Enhancing Quality of Care, Supervision, and Resident Professional Developmen

# The ACGME 2011 Duty Hour Standard

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The members of the ACGME Task Force on Quality Care and Professionalism

# The ACGME 2011 Duty Hour Standards: Enhancing Quality of Care, Supervision, and Resident Professional Development

ACGME Task Force on Quality Care and Professionalism

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Accreditation Council for Graduate Medical Education (ACGME) Chicago, IL

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#### About the ACGME

The Accreditation Council for Graduate Medical Education (ACGME) is responsible for the Accreditation of post-MD medical training programs within the United States. Accreditation is accomplished through a peer review process and is based upon established standards and guidelines. The ACGME is a private, nonprofit organization established in 1981.

The mission of the ACGME is to improve health care by assessing and advancing the quality of resident physicians' education through exemplary accreditation.

#### **About the Task Force**

In February 2009 the ACGME charged a 16-member ACGME Task Force on Quality Care and Professionalism with the process of deliberating on the new common requirements for resident duty hours. The Task Force comprised 12 national leaders in graduate medical education, 3 residents, and 1 nonphysician public representative with experience in consumer advocacy.

The Task Force met 12 times during 2009–2010. During the Duty Hours Congress in June 2009, the Task Force heard 67 oral presentations as a follow-up to written opinions submitted by a range of organizations and other stakeholders. Six meetings were devoted to fact gathering from multiple experts on the history and background of duty hour restrictions, patient safety (including the perspective of the patient), sleep physiology, and research. The remaining 5 meetings were devoted to reviewing testimony and developing the recommendations. The Task Force completed drafting the recommendations in June 2010 and met a final time in August 2010 to review detailed, comprehensive stakeholder comments on all elements of the 2011 ACGME Common Standards.

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# The ACGME 2011 Duty Hour Standards: Enhancing Quality of Care, Supervision, and Resident Professional Development

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# CHAPTER 1 A COMPREHENSIVE APPROACH TO Ensure Safe Care for Today and the Future

#### Introduction

Residents' active involvement in clinical care is vital to the acquisition of knowledge, judgment, and skills required for entry into the unsupervised practice of medicine. One attribute of the 3 to 7 years of residency in the given specialty is the steep learning curve necessary to bring about the transformation from medical student to independent physician. Some see residents' long hours and intense involvement in patient care as an essential element of preparation for independent practice and a cultural symbol of a profession that requires availability to one's patients and putting their needs first. Others fear that the long hours of service may affect residents' alertness, and ability to provide safe and effective care, and may potentially compromise resident safety as well. These opposing views about the role of long hours in the clinical education of physicians have been the subject of intense debate for more than 2 decades. In 2008, when the Institute of Medicine (IOM) released its report entitled "Resident Duty Hours: Enhancing Sleep, Supervision and Safety," the competing perspectives were represented by members of the profession concerned about the adverse effects of duty hour limits on graduates' preparedness for practice and by members of the media and public, who expressed unease that the reductions achieved under the 2003 Accreditation Council for Graduate Medical Education (ACGME) duty hour standards were insufficient to have a positive effect on patient safety in the nation's teaching hospitals. The perspectives also highlight 2 competing goods: ensuring safe care today through limits on hours in the settings where residents learn clinical practice, and ensuring the safety of patients tomorrow by providing residents with adequate experience under graded supervision to prepare them for their future practice.

When the ACGME implemented common duty hour standards in 2003, it promised the profession and the public a comprehensive review after 5 years, with the aim of evaluating the effectiveness of these standards and identifying areas in need for refinement. In February 2009, the ACGME Board of Directors endorsed a review of its standards and appointed a Task Force to review the available scientific data and other relevant information and develop recommendations for new comprehensive standards to the ACGME Council of Review Committees and Board of Directors.

#### **Scope and Aims**

The aim of this monograph is to provide justification and contextual information to assist the profession, the education and research communities, and the public in understanding how the ACGME and the Task Force developed the 2011 standards. Data gathering for the work of the Task Force entailed an international duty hour symposium; 3 commissioned literature reviews; and a national duty hours congress during which the Task Force received written position papers from more than 140 medical organizations, and personal testimony from more than 70 organizations representing medical specialties, residents and students, and the ACGME's member and appointing organizations. A particular focus was on the educational community's interpretation of, and agreement with, recommended limits on resident hours, and the ACGME surveyed a broad group of stakeholders, including residents.

The Task Force also heard from patient safety leaders, the New York State Hospital Association, the Veterans Administration, sleep experts, safety net hospitals, associations, health care ''accreditors,'' members of the IOM Committee, patient advocates, and patients and families who had suffered a medical error in a teaching hospital.

Throughout its work, the Task Force sought to balance the sound bites that contribute to public concern, "Do you want a tired doctor?" and "Who can function after 24 hours awake?" with the complex task of reconciling the competing goods of safety today with safe and effective care tomorrow. An emphasis on deliberate practice with supervision, guidance, and availability of appropriate backup as key to the acquisition of competence and expertise was essential to this aim. At the same, these factors must be balanced by time limits on resident hours, which are needed in certain specialties to ensure that residents' or patients' safety and well-being are not compromised through excessive time on task.

# The 2011 Standards

The monograph begins with a historical perspective on the ACGME's effort to limit resident hours and with a summary of the Task Force's data gathering and comprehensive deliberations on duty hours and related considerations. Chapters 5 through 10 summarize the 2011 duty hour and related standards. The standards setting limits on resident duty hours and their underlying scientific basis are detailed in Chapter 5. The major changes encompass more restrictive duty hour limits for first-year residents; added flexibility for senior residents and under certain special clinical and educational circumstances; and reducing the length of the continuous duty period to respond to ample scientific evidence about the negative performance effects of long periods of wakefulness. An added area of refinement encompasses specialty-specific standards that limit resident clinical responsibilities.

Like the 2008 IOM report on resident duty hours, the Task Force affirmed that the standards would need to go far beyond limits on resident hours to promote high-quality education and safe patient care, and the Task Force's recommendations included comprehensive, graduated standards for resident supervision, discussed in Chapter 6. Much of the deliberations of the Task Force focused on an appropriate balance between supervision and graduated responsibility. This is an area where the graduate medical education (GME) community has voiced growing concern, progressing to alarm, that a principle that undergirds clinical education-graded authority and progressive responsibility coupled with graded supervision-may be eroding in America's teaching hospitals. The new standards incorporate validated approaches for supervision and graduated responsibility that balance delegation of patient care responsibility to residents, resident learning, and delivery of safe patient care. The new standards demand enhanced supervision for first-year residents, in keeping with research showing that this group benefits from added clinical guidance and immediate supervisory physician availability, important for learning patient safety and care delivery.

The 2011 standards extend beyond the recommendations of the IOM 2008 report and include new standards for resident professionalism and personal responsibility to maintain alertness, described in Chapter 7. Without attention to residents' activities in their hours outside the program, the added limits on duty hours may not ensure sufficient rest and alertness for residents' learning and participation in patient care. These elements of professional responsibility must be discussed and learned by all who provide care for patients. For the same reason, the ACGME decided to include all moonlighting hours under the weekly limit on resident hours. To educate residents for practice in the 21st century, the 2011 standards also include an explicit focus on teamwork, described in Chapter 8, and new detailed standards for transitions of care, which articulate programs' and institutions' added responsibilities to teaching and supervision of handover of patient care responsibilities to colleagues, and other transfers of care in the

teaching setting. Chapter 10 summarizes current scientific data on fatigue mitigation and alertness management, and how the standards address them. This is an area where future research has a high potential to produce added practical scientific methods to assess alertness and added future refinements to the standards. APPENDIX E of this monograph provides a side-by-side comparison of the 2011 ACGME standards with the IOM recommendations and the common standards implemented in 2003.

Several chapters provide context for the standards, including Chapter 11, which explores causes of errors in teaching hospitals and provides recommendations for solutions; Chapter 12, which articulates the need for flexibility in the standards to accommodate different specialties and levels of training; and Chapter 13, which summarizes the Task Force's thoughts on the graduate medical education community's responsibility to the safety of future patients by producing a fully trained physician at the completion of residency.

