Note: This APDS position paper has been accepted for publication in the Journal of Surgical Education.

ASSOCIATION OF PROGRAM DIRECTORS IN SURGERY

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January 26, 2016

Thomas J. Nasca, M.D., MACP
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Dear Dr. Nasca,

On December 21, 2015, The Association of Program Directors in Surgery (APDS) received a request to provide a formal position paper for an anticipated comprehensive review of accreditation requirements by the Accreditation Council for Graduate Medical Educations (ACGME) with a deadline of February 1, 2016. The following document is the APDS response to this request. The requested topics to be addressed are as follows:

I) APDS formal position on current ACGME resident duty hour requirements
II) APDS formal recommendations regarding dimensions of resident duty hour requirements
III) APDS formal recommendations regarding standards governing key aspects of the learning and working environment
IV) The willingness of APDS to participate in an ACGME sponsored Congress

The ultimate purpose of surgical education is to produce graduates who provide the highest quality care with the best possible outcomes. The APDS is an organization of program directors and associate program directors representing approximately 250 ACGME approved general surgery residencies. The APDS was founded in 1977:

- Provide a forum for the exchange of information and for discussion on a wide range of subjects related to post-graduate surgical education.
- Maintain high standards of surgical residency training by improving graduate surgical education and patient care.
- Provide advice, assistance, and support to program directors on matters pertaining to surgical education and to accreditation.
- Encourage research into all aspects of the education and training of surgeons and surgical subspecialties.
- Represent the interests of program directors in the education and training of high quality surgeons to other organizations, individuals and governmental agencies or regulatory bodies.

Given our membership and the goals of the organization we are uniquely situated to provide a first-hand perspective on the specific issues surrounding the education of general surgical residents.

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As individual program directors, members of our organization are responsible for maintaining general surgical residencies within the parameters of the ACGME standards and Surgery Resident Review Committee (RRC) in order to maintain residency accreditation. Therefore, despite any organizational reservations, the resident duty hours parameters established by the ACGME in 2003 and revised in 2011 have been the absolute standard that our residencies must maintain. Our members are also charged with maintaining standards established by the American Board of Surgery (ABS), so that our graduates meet the criteria for Board eligibility. The compression of time to maintain increasingly complicated standards with reduced and constricted duty periods is challenging. Our members are committed to research that will lead us toward a better understanding of the optimal work environments for residents. Currently a number of our residencies are participating in the trial of flexibility in duty hour requirements for surgical trainees (FIRST Trial). The results of the trial are expected to be released in February, shortly after this position paper is due. As a result of this timing, our position is based on the currently available literature and our daily experiences in the clinical learning environment.

APDS Concerns around Duty Hours: Overview of General Surgery:

General surgery residencies have complied with the original and revised duty hour limits instituted in 2003 and 2011, respectively. The 2011 requirements limiting PGY1 resident's to 16 hour shifts and overall 28 hour shifts have amplified concerns about the future safe practice of surgery which have been expressed by program directors, fellowship directors and the residents themselves. The fundamental and unified concern is the impact of duty hour requirements on the surgical educational process and the effect on patient wellbeing when the trainee no longer has the safety net or structure of the training environment. It is a consensus opinion that inadequately trained surgeons will lead to poor patient outcomes, which in part are due to duty hours that do not accurately reflect the practice of surgery within our communities.

Each specialty has unique educational needs. By its very nature, the practice of surgery has fundamental differences from other medical specialties. All residents are required to develop competency in six domains, however, surgeons are required to develop a seventh: technical operative competency. Achieving competency in technical skills largely accounts for the current length of general surgical residency. The 2003 duty hour changes decreased the available time to train general surgery residents by several thousand hours over the course of 5 years. Due to the fact that the five- year duration of training has not increased, this reduction in the hours of training compared to previous generations has led to grave concerns in the surgical community as to our graduates' preparedness to enter independent practice. One response to this concern is the establishment of transition to practice training programs by the American College of Surgeons (ACS). Availability of this additional year of monitored experience is felt to be necessary for some graduates who are not confident to enter independent practice. Several other proposals are under debate and consideration to better ensure safe entry into independent practice; examples include more intense, focused training, required longer periods of training, and a complete restructuring of the training paradigm to qualify for the ABS examination.

