



**COMMENT OF
THE AMERICAN BOARD OF SURGERY**

ON

**THE RECOMMENDATIONS OF THE
INSTITUTE OF MEDICINE REPORT:**

***RESIDENT DUTY HOURS:
ENHANCING SLEEP, SUPERVISION, AND SAFETY***

Prepared for the Accreditation Council for Graduate Medical Education

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INTRODUCTION

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

BACKGROUND

American Board of Surgery

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

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

IOM Report

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

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

Changes Recommended in the Report

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

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

What the Report Lacks

Unfortunately, with all of its analysis and detailed recommendations, the Report lacks a prudent consideration of the effect of resident hour restrictions on surgical practice and surgical resident education. Though the report repeatedly acknowledges differences in the effect of previous resident hour restrictions on general medical practice versus surgical practice, it gives this no consideration in formulating its recommendations, which are broad recommendations of general applicability and do not consider specialty-specific patient needs. This failure, which undermines the credibility of the report, was perhaps a result of the composition of the Committee. Of seventeen members, only one was a surgeon, and none were present from the disciplines most affected by work hours restrictions — general surgery, orthopedics, and neurosurgery. None of the members were actively practicing surgeons. Six members were clinicians, from non-surgical disciplines, but only two were in active practice that would put them in daily contact with residents; most were in senior administrative positions. The remaining members were principally non-physician experts in

medical quality and safety, and had no involvement with resident training. Thus the membership of the committee had limited current experience with resident training (2/17) and no experience with the surgical disciplines where emergency care is an integral part of practice. The group was therefore not representative of the constituency to which its recommendations were directed, and it is not surprising that those recommendations would be incompatible with the realities of surgical resident training. It is unclear why the IOM constituted a committee to address such important regulations which excluded the disciplines most affected.

General History and Significance of Professionalism Training in Surgical Residency

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

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

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

The same is true for surgical residents, who must comply with the same demands of surgical practice if they are to provide competent surgical care as residents and to become capable surgeons by the end of their residency programs. Surgical residency programs have demonstrated over time that emphasis on personal responsibility and rigorous experience produce surgeons with the skill necessary to practice independently and competently on their own. Surgical residents need

adequate opportunities and experience for the development of mature surgical judgment — that quality that separates excellent from marginal surgeons in and out of the operating room.

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

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

ABS PERSPECTIVE

Summary

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

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

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

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

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

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

Impetus for the Report

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

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

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

Patients' subjective perception that they would not want to be treated by a doctor who has been on duty for twenty-four hours, without objective evidence or consideration of the potential risks of the alternatives, should not mandate a change in resident work hour restrictions. From a surgical perspective, one is left wondering how surgical patients would answer the survey question if posed

in a more realistic context: “Would you prefer a well-rested doctor who is not familiar with your condition, to a tired doctor who is knowledgeable about your problems and can provide the care you need?” “Would you prefer your doctors to leave in the middle of your surgical procedure so that fresh doctors completely unfamiliar with the first half of your surgery and your unique surgical needs can take over?” Intuitive responses to hypothetical questions regarding doctor and resident hours should not be the basis for profound changes to surgical residency programs. Instead, we should be guided by demonstrable evidence of how such changes affect patient care.

Lack of Causal Evidence

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

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

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

Continuity of Care — A Special Requirement of Surgical Practice

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

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

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

Disruption in Continuity of Care Provided by Residents

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

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

The Report recommends several ways to improve handoff procedures, but fails to recognize the insurmountable difficulties of accurately transmitting the qualitative and subjective data essential to continuous treatment of a critically ill patient. Both resident and non-resident surgeons are aware of this problem and sacrifice their personal time for their patient's safety by caring for their patients until it is safe for them to stop, not until an arbitrary shift ends. The Report recommends that handoffs be improved, but does not consider that they may not be amenable to improvement. The

need for improved handoffs has been recognized in surgical care for more than two decades, and major efforts have been made to “improve” the process through computerization, check sheets, and a variety of other mechanisms, all with no discernable effect. This suggests that future improvement in handoffs cannot be assumed.

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

Reduced Resident Experience in Operative and Postoperative Care

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

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

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

necessary. This is obviously inefficient, but a resident's training is necessarily subject to the vagaries of patient presentation.