A major thrust of the IOM's 2008 report was concern about the rigor of the ACGME's enforcement of the 2003 duty hour standards. While much of this arose from differences between the substantial compliance model used by the ACGME as an educational accreditor and a "zero-tolerance" approach favored in some proposals for regulation of resident hours, the ACGME and the Task Force deliberated on enhanced enforcement of the standards, including a regular site visit for sponsoring institutions, to assess their ability to provide an appropriate, safe learning and care environment, and to assess their capacity for educating residents about error reductions through engagement of all residents in the patient safety and quality improvement programs of the sponsor. In this manner, the competency of systems-based practice will be inculcated in each resident in his or her daily activities. Detailed information addressing questions about enforcement of the standards is provided in Chapter 14.

#### **Looking Toward the Future**

The 2011 standards are based on the available scientific evidence and the literature, and the balancing of competing needs that are the reality of the clinical educational environment. However, both the IOM report and the Task Force found a relative dearth of scientific evidence in many areas important for setting standards to promote sound education and safe and effective patient care. In response, in Chapter 15, the ACGME and Task Force begin the process of laving out an initial research agenda, in the hope that the GME and research community will expand it and contribute to the work that needs to be done to assess the effectiveness of the 2011 standards and to provide for future refinements based on sound, scientific principles.

The outcomes of patient care in teaching hospitals, as judged by severity of adjusted morbidity and mortality and when compared to nonteaching hospitals, are equal or better. At the same time, we acknowledge that patient safety and outcomes must continue to improve, and America's teaching hospitals should lead the way. The ACGME hopes to work with all teaching hospitals to demonstrate commitment to, enhancement of, and leadership in patient outcomes and parameters of patient safety in the clinical environments. The enhanced focus of the ACGME on resident involvement in quality and safety will benefit both teaching hospitals today and the institutions and settings where residents will practice after graduation. Most important will be the benefit that accrues to each patient when a resident pursues a career of service to the public.

Educating the next generation of physicians to ensure safe, high-quality care for future generations is a highly important undertaking. While the ACGME establishes standards, educating residents and assuring safe and effective care of those we serve now and in the future will require the active participation and commitment of the graduate medical education community and the profession. Critical elements in successful achievement of these goals are honesty in assessing the learning environment; courage to monitor and self-regulate; continued voluntarism, which is essential in the peer review process; and willingness of all to continue to learn and innovate. Anything less may result in the removal of the right of the profession to govern the education of future physicians. However, we believe that our community of educators and physicians-in-training is committed to the ultimate goal of enhancing the health of the citizens of the United States by educating motivated, professional, knowledgeable, and humanistic physicians, devoted to excellence, in settings where these learners are taught about quality and safety by example. This monograph outlines the next step in that journey.

I would be remiss if I did not to thank all those who participated in this process of national

standard setting. To the hundreds of members of societies who rendered formal recommendations; to the many experts who gave of their time and wisdom; to the thousands of individuals who shared their comments on the draft standards; to the members of the Task Force for their contributions of time, effort, wisdom, and expertise, we express our deepest gratitude and appreciation. To the patients and patient advocates who shared their deepest wishes for a better health system, we hope our work was worthy of their sacrifices. Finally, to the Co-Chairs of the Task Force, Susan Day, MD, and E. Stephen Amis Jr, MD, FACR; to the editors of this monograph, Dr Amis and Ingrid Philibert, PhD, MBA; and to the coordinator of the Task Force, Emily Vasiliou, MA, we extend our deepest appreciation.

# CHAPTER 2 A BRIEF HISTORY OF DUTY HOURS AND RESIDENT EDUCATION

Ingrid Philibert, PhD, MBA Cynthia Taradejna, MEd

#### **Accreditation of Resident Education**

Historically, review of residency programs has been provided by the American Medical Association (AMA), which provided listings of "approved" programs as early as 1910. The Residency Review Committees (RRCs) that accredit resident education in the individual specialties emerged in the 1950s, with surgery and internal medicine first forming committees in 1950.1 Before 1974, the RRCs performed their peer review and accreditation function independently, with support and staffing from the AMA.<sup>1</sup> In 1972, the Liaison Committee for Graduate Medical Education (LCGME) was inaugurated and began to provide a convening function for the RRCs.1 The ACGME was organized in 1981 by transitioning the LCGME to an unincorporated entity with 5 member organizations (the AMA, the American Board of Medical Specialties, the American Hospital Association, the Association of American Medical Colleges [AAMC], and the Council of Medical Specialty Societies).<sup>1</sup>

Like the ACGME in later years, the LCGME used documented accreditation standards comprising general requirements that applied to all accredited programs and specialty-specific program requirements.<sup>2</sup> The early requirements did not explicitly reference resident hours: instead, they mentioned resident supervision and the learning environment, requiring a "well organized and well qualified teaching staff'' and "an educational committee of the staff which is responsible for the organization, supervision, and direction of the residency program."<sup>3</sup> The requirements further stated that "[t]he educational effectiveness of a residency depends largely on the quality of its supervision and organization," and that "[t]he responsibilities for these important functions lie with the department heads and a representative committee of the medical staff."3

As an educational accreditor, the ACGME monitors compliance and cites programs that do not meet its standards. It promotes resident learning and patient safety by requiring an educational curriculum; specifying the patient care experiences important to competence for independent practice; and ensuring that programs track the progress of residents through regular evaluations, including assessment of their knowledge, clinical and procedural skills, and competencies such as communication and interpersonal skills. Programs that do not comply with these standards are cited, and may be placed on probation, and residents and applicants must be notified that this has occurred. As this negatively impacts the ability to attract good residents, it is a powerful incentive for compliance. The accreditation of programs that fail to improve ultimately is withdrawn, after a system of due process. The ACGME also periodically (at minimum every 5 years)<sup>4</sup> updates its accreditation standards and enforcement processes to accommodate changes in the practice of the medicine and in educational theory and methodology, and other factors affecting graduate medical education, such as enhanced public calls for accountability.

The US Congress, the Department of Health and Human Services, and the Centers for Medicare and Medicaid recognize that the ACGME fosters high-quality education and safe and effective patient care by requiring accreditation of programs that receive graduate medical education payments under the Medicare program.<sup>5</sup> In addition, state medical licensing authorities expect residents to complete 1 or more years in an ACGME-accredited residency program as a condition of physician licensure.<sup>6</sup>

#### **Duty Hours: The Early Years**

Long hours are a component of medical residency and preparation for an occupation that

requires hard work and dedication. Their origin, along with the term ''resident,'' are found in traditional models of physician education as brief periods of intense training, during which responsibility for patients rested with residents 24 hours a day, 7 days a week. By the latter part of the 21st century, this had given way to a multiyear experience that combined exposure to patients with new learning modalities in a vastly changed delivery system.

The formal study of the effect of residents' long hours on performance began in 1971, when a study showed postcall residents made more errors in reading a standardized electrocardiogram than their rested colleagues.<sup>7</sup> Earlier research using military personnel and college-age volunteers had shown that sleep deprivation affected performance across a range of dimensions including vigilance, cognition, and executive function.<sup>8,9</sup>

As early as 1980–1981, the specialty-specific Program Requirements for Internal Medicine and Pediatrics included statements on a balance of education and service demands, and the need for time for educational and personal pursuits.<sup>10</sup> The pediatrics standard stated that ''[h]ospital duties should not be so pressing or consuming that they preclude ample time for other important phases of the training program or for personal needs.''<sup>11</sup> Several specialties adopted similar language throughout the 1980s.

#### Regulation of Resident Hours in New York State

In 1984, the death of Libby Zion in a New York teaching hospital initiated a debate about resident hours and supervision.<sup>12</sup> Zion, a college freshman, died within 8 hours of her emergency admission to a major New York teaching hospital where she had been cared for by first-year and second-year residents. Initially, her death was ascribed to an infection, but today most agree she died from serotonin syndrome, prompted by the closely timed administration of 2 psychiatric drugs, meperidine and phenelzine.<sup>13,14</sup> Her father, an influential newspaper columnist, began a campaign that targeted the long

resident hours and poor supervision he felt had contributed to his daughter's death.