Besides a need for training in an additional competency, the nature of the surgical disease and its complications, for which the general surgical resident must be trained, lends itself to intense involvement over relatively short periods of time (typically hours to several days). An example of this is one of the primary diseases for which the general surgeon is required to be an expert - the evaluation and treatment of the patient with an acute abdomen.

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Typically, such disease processes are evaluated, diagnosed and treated over a 6 to 48 hour period which requires the resident to be available for serial assessments. Additionally, training in the operating room does not lend itself to defined duty period nor shift work mentality. Predicting the duration of operative procedures can be inaccurate due to patient factors and unanticipated events during operations. Rotating residents in and out of operations to conform to duty hour restrictions is disruptive to their education and constitutes a significant patient safety issue. Strict adherence to duty hours is not reflective of actual practice in which a surgeon must execute all steps of a complete operation. The scope of general surgery is such that, procedures which might be critical to the training of the surgeon may occur infrequently or at such a time that they are in conflict with duty hour requirements. The need to participate in these procedures is essential for all levels of surgery residents but especially important for senior residents.

All of the above issues are further magnified by the fact that a significant proportion of general surgery residents are slated to practice in environments where there will be a scarcity of other practitioners who can provide relief for them. This will invariably lead to periods of time when they are called to work long hours in the interest of their patients. A system which arbitrarily limits senior residents by the clock rather than allowing some flexibility is doing them a disservice in preparation for practice and, for their future patients.

Resident well being is at the heart of every program director and is a main focus of the APDS. Since the inception of the duty hours, residents have expressed a great degree of stress in trying to learn what is required in a time-pressurized system. They also feel conflicted in their duty to care for sick patients and the requirement to transition them to another provider in the name of compliance with duty hours. When the resident chooses patient care over duty hour accuracy, he or she is further placed in a professionalism dilemma of patient care versus honesty. Residents are also anxious about their own preparedness to enter practice with less formal educational time. Finally, differential duty hour limits have disrupted the culture of resident-to-resident support to navigate the rigors of training. Of particular concern is the adverse effect on PGY-1 residents, who are in the most need of peer support but are not considered full-fledged members of the team due to differential duty hours. Whereas in the past residents functioned as a team, now, they function primarily as a loose affiliation of individuals. This robs the resident of support in completing clinical tasks but more importantly decreases the amount of peer support which is crucial for their development.

It is with this background and summary in mind which we submit the requested review.

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

The APDS recognizes that the ACGME approached the 2011 Duty Hours rules with an attempt to adhere to the best available evidence for guidance. A multitude of published manuscripts and surgical society position statements reflected on anticipated outcomes of those proposed duty hour limitations.[1-4] Notably, a letter by Britt et al[1] from the ACS to the ACGME on August 19, 2010 outlined several concerns which were echoed with potential strategies for adaptation in a publication by Friedell et al.[2] While some of these regulations were predicted to enable an improved level of independence and continuity of patient care

for senior residents, the 16 hour duty hour limitations for PGY 1, shortening the maximum duty period length from 24 + 6 hours to 24 + 4 hours, and the strict adherence to minimum time off between duty hour periods were anticipated to negatively affect residents' educational experience and to potentially jeopardize patient care owing to increased transitions in care and less resident continuity with individual patients. Furthermore, it was anticipated that there would be an increase in work load for PGY 2-4 residents and that there would be challenges with adequate preparation for the PGY 2 year. The APDS voiced similar concerns and in addition, raised concerns of decreased operative volumes, the development of a "shift work" mentality and the erosion of patient ownership and commitment among our surgery residents.

One referenced study supported the PGY 1 sixteen hour maximum duty period.[5] This study was focused on internal medicine residents, was limited by a low index of residents and was unrealistic with the presence of 33% more PGY1 resources (4 vs 3 PGY 1 Residents) on the teams that had limited shift lengths in order to remain compliant with the proposed work schedules. A subsequent and more in depth study performed by the Canadian Critical Care Trials Group analyzed residents from a multitude of specialties and were unable to reproduce the findings.[6] They reported on significant challenges with patient safety owing to increased transitions in care and concerns with resident knowledge base and decision-making with 16 hour shifts.

