator, Uchal et al. found no significant difference in surgical performance between surgeons who had been on call overnight and those who had not been on call.²⁰ The results of clinical studies focusing on attending physicians have been mixed. A single-institution study by Rothschild et al. suggested that outcomes were compromised when surgeons had less than 6 hours of sleep opportunity,⁶ a scenario that can occur when physicians provide medical care after mid-

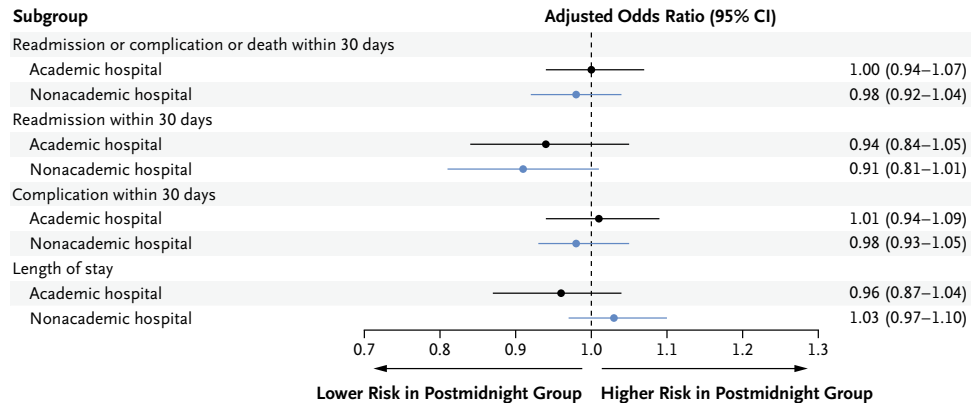
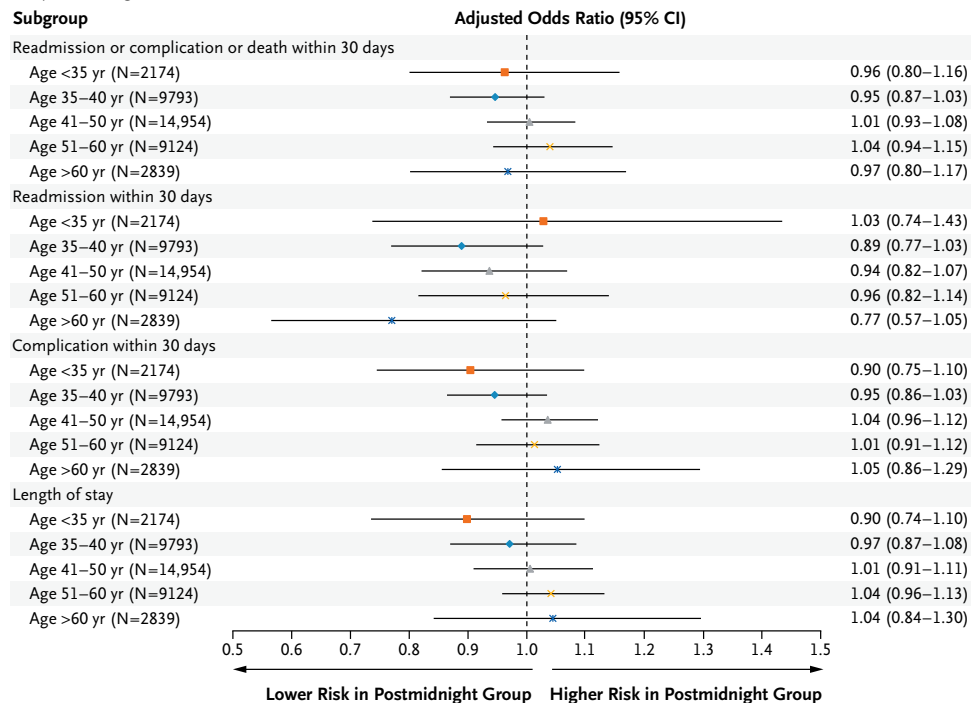
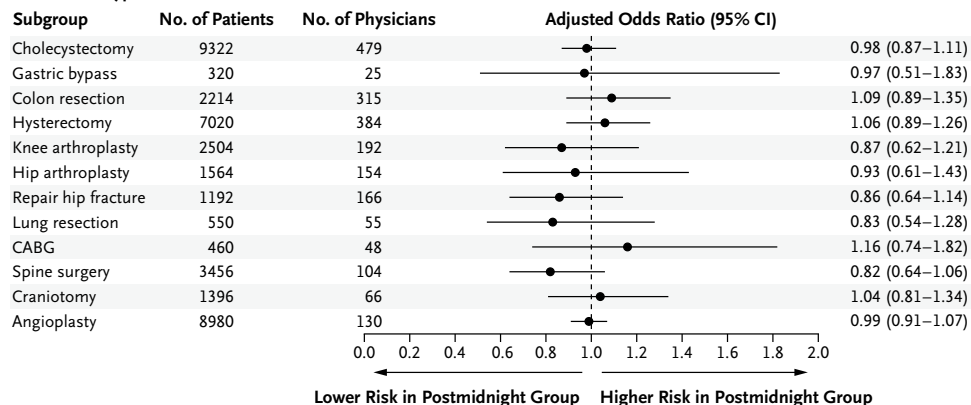
A Hospital Type**B Physician's Age****C Procedure Type**