A 1986 grand jury investigation found the death was related to 36-hour duty periods worked by the residents involved in her care and to inadequate supervision by the attending physicians.<sup>12,15</sup> Testimony provided to the grand jury showed awareness of the complexity of duty hour regulation: "It would be unrealistic to expect residents to absorb the realities of caring for their equally fragile and needy patients if their working hours were fixed according to an arbitrary schedule, however well-intended" (F. Davidoff, MD, testimony to the 1986 Ad Hoc Committee charged with the inquiry into Libby Zion's death). The grand jury called for reforming resident education, including regulation of resident hours and supervision, and the New York Health Commissioner appointed an Advisory Committee, which became known as the Bell Commission.<sup>15</sup> The Committee's findings were released in 1987 and included a recommendation for an 80-hour limit on weekly resident hours, a maximum of 24 consecutive hours on duty, and a requirement for the presence of senior physicians in the hospital.<sup>16,17</sup>

Despite controversy and resistance by the teaching hospital community, the recommendations were incorporated into the New York State Health Code in 1989, making New York the first state to regulate resident hours.<sup>17</sup> The regulations, incorporated into the state hospital code at section 405.4, which governed service delivery by the organized medical staff, encompassed the duty hour limits and enhancements to supervision recommended by the Bell Commission.<sup>18</sup> Adoption was gradual and 10 years after the regulations had been issued, site visits to assess compliance with the regulations revealed widespread noncompliance.<sup>18</sup> In 2002, site surveys by a contractor hired by New York State to monitor compliance showed that more than 60% of the 118 teaching hospital surveyed were in violation of the limits.<sup>19</sup> Today compliance is improved in part due to vigilant monitoring by the State and the ACGME.

New York remains the only state that has adopted regulatory standards for resident hours.

Other states (California, Connecticut, Florida, lowa, Massachusetts, and Pennsylvania) considered and rejected adopting similar regulation. The Commonwealth of Puerto Rico instituted local regulation of duty hour limits in 2003, though it does not provide specific enforcement mechanisms.<sup>20</sup> Adoption of the New York duty hour regulation has been costly. A 1989 survey estimated that the regulation produced additional staffing costs for New York hospitals of more than \$358 million.<sup>21</sup> An added concern is that regulation did not appear to meet the primary aim of making patient care safer or better.<sup>22,23</sup>

# The ACGME 1987 Task Force on Resident Hours and Supervision

In response to interest in duty hour limits prompted by the death of Libby Zion, in June 1987 the ACGME authorized the formation of a Task Force on Resident Hours and Supervision and charged it with studying 3 areas: the adequacy of resident supervision; resident schedules and number of hours of work; and the changing educational sites for resident education. The Task Force developed preliminary recommendations for standards for review at the February 1988 ACGME meeting.<sup>23</sup> The group also affirmed the following: (1) education is the primary objective of residency; (2) a relationship exists between the quality of training and the quality of medical care provided by physicians after graduation; (3) residents play a role in providing continuity of care; (4) attending physicians have ultimate responsibility for care; and (5) education and patient care benefit when resident schedules maximize educational experiences, while allowing for rest to avoid stress, fatigue, and depression. In addition to addressing resident hours, new standards defined the clinical support services, including pathology, radiology, results retrieval, and messenger and transport services that would need to be available to residents at all times, including evenings and nights.<sup>24</sup> Specific recommendations included (1) 1 day in 7 away from the hospital; (2) on-call duty in the hospital no more frequently than every third night; (3) adequate backup if sudden and unexpected patient care needs create resident fatigue sufficient to jeopardize patient care; and (4) institutional policies to ensure that all residents are adequately supervised and reliable methods of communication between residents and supervising physicians.<sup>24</sup> The Task Force also recommended that each RRC develop standards regarding the frequency of duty and on-call assignments for residents.<sup>24</sup>

# **The AAMC 1988 Position Statement**

In March 1988, the AAMC released its position on resident hours and supervision.<sup>25</sup> In keeping with its role as an academic member organization, the AAMC presented its position as a set of guidelines for hospitals to consider and use in a manner appropriate to their setting, role, and resources.<sup>25</sup> The guidelines asked each hospital to develop operational mechanisms to ensure that resident education enhanced the quality of care provided to patients.<sup>25</sup>

The AAMC guidelines specified that hours should not exceed 80 per week, averaged over 4 weeks, and recommended curtailing moonlighting by limiting the total hours of residency and moonlighting to 80 hours per week.<sup>25</sup> It called for changes in resident hours to be phased in gradually to avoid compromising patient care or the educational goals of residency programs, and it recommended that all payers reimburse teaching hospitals for the incremental costs incurred as a result of these changes.<sup>25</sup>

## The 1992 Common ACGME Standards

In February 1988, the ACGME adopted the Task Force's report and assigned an ad hoc committee to incorporate them into the general requirements. The ACGME continued to debate general duty hour standards for the next 2 years and the revised general requirements were accepted at the ACGME's June 1990 meeting and forwarded to the ACGME's 5 member organizations.<sup>26</sup> The 1990 version specified that (1) at least one 24-hour day in 7 should be free of patient care responsibilities and that (2) oncall in the hospital should be no more than every third night, averaged over a 4-week period.

As the ACGME debated common standards, several RRCs established specialty-specific standards that set limits on weekly duty hours. The RRC for Internal Medicine (RRC-IM) instituted an 80-hour weekly limit, averaged over 4 weeks, to become effective in July 1989.27 In 1990, 3 additional RRCs set limits on weekly hours. The RRCs for Dermatology and Ophthalmology established a weekly limit of 80 hours, averaged over 4 weeks,<sup>28,29</sup> and the RRC for Emergency Medicine established a limit of 72 hours, of which only 60 could be devoted to clinical activity.<sup>30</sup> In the early 1990s, 2 additional specialties set limits of 80 weekly hours, averaged over 4 weeks. For allergy and immunology, the standard became effective in July 1992, and for preventive medicine, in July 1993.<sup>31,32</sup> By 1993, 6 specialties, including internal medicine, the largest accredited specialty, had established a weekly duty hour limit.

Because of the multilayered approval process in operation before the ACGME became an independent corporation in 2002, seven additional sets of revisions were made to the standards, with the 5 member organizations opposing various sections of the draft.<sup>33</sup> The revised draft for the general requirements ultimately was approved in February 1992, with an effective date of July 1, 1992.34 Two of the 5 member organizations had withheld their approval until revisions were made in the duty hour language, and the revised requirements asked that "each residency program establish formal policies governing resident duty hours and working environment that are optimal for both resident education and the care of patients."33,34

#### The Early Years of the 21st Century

In 1999, the Institute of Medicine released "To Err Is Human: Building a Safer Health System."<sup>37</sup> The report did not particularly implicate resident physicians or their long hours; instead, it recommended interventions to reduce the potential for errors in health care, including labeling and packaging strategies for high-risk drugs and substances with similar names, training issues for residents, work-rest cycles, how relief and replacement processes could be improved, and improvements to equipment (eg, standardizing equipment in terms of the shape of knobs and the direction in which they turn).''<sup>37(p64)</sup> Its release prompted the ACGME Board of Directors and its Strategic Initiatives Committee to explore sources of errors in the resident education environment, with reviews of the literature and other sources again suggesting limitation of resident hours and enhancing supervision as important strategies to enhance safety in teaching settings.<sup>38</sup>

An added reason for a reassessment of the duty hour standards was enhanced public focus on resident hours, and the observation that the specialty-focused and nuanced nature of the ACGME's approach to setting limits made it difficult to explain the standards and their benefits to patient safety to the public. A commentary by the ACGME's director noted, "patients have the right to expect competent care in all phases of an acute illness, and residents have a right to expect competent supervision in all aspects of their education in which they interface with patients."<sup>35(p1)</sup>