Lee et al[7] reviewed surgical residents' perceptions of the 16-hour work day restriction. Four hundred and sixty four PGY 1-5 general surgery residents were surveyed. There was 75% dissatisfaction overall with PGY 2 to PGY 5 more dissatisfied than PGY1 residents (87% vs. 54% $P<0.01$)). Seventy-five percent of PGY1 and 94% of PGY2 – PGY 5s were concerned about the education of the PGY1 resident. There were problems due to inadequate sign-out with 59% of PGY1s and 85% of PGY 2-PGY 5s reporting as such. Eighty-nine percent of PGY2 to PGY5s stated a shift in responsibility from interns to them occurred. Eighty-six percent of PGY2 to PGY5 residents believed a decreased level of intern ownership of patients had occurred.

Two notable reviews of the effects of the revised 2011 duty hour requirements on internal medicine residents demonstrated increased hand-offs, fewer teaching conferences, decreased PGY I daytime availability, the noted perception of residents and nurses of a reduced quality of care, an increased resident concern of the risk of making serious medical errors and no improvement in resident well-being.[8,9]

A survey of residency program directors in pediatrics, internal medicine and surgery regarding the 2011 duty hour requirements was administered by Drolet et al.[10] There was a response rate of 75%. Surgery program directors were 2.9 times as likely to report that patient safety was worse ($p<0.01$). Of all the 2011 duty hour requirements, the one that gave the most concern for the program directors was the 16-hour shifts for PGY 1 residents with a 71.6% disapproval. Most important were the perceived effects of the 2011 ACGME regulations. The main concerns were patient safety, quality of patient care, resident education, resident preparation for more senior roles, resident ownership of patients, continuity of care, number of patients seen or operative cases and the increased frequency of hand-offs.

We are aware of numerous studies which report on links between fatigue and diminished performance of specific non-clinical tasks. However, we question whether this

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rises to clinical significance in a training environment characterized by appropriate supervision, teamwork and fatigue mitigation. Govindarajan et al[11] recently published their work regarding patient outcomes and surgeon fatigue. 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. There was no significant difference in the primary outcomes (death, readmission, or complications) between the two groups. This has remarkable implications for resident performance with regard to the equivocal effect of prolonged duty hour periods on surgical outcomes and patient safety.

The impact of resident duty hour requirements on surgical trainees and surgical patients was systematically reviewed in 2014.[12] They reported an improvement in resident well-being as a result of the 2003 duty hour requirements. However, the 2011 PGY1 16 hour requirement appears to have had, at best, a neutral effect on resident well-being with a potentially negative impact with regard to how the PGY1s are incorporated into surgical teams and the overall culture of surgical training. This review also addressed the impact of resident duty hour requirements on resident education. The 2003 resident duty hour requirements were noted to have a negative impact on resident education. Residents trained after implementation of these rules were less likely to pass their board examinations and have less operative experience, particularly as first assistant and teaching assistant.

Philibert et al[13] published an in depth formal review of the literature surrounding the effect of duty-hour limits on quality and safety of care in teaching settings and on resident learning outcomes in addition to the effect of resident workload on patient and resident outcomes. This review encompassed studies regarding the ACGME 2003 and 2011 duty hour requirements. They noted a variety of concerning issues regarding patient care in teaching institutions to include increased patient complications, increased rates of patient safety indicators and decreased perioperative continuity. Importantly, the authors noted that the focused question of causality between duty hour changes and these undesirable outcomes was difficult to establish.