Figure 1 (facing page). Risk of Adverse Outcomes for Patients Undergoing Daytime Surgical Procedures Performed by a Surgeon Who Had Provided Clinical Care the Previous Night, as Compared with Patients Undergoing Procedures by the Same Physician on a Day Not Preceded by Night Work, According to Type of Hospital, Physician's Age, and Type of Procedure.

Shown are forest plots of adjusted odds ratios for adverse outcomes in patients undergoing a daytime procedure performed by a surgeon who had provided clinical care after midnight (the postmidnight group), as compared with patients undergoing a daytime procedure performed by the same physician but not after the provision of nighttime care (the control group). Odds ratios greater than 1 indicate a higher risk in the postmidnight group. Panel A shows odds ratios for the primary outcome (death, readmission, or complication within 30 days) and secondary outcomes, stratified according to hospital type. A total of 15,827 patients were treated at academic hospitals, and 23,151 patients were treated at nonacademic hospitals. Panel B shows odds ratios for the primary and secondary outcomes, stratified according to the physician's age. The numbers of patients are in parentheses. Panel C shows odds ratios for the primary outcome, stratified according to the type of procedure. CABG denotes coronary-artery bypass grafting.

night. In contrast, other single-institution studies have suggested that outcomes of surgical procedures may not be adversely affected by sleep deprivation or fatigue on the part of the surgeon.^{8,10-12} These studies lacked generalizability, since they were conducted at single academic centers, and the relatively small number of surgeries and the relatively low event rate in the group who had been on call the previous night significantly limited the power to detect important outcome differences. In a population-based study of cholecystectomy performed at community hospitals, Vinden et al. found no significant difference in outcomes between surgeons who had worked overnight and those who had not.⁹ However, this study was restricted to a single ambulatory procedure with a low event rate.

In the present study, we did not find any significant difference in outcomes overall or in analyses stratified according to the type of procedure, the physician's age, or the academic status of the hospital. There are some possible explanations for these null findings. Attending physicians have greater experience than trainees, which may compensate for decrements in performance so that clinical outcomes are not affected. More important, attending physicians may

exercise professional judgment and self-regulate their practice the next day by canceling surgeries or arranging for coverage by colleagues if they feel too fatigued to perform surgery safely. Before a night on call, physicians may also proactively change their surgical caseload in anticipation of being sleep-deprived. A small but significant increase in complications was observed in the subgroup of patients whose physicians had performed two or more procedures the night before, which may have resulted in more profound sleep loss than the performance of a single procedure; however, no significant differences were noted in other outcomes in this subgroup. Similarly, Rothschild et al.⁶ found an increase in complications in a subgroup of patients whose physicians had less than 6 hours of sleep opportunity. It is important to note that our finding was from a post hoc subgroup analysis, and an isolated significant result among multiple secondary comparisons may be due to random error.

The current study addresses the gap in the literature on the effects of sleep deprivation and can help inform policy discussions of this issue. We included almost 40,000 patients undergoing 12 different procedures by 1448 physicians across 147 academic and community hospitals. Sleep studies have suggested that tasks requiring longer periods of concentration may be more affected by sleep deprivation; therefore, we selected procedures that varied in duration and were associated with a range of complication rates. The broad scope of this study enhances its generalizability, a particularly relevant consideration if policy changes are being contemplated with respect to duty hours of attending surgeons.⁷ In addition, the matched study groups strengthen the findings of the study by accounting for unmeasurable confounding related to individual surgeon and hospital factors associated with complications, readmission for complications, and death from complications. The cohort size and event rate also provide this study with adequate power to show clinically meaningful differences.