After approval of the new duty hour standards in 1992, the RRCs had begun to monitor compliance and to cite programs for noncompliance. The ACGME did not make summary compliance data public for nearly 10 years, and there was variability among the RRCs in citing programs with violations on the duty hour standards. In 2000, the ACGME first published aggregated data on compliance with the duty hour standards for the year 1999, and a report released in 2001 compared duty hour compliance for 1999 and 2000.35 It contrasted the percentage of programs and institutions cited for violations in 1999 with data for the year 2000, showing that in 1999, 17 of 87 institutions (20%) sponsoring residency education programs that were reviewed during the year had failed to comply substantially with the duty hour requirements. By 2000, that number had fallen to 10 of 127 institutions (8%)

reviewed. The percentage of internal medicine programs cited for duty hours fell from 30% in 1999 to 10% in 2000, and the percentage of orthopedic surgery programs cited declined from 29% to 10%. In contrast, the percentage of surgery programs cited remained constant (36% versus 35%).<sup>35</sup>

In 2001, citation rates for duty hour violations were 18% for surgery programs (of 99 programs reviewed), 21% for thoracic surgery programs (of 19 programs reviewed), 19% for internal medicine (of 81 programs reviewed), 11% for pediatrics (of 35 programs reviewed), 10% for family medicine programs (of 136 programs reviewed), and 5% for obstetrics and gynecology programs (of 81 programs reviewed).<sup>36</sup>

## Proposals for Federal Regulation of Resident Hours

On April 30, 2001, a petition requested that the Occupational Safety and Health Administration regulate duty hours as a workplace health hazard.<sup>39</sup> Federal legislation, called the *Patient and Physician and Protection Act* (HR 3236), was proposed in November 2001 by Representative John Conyers of Michigan, which would limit resident work hours and provide federal enforcement.<sup>40</sup> Approximately 6 months later, Senator John Corzine of New Jersey introduced comparable legislation in the Senate (S 2614).<sup>41</sup>

Several major academic organizations issued position statements on resident hours. In June 2001, the AMA Board of Trustees formally affirmed it would (1) encourage the ACGME to enforce its work-hour guidelines to the maximum limit and develop mechanisms to assure that noncompliance would be corrected quickly and completely; (2) facilitate discussion on legislative and other options to enforce workhour standards; and (3) investigate the enforcement of the current duty hour standards.<sup>42</sup> The AAMC issued a statement on graduate medical education policy relevant to duty hours and supervision that echoed many elements of its 1988 duty hour position, including that "prudence favors the establishment of a reasonable upper limit," and concluded that "80 hours per week constituted a reasonable limit, albeit a generous one by any conventional standard."<sup>43</sup> The American College of Surgeons issued a statement noting that "[i]mplicit in a residency program is the principle that all patient care provided by residents is safe and well supervised...quality patient care, now and in the future, is dependent on quality graduate education. It is critical to monitor, modify, and optimize the work environment to achieve this important goal."<sup>44</sup>

## Formation of the ACGME Work Group on Duty Hours and the Learning Environment

In September 2001, the ACGME authorized the formation of a Work Group on Resident Duty Hours and the Learning Environment and charged it with the development of enhanced ACGME-wide general standards for resident duty hours and with providing recommendations in a number of related areas, such as enforcement and educational activities.<sup>45,46</sup> The Work Group's report was scheduled for review in February 2002. The charge called for the Work Group to develop a comprehensive approach that considered the relationship between resident hours and the elements of the learning and working environment, building on the ACGME's role and success in fostering high-quality education and patient and resident safety.47 The Work Group was asked to provide recommendations for how the ACGME could enhance its efforts related to duty hours, minimize any negative impact on physician learning, explore innovative approaches for education under restricted hours, and communicate the ACGME's duty hour standards, policies, and related efforts to stakeholders, legislative and regulatory bodies, and the public.

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# CHAPTER 3 THE 2003 COMMON STANDARDS AND THEIR EFFECT

## On behalf of the 2001–2002 ACGME Working Group on Resident Duty Hours and the Learning Environment

#### Background

In late 2001, when the ACGME Work Group on Resident Duty Hours and the Learning Environment began deliberations on common standards limiting resident duty hours, studies, editorials, and commentaries discussed the effect of sleep deprivation in residents on patient safety, resident safety, and resident learning and well-being. The individual Residency Review Committees had developed and enforced established specialtyspecific duty hour limits, and the ACGME had established a few common duty hour standards that applied to all accredited programs.

The decision to set common duty hour standards for all accredited specialties and subspecialties was prompted by 3 factors: 1) changes in the delivery system, including increased patient acuity and intensity of service; 2) research showing negative effects of sleep loss on performance; and 3) public attention on resident work hours.<sup>1</sup> Independent research on resident hours and those worked by practicing physicians showed that resident hours increased between 1996 and 2000, after being steady between 1982 and 1985.<sup>2</sup> A contributing factor may have been the introduction of caps on institutional resident complement as a consequence of the INGRID PHILIBERT, PHD, MBA BETTY CHANG, MD TIMOTHY FLYNN, MD PAUL FRIEDMANN, MD REBECCA MINTER, MD, PHD ERIC SCHER, MD WILLIAM T. WILLIAMS, MD

Balanced Budget Act of 1996.<sup>3</sup> In late 2001, growing focus on the hours worked by residents culminated in the introduction of legislation to limit resident hours and a petition to regulate duty hours as a workplace health hazard.<sup>4–6</sup> This prompted concern that lack of action on the part of the ACGME might be interpreted as the profession ignoring public opinion and the scientific evidence on sleep and performance.

The Work Group set out to develop standards as part of a comprehensive program to address resident duty hours that would include standards that promote safe care, resident learning, and well-being; consistent enforcement at the program and institutional level; and education of residents and faculty about sleep loss and its effect on performance and learning. The effort was sensitive to differences among specialties. At the same time, it was important that the proposed standards be easily explained and viewed as comparable to the perceived ''safety and effectiveness'' of a legislative or regulatory approach.

The dialogue with the academic community and the public highlighted a gulf between the 2 stakeholder groups, and the Work Group developed 2 guiding principles to bridge the differing perceptions: (1) sensitivity to education and patient care needs of the 26 ACGMEaccredited specialties and (2) a need for the standards to reflect the science on sleep loss and performance. This led to the development of common standards that were flexible and sensitive to specialties, programs, and residents, while allowing the ACGME to make the case for public accountability by having all residents under a comparable limit.

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#### **The ACGME 2003 Standards**

In the summer of 2002, ACGME granted preliminary approval to common duty hour limits that became effective in July 2003. In 1992 the ACGME adopted limits for all specialties, which became part of the current duty hour standards, including in-house call no more frequently than every third night and 1 day in 7 free of all program responsibilities. These standards were enforced before 2003, and 6 specialties established a weekly duty hour limit.