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

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

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

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

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

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

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

Data on How Previous Resident Hour Restrictions Affect Surgical Residency

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

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

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

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

Attending physicians felt residents were less prepared for their cases and teaching conferences after the restrictions. They also felt "the covering resident at night knew the patient less well" after the

restrictions. (37) One year after the restrictions, attending surgeons perceived their interns to have “less technical skill, less clinical judgment, less sense of responsibility for the patient, less preparedness for cases, and less efficiency compared with the interns before the work hour changes.” (38)

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

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

Effects on Other Specialty Residencies

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

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

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

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

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

The New York Model

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

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

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

These results are important because they suggest that the true impact of resident hour restrictions on surgical patient outcomes may not be evident immediately, and that they may worsen over time.

They also provide measurable evidence over a sufficiently long period of time of such effects, which were ultimately non-existent or negative. This is consistent with the Board's assessment of the current data on resident hour restrictions as applied to surgical residents. As described above, the Board finds and the data shows that duty hour restrictions produce either no change or a negative change on surgical patient safety and that initial data may be inflated, reflecting more positive patient outcome rates than will be the case in later years.

The European Model

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

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

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

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

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

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

Public Perception

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

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

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

The unfortunate aspect of this scenario is that the management of resident work hours has become a highly politicized issue in which objectivity and rationality have been submerged to hype, biased investigation, and third-party goals other than improvement in patient care. As we have tried to demonstrate, this has gotten us to a situation in which arbitrary hours regulations have assumed operational primacy over medical ethics and quality of resident training. Paradoxically, the very regulations which were promulgated to promote patient safety have had the opposite effect on continuity of patient care, have resulted in mandated resident behaviors which constitute definable malpractice, and have degraded the training of residents in specialties which are heavily dependent on experience with emergency care. The recommended modifications of the IOM Report in regard to shift limitations of 16 hours, mandated sleep of five hours, and other specific hour restrictions, are basically unworkable in the context of real patient care and resident training for these specialties, and in some cases would actually worsen sleep cycles of residents. The constitution of the IOM Committee was such that only two of 17 members had any present involvement with resident training, and none of the 17 had any experience with the surgical specialties which are most affected by the regulations; it is not surprising that they would lack the experiential base to understand the effects of their recommendations on real-world resident training.

RECOMMENDATIONS

Restoration of Ethical Priorities

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

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

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

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

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

Individualizing Work Hour Restrictions by Resident Level

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

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

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

CONCLUSION

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

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

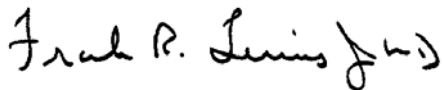
The problem with currently mandated work hour restrictions is not per se with the 80-hour limit, but with the rigidity with which shifts are defined. Flexibility needs to be introduced into the work hour

requirements such that unique needs of different specialties can be accommodated, and the work hours can be made secondary to the primacy of patient care and the opportunities for resident learning. Medicine for centuries has been self-regulating as a profession, and the arbitrary external enforcement of work hour restrictions attacks the very professionalism that has served the best interests of patients and residents alike. The present restrictions therefore need to be modified to allow flexibility in application, especially for residents at a senior and chief level who are at a point in their training where they are developing independent judgment and decision making capabilities. It is inherently unacceptable at present that a system has been constructed which forces dishonesty among residents in order to allow them to meet their moral obligations to care for patients or to pursue unique learning opportunities.

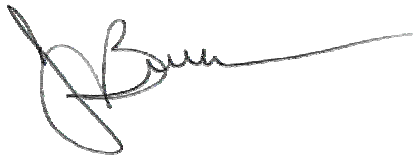
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The following surgical boards wish to endorse the preceding position paper and indicate their substantial agreement that similar concerns and problems are seen in their specialty area.

American Board of Colon and Rectal Surgery



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American Board of Neurological Surgery



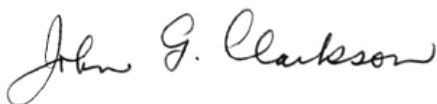
M. Sean Grady, M.D., Chair

American Board of Obstetrics and Gynecology



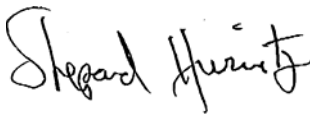
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American Board of Otolaryngology



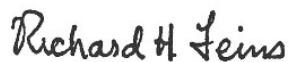
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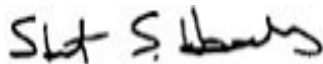


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