The query for a formal "cost" analysis of the 2011 duty hour requirements is challenging to construct. The majority of hospital systems with graduate medical education have developed formal plans for the incorporation of Physician Extenders (Nurse Practitioners and Physician Assistants) to offset compromises to patient coverage owing to less resident availability.[3,14,15] While the financial impact to our institutions is of great magnitude (estimated at $150,000-$175,000 per Physician Extenders with even small residency programs incorporating 4-5 Physician Extenders following the 2011 duty hour changes), our more immediate concern with this transition is the loss of clinical experience during residency for those residents in our programs when their clinical time has already been compromised. This is clearly a difficult issue to assess, but in light of the perceptions of a lack of confidence of graduating residents[16], the incorporation of Physician Extenders into our educational environment is one additional avenue of lost experience for our residents and this deeply concerns our membership.

Overall, the current literature and the well-educated opinion of our experienced membership support that the 2003 duty hour requirements improved resident well-being

at the expense of education and patient safety and that the 2011 duty hour requirements resulted in detriments to resident well-being while continuing a trend of compromised resident education and patient outcomes. Perhaps more importantly, there have not been anticipated improvements in PGY 1 resident well-being or improvements in patient care as desired.[17-19] The 2011 restrictions have contributed to a delay in PGY I maturation and have had negligible effects on resident wellness.[16,18] A dramatic increase in transitions in care have contributed to increased patient vulnerability with documented increases in the failure to rescue patients and serious morbidity, decreased resident overall clinical experience and delayed preparation for senior levels of training.[5,18,20-22]

II. APDS formal recommendations regarding dimensions of resident duty hours requirements and justification for these recommendations with evidence:

Based on our analysis and the opinion of the APDS leadership and constituency regarding duty hour requirements, we recommend the following:

1) Limit resident duty hours to no more than 80 hours per week averaged over 4 weeks
2) Limit in-house call to no more frequently than every-third-night averaged over 4 weeks
3) At least one 24 hour period free of duty per week averaged over 4 weeks
4) An 8 hour minimum period between duty hour periods for all PGY levels
5) Maximum 30 hour shift with 6 hours beyond 24 allowed for educational purposes or transition of patient care
6) Flexibility at the senior resident level (PGY3-5) for patient care or educational purposes with regard to any of the above limitations

In order to achieve this framework, we recommend the following changes to the current ACGME common program requirements and frequently asked questions for General Surgery:

1) Retracting the ACGME 2011 restrictions which limit PGY I residents to 16 hour duty periods (ACGME CPR VI G.4.a:)

We consider this regulation to be the most detrimental of the 2011 implements and note a preponderance of data which confirms the negative impact of the 16 hour duty period on the PGY I residents well being, education, relationship with senior residents and ability to safely care for patients.

2) Modification of the maximum duty period length to 24 hours + 6 hours (ACGME CPR VI.G.4.a,b)

Further flexibility in the maximum duty period length is needed to take advantage of clinical and academic learning opportunities, provide continuity of patient care, and prepare residents for the realities of a general surgery career. Individual programs have the responsibility to structure this type of system on an individual basis and should be held accountable for their clinical learning environment. We recommend 6 hours be permitted to take advantage of educational opportunities to include elective operations, conferences and patient care responsibilities.

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3) Modification of the minimum time off between scheduled duty periods for PGY-1 and Intermediate level residents – 8 hour periods for all resident levels (ACGME CPR VI.G.5.a,b):

The current flexibility for PGY 4-5 residents with regard to minimum time off should be extended to all PGY levels. Clinical opportunities to provide continuity of care during the PGY 1-3 years is essential to progressive training and establishing patient ownership among maturing general surgeons. Remarkable challenges with transitions in care leading to adverse patient outcomes support that minimal time off periods between duty periods are not effective. The required periods off disrupt the flow of teamwork and compromise the integration of surgery residents into patient care. We recommend a minimum time off of 8 hours between duty periods for all surgery residents.

4. Modification of circumstances of return-to-hospital activities – Extend to PGY 2-3 residents (ACGME CPR VI.G5.c).(1).(a,b):
We recommend that the opportunity to return to the hospital activities for those circumstances defined in section b of the section be extended to PGY 2 and 3 residents. We agree with the importance of program director monitoring of such activities with fewer than eight hours away from the hospital.