Advances in the scientific study of sleep deprivation generated evidence relevant to residents' clinical and educational performance, including meta-analyses that showed sleep deprivation negatively influenced performance in controlled experiments and in clinical studies involving residents.<sup>7–9</sup> This supported a limit on continuous duty hours, to avoid acute sleep loss, and a limit on weekly hours and provisions for intermittent rest to avoid chronic, progressive sleep debt. The Work Group's deliberations about optimal standards highlighted tensions between the benefits of shorter hours, which would render residents more alert and able to learn, and the need for time and exposure to patients for the significant amount of learning that needs to occur during residency. It also showed that there was (and still is) little scientific guidance for the number of weekly and continuous hours at which residents safely and effectively learn and participate in patient care. The new standards needed to balance the strengths of a common approach, as perceived by legislators and the public, and its limitations, given differences among specialties in patient care and educational processes. The Work Group chose 80 weekly hours as the upper limit to safeguard against chronic sleep loss, and a 24-hour limit on continuous duty to mitigate acute sleep deprivation.1 Both were selected because they allowed residents to participate meaningfully in care and to gain an understanding of the dedication expected from physicians, while allowing them to be reasonably rested and alert.<sup>10,11</sup> The added period of up to 6 hours after overnight call preserved flexibility in scheduling

didactic activities, minimized exclusion of postcall residents from educational programming, and avoided residents going home at the time of their circadian nadir.<sup>10,11</sup>

The Work Group emphasized both the strengths of a common set of standards for assuring legislators and the public, and the limitations of this approach, given interspecialty differences in patient care and educational processes and individual differences in the response to sleep loss. The Group considered a narrow focus on hours alone an imperfect approach, and the standards emphasized educational content-an approach that reflected the longer hours of physicians in practice—and safe patient care by emphasizing that residents and faculty collectively have responsibility. The Work Group was aware that concerns emanating from New York State's experience with state regulation included high costs<sup>12</sup> and evidence that it did not appear to improve patient care.13,14

The 2003 common duty hour standards represented a compromise between the need for specificity and the desire to allow some flexibility to benefit education and patient care. They allowed RRCs such as Emergency Medicine and Anesthesiology to maintain different requirements that accommodate patient care, safety, and education needs within the specialty. In 2003, when the community faced a threat of legislated limits on resident hours, it was important to create common standards, while emphasizing that accreditation offers greater flexibility and sensitivity to specialty considerations than regulatory or legislative approaches.

## Experience With the 2003 Common Duty Hour Standards

The Work Group recognized that duty hours, attributes of the learning environment, and curricula and education models were linked and expected that implementation of the new standards would be accompanied by changes in the delivery and educational systems. In the more than 7 years since the 2003 implementation of the standards, programs and institutions have made changes in resident education and patient care activities and in the mechanisms for duty hour monitoring and oversight. Many programs used night float and other schedule changes to adapt hours to the common limits, while others replaced resident services with mid-level practitioners or hospitalists, and a few reengineered their patient care and education systems. Virtually all increased the clinical responsibilities of faculty physicians.

Ideally, information about the effects of limits would be gathered in prospective studies showing a negative effect of long hours on the clinical performance of physicians after residency and in the settings where residents participate in care. This information does not exist. Studies predominantly consisted of opinion surveys, single-site studies without the power to demonstrate effect, and analyses of secondary data that show associations but cannot establish cause and effect. Speculation on the effect of the limits included overstatements of their negative effect on learning, based on faculty perceptions of "inadequate clinical experience," and disappointment arising from unrealistic expectations that the limits would produce an immediate, profound improvement on the quality and safety of patient care.

# **Effect on Resident Professionalism**

In many specialties, implementation of the common limits reduced resident fatigue, improved well-being, and contributed to an improved balance between residents' professional and personal lives. One concern was that the limits would contribute to a loss in professionalism, with residents comfortable working in hourly settings but unfamiliar with the obligations physicians have to their patients.<sup>15</sup> Paradoxically, supporters of regulating duty hours argued that excess hours also diminished resident professionalism, contributing to cynicism, indifference, and hostility toward patients, and suboptimal care.<sup>16,17</sup> A study of resident perceptions of New York State's duty

hour regulations showed ambivalence about the effects of limits on professionalism. Residents experienced the limits as "an open-ended workday and competing considerations-including concerns about leaving patients at critical junctures in their care, regard for the workload of their colleagues, and uneasiness about the educational consequences."<sup>18</sup>

Faculty perceptions about diminished resident professionalism often appear tied to a traditional view that emphasizes physicians' continuous availability to their patients. At the same time, established definitions of professionalism that emphasize altruism and self-effacement do not equate these attributes with an unlimited number of hours devoted to patient care.<sup>19,20</sup> One predicament of the current cohort of residents is their need to deal with the unstated, perhaps unconscious, expectations of faculty, program leaders, and administrators. If residents leave too early, it is seen as a lack of the professionalism and dedication exhibited by prior cohorts. If they linger, they are viewed as inefficient and a threat to compliance. Interviews and commentaries suggest that residents' decisions to remain at work or go home are more sophisticated and influenced by a number of factors, including the extent a given activity is viewed as educationally valuable or essential to a good patient outcome (eg, transitioning a patient to the intensive care unit versus paper work to arrange for home delivery of oxygen).<sup>21</sup> Another study found that residents on occasion stay to complete patient care tasks when they should leave because of the organizational emphasis on thoroughness, and to think carefully about the tradeoffs inherent in the standards and other educational and patient care considerations important to them.<sup>22</sup>

# **Effect on Acquisition of Clinical Skills**

Research and commentaries on the effect of the work limits on clinical skills' acquisition suggest that the effect varies by specialty. One reason is that when data on the effect of the limits are disaggregated by specialty, several patterns emerge. First, in a number of specialties, such

as dermatology, psychiatry, radiology, and preventive medicine, weekly duty hours did not reach any of the common limits, and in other disciplines, only selected months in inpatient and intensive care unit rotations were affected. In contrast, the surgical community expressed concerns that an unintended consequence of the limits could be reduced operative skills for surgeons trained under the limits, especially during the early period following implementation, when clinical and education systems were still adapting. One reason is that surgical disciplines have traditionally worked the longest hours and made the largest adjustments. Another is that the extent to which reductions in resident hours may have curtailed activities vital to the professional development is greater in procedural disciplines. Residents in medical disciplines can use the added time for selfstudy and reflection (although informal evidence suggests that time devoted to selfstudy has not increased under the 2003 limits), but the common duty hour standards restrict surgical residents' time for operative experience, the activity potentially most relevant to the development of surgical skills. In addition to a sizable number of commentaries warning about declining skills in graduates of surgery and surgical specialty programs, recent research<sup>23</sup> has found that the skills of recent graduates may be lower than those of earlier cohorts.

Contrasting learning opportunities for medical and surgical specialties does not suggest that procedural skills are irrelevant in nonsurgical disciplines, or that surgical residents do not learn from reading. Instead, clinical learning is about acquiring the accepted knowledge, skills, and attitudes of the domain. Informal evidence suggests that bedside and clinical learning is important in a range of specialties and that pediatric residents in programs with more hours and months of clinical learning perform better on the board certification examination (J. Gilhooly, MD, verbal communication, May 2009). Acquisition of clinical skills requires practice and benefits from opportunities to apply new skills under supervision and guidance from faculty or more advanced learners.

There probably are added effects of the duty hour limits on medical students' and junior residents' education owing to the diminished hours available for senior residents under the limits. A study in New York found that this may exacerbate existing conflict in residents' role as teachers, including their learning needs conflicting with those of students and junior residents; this suggests that residents' first priority is to address the medical needs of patients, and the learning needs of junior learners may be secondary.<sup>24</sup>

#### **Effect on Quality and Safety of Care**

One reason for the public demand for duty hour limits in the United States was to reduce excessive duty hours and fatigue as potential performanceshaping factors and contributing causes in health care errors. Residents function in a health care system in which the financial and human costs of errors are significant. In their role as learners, with short tenure, and lack of familiarity with settings, residents may be more vulnerable to errors. Systems approaches to reduce the sources of errors have emerged as fertile interventions to enhance safety. Limits on work hours, to some extent, fit within these interventions because they address the effects of sleep loss, which may add to residents' vulnerability.

While some studies of the effect of duty hour regulations in New York State reported improved patient care, a larger number found fragmentation and reduced continuity, reduced actual or perceived quality of care, and higher rates of complications.<sup>13,14,25</sup> Studies of the effect of the common duty hour limits at the national level, despite large sample sizes, found little change in patient mortality during the 2 years following the implementation of the ACGME common duty hour standards.<sup>26–31</sup> Reductions in in-hospital mortality for Medicare beneficiaries and patients receiving care in Department of Veterans Affairs hospitals was not associated with hospitals' teaching status, suggesting that other factors accounted for this

improvement and that the duty hour limits did not net positive or negative association of the resident work hour regulations with a major patient-centered outcome.