Our study has several limitations associated with the data sources used. We used billing codes to define periods when care was provided (i.e., the period between midnight and 7 a.m. and the daytime period), but we do not have information on the exact hours when the care was provided. Therefore, we cannot quantify the num-

ber of hours that a physician was deprived of sleep. However, we did assess outcomes in a subgroup of patients whose physicians were likely to have had profound sleep loss. Similarly, we cannot determine whether there was a difference in outcomes between daytime procedures performed later in the day and those performed earlier in the day or whether procedures may have been postponed till later in the day because of substantial sleep deprivation. However, given the constraints of operating room schedules in Ontario, it would not usually be feasible to postpone an operation until later in the day on short notice.

In addition, we could not control for other sources of short- or long-term sleep deprivation; however, policy changes that have been advocated are based on short-term sleep deprivation related to the provision of medical care, and consequently, our inability to measure other sources of sleep deprivation does not detract from our ability to inform policy discussions. Our outcome measures were limited to those that could be identified in administrative data, and it is therefore possible that our measures did not capture all complications in the study patients. However, we used a variety of complementary measures for capturing a complicated postoperative course, including readmissions and length of stay, which are highly accurate.²¹ In this study, we examined only short-term outcomes, and it is possible that other outcomes are affected to a greater degree.²² In addition, systematic undercoding or overcoding of complications on the part of hospital coders would be mitigated by the matched na-

ture of the study cohort, and given that outcome ascertainment is not plausibly associated with sleep deprivation, this should not be a source of confounding. Finally, the present study included only attending physicians and therefore does not inform the discussion about duty hours for residents and other trainees.

In conclusion, we found that sleep loss resulting from the provision of overnight medical care did not measurably affect the short-term outcomes of elective procedures performed the next day by attending surgeons in Ontario, Canada. These data suggest that calls for broad-based policy shifts in duty hours and practices of attending surgeons may not be necessary at this time. However, the effect of profound sleep loss may warrant further study, and it remains important for physicians to critically assess the effects of all sources of fatigue on their individual ability to treat patients and self-regulate their practices appropriately.

The opinions, results, and conclusions reported in this paper are those of the authors and are independent from the funding sources. No endorsement by the Institute for Clinical Evaluative Sciences or the Ontario Ministry of Health and Long-Term Care is intended or should be inferred. Parts of this material are based on data and information compiled and provided by the Canadian Institute for Health Information (CIHI). However, the analyses, conclusions, opinions, and statements expressed herein are those of the authors and not necessarily those of the CIHI.

Supported by the University of Toronto Dean's Fund, an operating grant (MOP-130399) from the Canadian Institutes of Health Research, and the Institute for Clinical Evaluative Sciences, which is funded by an annual grant from the Ontario Ministry of Health and Long-Term Care.

No potential conflict of interest relevant to this article was reported.

Disclosure forms provided by the authors are available with the full text of this article at NEJM.org.

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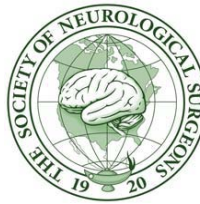
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Comments

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

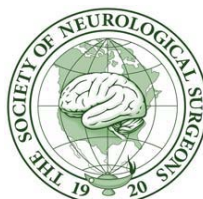
on the subject of

Resident Duty Hours

April 30, 2009

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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:

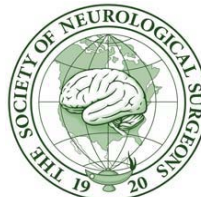
- The production of well-trained neurosurgeons requires:
 - Technical mastery, which requires many hours to achieve and effective duty hours standards should not limit necessary operative experience
 - Professionalism and surgical ownership; patients expect their surgeon will be present to see the patient 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 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***

- 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.



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

[illegible]