5. Modification of the Resident/Fellow levels of Training as Defined by Specialty for General Surgery Residents - ACGME PDF available at:

http://www.acgme.org/acgmeweb/Portals/0/LevelOfTrainingbySpecialty.pdf

For General Surgery Residents: We recommend that PGY 1 residents be defined as "beginning level" residents, PGY 2 residents as "intermediate level" residents" and PGY 3-5 residents as "senior" or "final years of training" residents. This would permit appropriate flexibility in training for PGY 3 residents.

III. APDS Formal recommendations regarding standards governing key aspects of the learning and working environment

The APDS values and respects the effort the ACGME has made through the Clinical Learning Environment Review (CLER) program[23,24] to elevate standards for the learning environment that directly and indirectly impact the training of surgical residents. The six areas identified for focus in the CLER program, namely patient safety, quality improvement, transitions in care, supervision, duty hour oversight and fatigue management, and professionalism, encompass much of the necessary infrastructure for training competent surgeons. The APDS recognizes the critically important 'hidden curriculum' that the learning environment comprises and its impact on the development of physicians in training. While much could be said in regard to each of the above areas, the APDS would particularly highlight the following with regard to standards governing the clinical workspace.

First, the APDS recognizes the outcomes data from state and national sources documenting the impact that institutional participation in national benchmarking and quality programs such as National Surgical Quality Improvement Program (NSQIP) can have on institutional and individual performance in patient care.[25] Participation in such programs, coupled with efforts to train residents in a context where they become familiar with the use of this data in assessing their own performance (such as the Quality In-

Training Initiative (QITI))[26] seems an appropriate strategy for surgical training, and is encouraged. The potential that such tools may have in defining a more meaningful assessment of educational product for surgical residencies is something we feel should be developed in the upcoming years.[27]

Second, the APDS would highlight our agreement with principles suggested in the literature to date that there may be a need for specialty-specific strategies to duty hour oversight and fatigue mitigation, if the goal of optimal patient and educational outcomes is to be achieved.[13] In this vein, the APDS would encourage that surgical training specific interpretations of the CLER focus areas be incorporated in future iterations and best practice outlines. Appropriate flexibilities to ensure continuity of the learning and care paradigm are particularly critical in surgical disciplines, and we believe can be incorporated within the spirit of the duty hour limit era, with appropriate continuing efforts to accomplish this as informed by well-conducted research.

Third, the APDS would highlight the need for a supervision strategy that meets hospital and patient safety standards, including those required for reimbursement, and at the same time, allows appropriate progression of resident function to true independent capability as an attested skill by the time of graduation. Cooperative dialog is needed with learning environment partners to address time, fiscal, and other pressures that must be managed in collaborative institutional partnerships if the required product is to be delivered during residency, and assured at the completion of the same. The CLER emphasis on supervision promotes this discussion, though specific focus on these pressures and how they are managed for surgical trainees may be an appropriate area for heightened contextual focus in the future.

Finally, the APDS recognizes and applauds the focus the ACGME's CLER program has brought to the negotiation between program directors and departments and their institutional partners over resource allocation issues fundamental to the process of GME. The CLER effort has brought the detail orientation and specificity with which program directors have long been familiar in the accreditation process to the institutional home, and this has enhanced dialog and partnership through the accountability and focus lent to such discussions.

IV. APDS willingness to participate in a Resident Duty Hours in the Learning and Working Environment Congress:

The APDS leadership is looking forward to participating in this Congress. We participated in the previous ACGME Duty Hours Congress in 2009 and would appreciate the opportunity to voice our recommendations formally to the ACGME and the other represented institutions during the upcoming session. We would appreciate prompt notification of the date and location of the venue for appropriate planning.

Thank you for the opportunity to submit our formal review and recommendations. We believe that with our recommendations, general surgery program directors can continue to modify our individual systems to optimize resident education and development to meet the ACGME accreditation demands and ABS certifying requirements. In addition, when considering all of this information and our belief that all specialties have unique challenges, we recognize the need for specialty-specific duty hour research going forward such that data can be generated to ultimately determine specialty specific duty hours regulations.

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Respectfully submitted,

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