## **Effect on Resident Well-Being**

Resident well-being and an improved balance between residents' professional and personal lives is one area where the body of literature on the effects of common duty hour limits has produced relatively unequivocally positive findings. At the same time, there is evidence that residents work harder in the hours shortened by regulatory limits, and residents now appear to be more concerned with the intensity of their workload than with the number of hours worked. There are indications that resident work has not diminished proportionately to the reductions in hours and that work intensity has increased. One reason is that financial pressures force many hospitals to largely preserve residents' contribution to patient care.<sup>32</sup> This may contribute to upsetting a balance between service and education, with fewer elective rotations, less formal didactic activities, and a feeling there is less time for resident learning at the bedside, in the clinic, and particularly the operating room, where opportunity to observe and assist in procedures before performing them under supervision is becoming the exception rather than the norm. There are fewer senior residents who are available to teach and mentor junior residents and students, and to benefit themselves from participation in this timehonored process of education in the profession.

During the early implementation of the 2003 duty hour standards, some residents reacted negatively to interventions that reduce time they considered important for their learning and professional development. Initial informal data suggested that the coexistence of duty hour limits and an overarching focus on meeting clinical demands for some residents might contribute to their viewing themselves as workers and championing reductions in hours, whether they are applied to educationally valuable time or hours used to meet service demands.

## **Reducing Hours**

In most programs, reducing resident hours required that some patient care activities be transferred to other providers, and the complexity and challenges posed by these transfers merits further attention. Transferring work to faculty and other providers is made difficult because of shortages in many health professions and because faculty already feel overburdened. Replacement is complicated by the fact that most mid-level practitioners cannot perform the full range of activities that can be performed by a physician.<sup>33</sup> Efforts to redesign care in teaching settings may be the ultimate solution but have been relatively limited in the 5 years since the implementation of the common standards.

## **Future Refinements to the Standards**

In the more than 7 years since the implementation of the common duty hour standards, programs and institutions have made changes in education, patient care, and the mechanisms for duty hour monitoring and oversight. However, much of the large-scale change and innovation to adapt to the duty hour limits did not materialize. A small number of programs reengineered their patient care and education systems,34 but most used schedule changes, substitution of residents' clinical work with mid-level practitioners or hospitalists, and an increase in faculty clinical load. Resident education and patient safety are influenced by multiple factors. No single intervention, including limits on resident hours, can ensure safe patient care. There are dangers in implementing added changes without evidence that they will contribute to safer care and better education and offer value for what is likely to be their sizable added cost in a health care system with many demands for constrained resources.

In most programs, residents spend some amount of time performing activities that have little relation to their education. The first encompasses extraneous work that does not require a physician and is addressed in the accreditation standards. The ACGME Institutional Requirements stipulate that sponsoring institutions provide phlebotomy, radiology, laboratory results reporting, and patient transport to ensure that residents spend minimal time in these activities.<sup>35</sup> Institutions that fail to provide these services are cited.

Beyond this, focusing reductions in hours on "noneducational work" is quite difficult, and some added hours are due to inherent inefficiencies in teaching hospitals' clinical settings. Work in a second category of "noneducational work" includes potentially redundant activities, and wait and travel times, which could be eliminated though reengineering of the teaching environment,<sup>36</sup> but interventions would be both costly and complex to initiate. The third type of work with low educational value has proved even more difficult to address. It entails repeated performance of activities that require a licensed practitioner but that residents have learned sufficiently well, such that performance is no longer valuable from a purely educational perspective. The issues related to minimizing this category of work are 2-fold. The first is that reducing this work for residents involves transfer of these activities to faculty or a "mid-level practitioner''; the second is that residents should perform some volume of these activities to maintain skills, with frequency dictated by the learning and practice style of the given resident.

The development of the standards and their implementation proceeded with extensive input from the RRCs and the GME community. The community provided feedback on its experience with the common duty hour standards, including concerns about the negative effects of the limits on learning, patient care, and residents' professional development. The ACGME had resolved that no revisions to the standards would occur for 5 years, to allow programs to adapt education and patient care systems, and that it would solicit feedback on elements that appeared to reduce educational quality or had other unintended effects, with the goal of identifying areas for refinement. Future changes would be evidence based and would incorporate input from the medical education community and the public.

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# CHAPTER 4 THE PROCESS FOR DEVELOPING THE 2011 DUTY HOUR STANDARDS

#### Introduction

In 2008, the common duty hour standards instituted in 2003 had been in effect for 5 years. and the ACGME was prepared to explore refinements that would be based on programs'. institutions', and residents' experience with the 2003 standards. Concurrently, the Institute of Medicine announced that at the request of elected officials and the Agency for Healthcare Research and Quality (AHRQ) it had convened an expert group to deliberate about resident hours and conditions to optimize patient safety.<sup>1</sup> The ACGME decided that it would await the release of the IOM report,<sup>2</sup> scheduled for December 2008, and initiate a comprehensive, multifaceted process to develop new standards for duty hours, supervision, and professionalism. A key attribute of the approach would be an explicit commitment to provide all interested and affected stakeholders with the opportunity for input into the revisions of the common requirements.

#### ACGME Task Force on Quality Care and Professionalism

The ACGME adopted a process for the development of new standards for duty hours, supervision, and professionalism that sought to ensure that all interested and affected stakeholders had the opportunity to provide input. After the release of the IOM report, in February 2009, the ACGME charged a 16member ACGME Task Force with the process of deliberating on the new common requirements for resident duty hours. Initially named the Duty Hours Task Force, one of its first actions was to change its name to the ACGME Task Force on Quality Care and Professionalism, to reflect the complexity and comprehensiveness of the issues being addressed. The Task Force comprised 12 national leaders in graduate medical education, 3 residents, and 1

nonphysician public representative with experience in consumer advocacy.

The members of the Task Force were drawn from the Council of Review Committees (CRCs) and the ACGME Board of Directors and included program directors, department chairs, and designated institutional officials (DIOs), hospital administrators, and residents/fellows. The CRC consists of the chairs of each of the 27 specialtyspecific Review Committees and the Institutional Review Committee, 2 ACGME directors and nonvoting observers from the Royal College of Physicians, the Council of Medical Specialty Society's Organization of Program Director Associations, and the Veterans Administration.<sup>3</sup> The Council is responsible for the content of the Common Program Requirements, which it must review and revise at least every 5 years and as needed.<sup>4</sup> All members (with the exception of the public member) had extensive current or recent experience in graduate medical education, collectively representing more than 250 years of activity in training future physicians. Susan Day, MD, chair of the ACGME Board of Directors, and E. Stephen Amis Jr, MD, FACR, chair of the CRC, served as cochairs, and Thomas Nasca, MD, MACP, chief executive officer of the ACGME, served as vice-chair.

The membership represented a host of specialties, including internal medicine, pediatrics, family medicine, emergency medicine, surgery, pulmonary disease and critical care, neurosurgery, vascular surgery, diagnostic radiology, anesthesiology, ophthalmology, obstetrics and gynecology, colon and rectal surgery, and nephrology. Members felt this spectrum of medical, surgical, and hospitalbased disciplines capably represented the interests of those specialties not on the Task Force. The participation of residents and fellows also created generational diversity and brought to the table the perspectives of individuals

#### TABLE 1 TASK FORCE ON QUALITY CARE AND PROFESSIONALISM MEMBERS

E. Stephen Amis Jr, MD, FACR, Chair, Council of Review Committees and Task Force Co-chair; University Chair, Department of Radiology, Albert Einstein College of Medicine and Montefiore Medical Center, Bronx, New York

Susan Day, MD, Chair, ACGME Board of Directors and Task Force Co-chair; Chair and Residency Program Director, Department of Ophthalmology, California Pacific Medical Center, San Francisco, California

Thomas Nasca, MD, MACP, Task Force Vice-chair; Chief Executive Officer ACGME and ACGME International LLC, Chicago; Professor of Medicine, Jefferson Medical College, Thomas Jefferson University, Philadelphia, Pennsylvania

Paige Amidon, Public Member, ACGME Board of Directors

Jaime Bohl, MD, Staff Surgeon, Department of Colon and Rectal Surgery, New Orleans, Louisiana. Dr Bohl served as a resident representative.