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

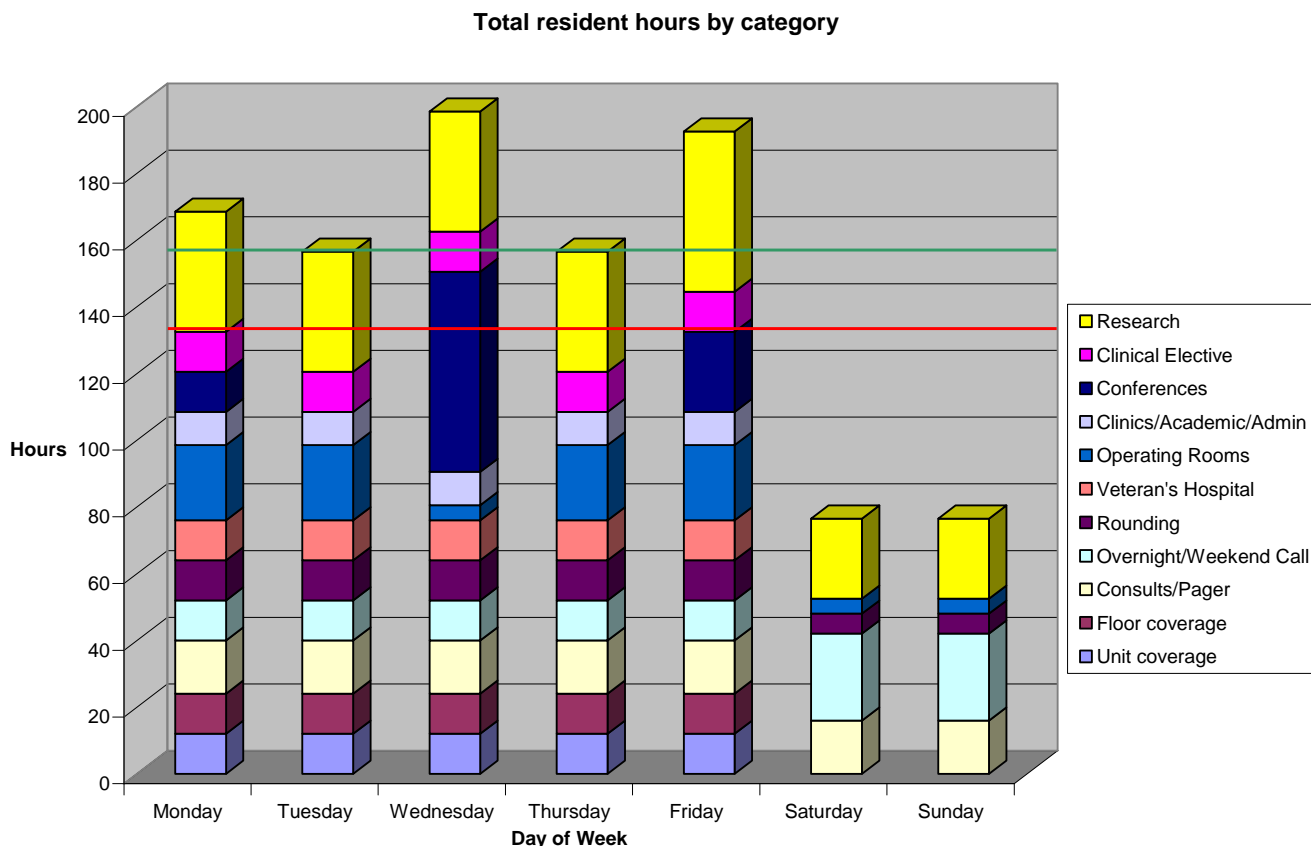


Table 3 graphically depicts the distribution of resident activity and specifies the category in which activity occurs. Categories are ordered bottom to top from most critical to least critical (as specified in the priorities identified above). The red line indicates 126 hours, or the evenly distributed 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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1. Grady MS, Batjer HH, Dacey RG Jr. *Resident duty hour regulation, and patient safety: establishing a balance between concerns about resident fatigue and adequate training in neurosurgery.* JNeurosurg (In press, 2009).
 2. Jagannathan J, Yates E, Pourtian N, Sheehan JP, Patrie J, Grady S, Jane J Sr. *Impact of ACGME work hour regulations on neurosurgical resident education and productivity.* JNeurosurg (In press, 2009)
 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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1. Letter from US House of Representatives Committee on Energy and Commerce to the Agency for Healthcare Research and Quality as cited by Grady, M.S., Batjer, H.H., and Dacey, R.G. *Resident duty hour regulation and patient safety: establishing a balance between concerns about resident fatigue and adequate training in neurosurgery*, Journal of Neurosurgery Volume 110: May 2009.
 2. Curet, Myriam J. *Resident Work Hour Restrictions: Where are we now?* Journal of the American College of Surgery Volume 207, No. 5, November 2008. (pp. 767-776)
 3. Gopal, Glasheen, Miyoshi, Prochazka AV, *Burnout and internal medicine resident work hour restrictions*. Archives of Internal Medicine 2005; 165: 2595-2600.
 4. Gelfand, Podnos, Carmichael JC et al. *Effect of the 80 hour work week on resident burnout*. Archives of Surgery 2004; 139: 933-938.
 5. Grady, M.S., Batjer, H.H., and Dacey, R.G. *Resident duty hour regulation and patient safety: establishing a balance between concerns about resident fatigue and adequate training in neurosurgery*, Journal of Neurosurgery Volume 110: May 2009.
 6. Barger, Ayas, Cade et al. *Impact of Extended Duration Shifts on Medical Errors, Adverse Events and Attentional Failures*. Public Library of Science (PLOS) Medicine December 2006; Volume 3, Issue 12 (pp. 2440-2451).
 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 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**

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,

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