Lois Bready, MD, Professor, Department of Anesthesiology and Associate Dean for Graduate Medical Education, University of Texas Health Science Center San Antonio, San Antonio, Texas

Ralph Dacey Jr, MD, Henry G. and Edith R. Schwartz Professor and Chair, Department of Neurological Surgery, Washington University School of Medicine, St Louis, Missouri

Rosemarie Fisher, MD, Attending Physician and Associate Dean for Graduate Medical Education, Yale-New Haven Hospital, Yale University, New Haven, Connecticut

Timothy Flynn, MD, FACS, Chair-Elect, ACGME Board of Directors; Professor, Department of Surgery, and Senior Associate Dean for Clinical Affairs, University of Florida College of Medicine, Gainesville, Florida

Stephen Ludwig, MD, Professor of Pediatrics and Emergency Medicine, and Designated Institutional Official, The Children's Hospital of Philadelphia, University of Pennsylvania School of Medicine, Philadelphia, Pennsylvania

Robert L. Muelleman, MD, FACEP, Professor and Chairman, Department of Emergency Medicine, University of Nebraska Medical Center; Medical Director, Emergency Medical Services, Nebraska Medical Center, Omaha, Nebraska

Janice Nevin, MD, MPH, Senior Vice President and Associate Chief Medical Officer, Christiana Care Health System; Associate Professor, Jefferson Medical College, Wilmington, Delaware

Meredith Riebschleger, MD, Fellow in Pediatric Rheumatology, University of Michigan Health System - Mott Children's Hospital, Ann Arbor, Michigan. Dr Riebschleger served as a resident representative.

William J. Walsh III, MD, MPH, Research Fellow, Division of Pulmonary and Critical Care Medicine, University of Utah, Salt Lake City, Utah. Dr Walsh served as a resident representative.

George Wendel Jr, MD, Professor and Residency Program Director, Department of Obstetrics and Gynecology, University of Texas Southwestern Medical School, Parkland Memorial Hospital, Dallas, Texas

Thomas V. Whalen, MD, MMM, CPE, FACS, FAAP, Chairman, Department of Surgery, Lehigh Valley Health Network; Professor of Surgery, Penn State University College of Medicine/The Milton S. Hershey Medical Center; Adjunct Associate Professor, Uniformed Health Services University of the Health Sciences, Allentown, Pennsylvania

currently in training. The public member, Paige Amidon, ACGME public director, played a critical role representing the voice of the patient and the public at large. A complete listing of Task Force members is provided in TABLE 1.

The Task Force was charged with reviewing the available evidence pertaining to the existing requirements, the findings of the IOM's 2008 report on resident duty hours,<sup>2</sup> and other relevant information and to make recommendations for new common standards. The group conducted a comprehensive review of duty hour standards, resident supervision, and related issues.<sup>5</sup> It also considered more than 100 written position statements by the organizations and individuals in the academic community, heard oral testimony, received 3 comprehensive external reviews of the literature that the ACGME had commissioned expressly for this purpose, and conducted multiple additional fact-gathering sessions. On behalf of the Task Force, the ACGME conducted a survey of residents, medical school faculty, program directors, and DIOs.

#### **International Duty Hour Symposium**

The first step in developing refined standards for resident duty hours entailed information gathering. A key event was an International Duty Hour Symposium that took place in conjunction with the annual ACGME Educational Conference in March 2009. Approximately 200 individuals participated in the symposium.<sup>6</sup> This began the process of soliciting the perspectives of residents, program directors, DIOs, faculty, ACGME review committee members, and others with a stake in graduate medical education. Participants heard from experts on sleep loss and performance and were briefed by representatives from other nations that have regulated resident hours and by members of the committee who developed the IOM duty hour recommendations. The symposium also addressed the issue of potential federal regulation of resident duty hours.

Attendees discussed ways to improve the ACGME's approach to monitoring duty hours and supervision arrangements that would enhance resident learning and ensure safe and effective care. An important concept that emerged during the symposium was the need to develop duty hour standards that would be sensitive to differences among specialties and levels of training, to ensure safe patient care in settings with resident participation while allowing for acquisition of competence for independent practice, and the professional development of physicians.

## **Duty Hours Congress**

In June 2009, the Task Force and the ACGME convened a 2-day Duty Hours Congress, held in Chicago.<sup>7</sup> Before the event, the ACGME invited the GME community and other stakeholders to provide written commentary on the impact of the current duty hour requirements and to make recommendations for the upcoming revision of the standards. Most respondents also provided opinions on the recommendations contained in the 2008 IOM report on resident duty hours.

More than 100 organizations responded to the request, including all of the major professional organizations representing the specialties and most of the major organizations in health care and medical education, such as the American Medical Association and the American Hospital Association. Organizations representing students, residents, and the public also submitted commentary.

During the Duty Hours Congress, the Task Force heard 67 oral presentations as a follow-up to the written opinions. Some disciplines collaborated and chose to present a consensus statement; others presented individually. Task Force members had the opportunity to question the presenters. The Duty Hours Congress provided the necessary foundation for the Task Force to begin its work, though additional information gathering would continue for several months.

# **Task Force Meetings and Fact Gathering**

During the 2009–2010 academic year, the Task Force met an additional 11 times, with 6 meetings entirely devoted to fact gathering from multiple experts. Topics were essentially grouped into 5 areas, including history and background of duty hour restrictions, needs of the medical profession, patient safety (including the perspective of the patient), sleep physiology, and research. A list of presenters and organizations providing testimony in these sessions is found in TABLE 2.

The remaining 5 Task Force meetings were devoted to reviewing testimony and developing the recommendations. While the initial time line called for draft requirements to be presented at the February 2010 ACGME Board Meeting, the Task Force appreciated the complexity of the issue and recognized that added work was needed to refine the revisions. This work was completed at meetings held in Chicago in April and June 2010.

The Task Force met personally with representatives of 72 groups, which included experts on fatigue mitigation, patient safety,

TABLE 2 PRESENTERS TO THE ACGME TASK FORCE ON QUALITY CARE AND PROFESSIONALISM	
Lawrence Opas, MD, Associate Dean, Graduate Medical Education and Designated Institutional Official, USC/LAC + USC Medic Center Cost Impact of Duty Hour Change	al
Lucian Leape, MD, Harvard School of Public Health Training Physicians for the New World of Health Care	
James Bagian, MD, Chief Patient Safety Officer, Director, National Center for Patient Safety Department of Veteran Affairs Fatigue Mitigation: Is It Just About Resident Duty Hours?	
Mark Chassin, MD, President, The Joint Commission The Joint Commission, Patient Safety, and Duty Hours During Physician Training	
Doug Carlson, ACGME Legal Counsel Duty Hours and the Law	
Dewitt Baldwin Jr, MD, ACGME Scholar in Residence; and Steven R. Daugherty, PhD, Director, Education and Testing, Kaplan Medical Past Date, Present Correlates, and Future Directions: Toward a Better Understanding of Residency Education	
Dewitt Baldwin Jr, MD, ACGME Scholar in Residence; Steven R. Daugherty, PhD, Director, Education and Testing, Kaplan Medical; and Patrick M. Ryan, MD, Research Consultant, ACGME Beyond Work and Sleep: Variations in Residency Training	l
Ingrid Philibert, PhD, MBA, Senior Vice President, Field Activities, ACGME The 2003 ACGME Common Duty Hours Standards: Development, Implementation, and Promoting Compliance—Lessons Learned	
Timothy Johnson, Senior Vice President, Greater New York Hospital Association Resident Duty Hour Limitations: Observations From New York	
David Dinges, PhD, Professor of Psychology and Psychiatry, and Chief, Division of Sleep and Chronobiology, University of Pennsylvani School of Medicine Sleep Research and Resident Duty Hours	a
David Dinges, PhD, Professor of Psychology and Psychiatry, and Chief, Division of Sleep and Chronobiology, University of Pennsylvani School of Medicine Fatigue Management Overview	a
Charles Czeisler, PhD, MD, Baldino Professor of Sleep Medicine, and Director, Division of Sleep Medicine, Harvard Medical School Medical and Genetic Differences in the Impact of Sleep Loss on Performance: Implications for Work Hour Standards	
Javier A. Gonzalez del Rey, MD, MEd, Director, Pediatric Residency Program, Cincinnati Children's Hospital The Recommendations of the IOM Consensus Committee to Optimize Residents' Hours and Work Schedules to Include Patient Safety: Pediatric Program Director's Perspective	A
Susan Sheridan, Consumers Advancing Patient Safety Keeping Patients Safe: Passion, Courage, and the Power of Partnership	
Lenora Janacek, Save the Patient The Life You Save May Be Your Own	
Helen Haskell, Mothers Against Medical Error Resident Working Conditions: We Have Questions	

sleep physiology, quality improvement,

transitions of care, and impact of the New York State duty hour standards. Finally, the members studied the IOM's 2008 report, "Resident Duty Hours: Enhancing Sleep, Supervision, and Safety" (the 2008 IOM report),<sup>2</sup> and engaged in in-depth discussions with the authors of that report.

#### **Literature Reviews**

In addition to hearing directly from experts and other persons invested in the GME system, the ACGME commissioned 3 comprehensive literature reviews of US and international peer-reviewed articles relevant to resident duty hours, supervision, and the

working environment; sleep physiology, sleep and deprivation, fatigue and well-being; moonlighting; causes of medical errors, and the effect of the 2003 duty hour standards, presented as Appendix A through C of this monograph.<sup>8-10</sup> A request for proposals was released in April 2009: eight proposals were submitted to the ACGME, and 3 were selected for authorization to proceed and receive funding. Analysis and synthesis of key elements and themes were the main focus of each review. The authors were asked to identify significant gaps in data and to recommend areas of needed research. Each review applied a quality index based on relevance, sample size, and methodology in order to determine which articles would be included. An annotated bibliography was produced to accompany each review. The reviews addressed the conceptual frameworks underlying proposed changes in the duty hour limits, the effect of varying resident duty hours and schedules on patient safety, and duty hours and related topics such as supervision and workload.

# **Consensus Building**

After assimilating the evidence, the Task Force began the process of drafting and reaching consensus for the revised standards. A drafting subcommittee produced the framework. This process resulted in 3 options with varying degrees of specialty- and training-level specificity. The decision was made to move forward with a framework based primarily upon level of training. Although specialty-specific requirements were desirable for some areas, the Task Force was not prepared to generate 27 different versions of the duty hour standards. In addition, the members were concerned that the complexity of specialty-specific requirements for all areas might be confusing for residents working across specialties, such as family medicine and emergency medicine, and for transitional year residents, as well as for sponsoring institutions that would need to monitor compliance.

The 3 major categories in which themes were identified—duty hours, professionalism and personal responsibility, and supervision—were used as subthemes for drafting the new standards. Each member of the Task Force was assigned to 1 of 3 writing groups and initial requirements were drafted. The writing groups considered scientific evidence, including the IOM recommendations, expert testimony, and the practical experience of its members when drafting the new requirements.

Each writing group brought its product to the entire Task Force for review, and the members discussed every requirement line by line and word by word during several roundtable meetings. The Task Force strove to reach full consensus for each requirement, and the members voted on the exact wording. Dissent by 3 members was necessary for a veto and further discussion.

# **Approval Process**

In June 2010, the Task Force presented its recommendations for enhancing the 2003 resident duty hour standards. A key aim was to expand the focus beyond duty hours and to set forth new standards for supervision, safety, and professionalism. After soliciting and reviewing comments from major stakeholders in the GME community and general public, the group chose to:

- Establish more restrictive limitations on continuous shift hours for first-year residents;
- Require the creation of mandatory transportation and in-hospital sleep facilities for resident physicians who may be too tired to drive home safely;
- Include all moonlighting in the 80-hour weekly limit; and
- Enhance the requirements for graded supervision of residents.

The 2011 duty hour, supervision, and safety standards did not receive special treatment with regard to the approval process for ACGME program requirements, despite the increased

magnitude of public attention and scrutiny from the GME community. Under the ACGME's policies and procedures for standards revisions, all significant revisions of any program requirement are sent to the Committee on Requirements (COR) before submission to the Board of Directors.<sup>7</sup> The COR considers the content, clarity of language, general reasonableness, and impact for the proposed requirements; makes any necessary modifications; and returns the document to the submitting committee or council for response. The Committee then submits the proposed revised requirements to the Board of Directors, which has ultimate responsibility for approving revisions. In addition, all changes in ACGME accreditation standards are posted for a 45-day period of public comment.<sup>4</sup> The committee or council proposing the revision must consider and respond to all comments. For the 2011 duty hour and professionalism standards, the CRC delegated that responsibility to the Task Force, which discussed all comments and considered making additional changes to the requirements during another roundtable consensus-building session.

Once the Task Force developed a document that met the spirit of their goals for improved resident education, with concomitant increases in resident and patient safety, the standards were subjected to the process of public notice and comment that is expected for any revision of the ACGME program requirements.<sup>4</sup> This included the development of an impact statement that addresses the effect of revision on resident education, patient care, and institutional resources, facilities, and services. The impact statement recognized that changes in residency requirements may affect how patient care is delivered and the allocation of resources within the sponsoring institution. The draft standards documents, including the impact statement, were forwarded to the CRC, who submitted the draft requirements to the ACGME Board for approval.

After approval by the Board, the new standards were posted on the ACGME website

for 45 days, as required by policy.<sup>4</sup> Stakeholders were notified of the posting and advised to submit comment if they desired, and the ACGME received comments from more than 1000 organizations and individuals. On August 29, 2010, the Task Force convened for the last time to review the comments received. Because of the constructive nature of the comments, the standards were reevaluated and revised in some areas. This final revision was endorsed by the CRC and Committee on Requirements before being submitted to the ACGME Board for review and approval. On September 27, 2010, the Board of Directors approved the new standards addressing professionalism, supervision, and duty hours. The new standards were scheduled to become effective July 1, 2011.

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# CHAPTER 5 New DUTY HOUR LIMITS: DISCUSSION AND JUSTIFICATION

#### Introduction

The ACGME Task Force on Ouality Care and Professionalism established 3 principles of enduring value that guided the Task Force in its work. The standards thus seek to ensure (1) the safety of patients in our teaching hospitals today; (2) the safety of patients who will be under the care of today's residents in their future independent practice of medicine; and (3) the establishment of a humanistic learning environment where residents learn and demonstrate effacement of self-interest in favor of the needs of their patients. This chapter provides a rationale for each individual standard. At the same time, the duty hour requirements were developed as a comprehensive package that emphasizes the importance of supervision, workload and work compression, professionalism and personal responsibility, transitions in patient care, and alertness management in the ability to achieve these 3 objectives. The goal was to create standards that would promote resident education, while protecting patient and resident safety, and the Task Force considered both the IOM recommendations<sup>1</sup> and the 3 comprehensive reviews of the literature commissioned by the ACGME.2-4

#### **Maximum Hours of Work Per Week**

Duty hours must be limited to 80 hours per week, averaged over a 4-week period, inclusive of all in-house call activities and all moonlighting.

In 2003, when the ACGME common duty hour requirements for all accredited programs were implemented, many educators were concerned about a negative effect of a limit on weekly duty hours. In the 7 years that the GME community has functioned under the 2003 common standards, studies have shown that

residents' clinical exposure,<sup>5–16</sup> academic achievement,<sup>17</sup> and medical knowledge<sup>12,18–21</sup> have remained constant or improved slightly. In addition, residents identified 76 to 82 hours as ideal for experiential learning, as shown in FIGURE 1, which presents data on hours worked per week compared to residents' perception of ideal duty hours for learning, based on learning styles.<sup>22</sup>

Some patient safety advocates predicted sweeping improvements in the quality of patient care after the institution of the 2003 standards, while others foresaw a significant worsening of the quality of care. Neither materialized, and quality of care appears to have been unaffected or only very slightly improved by the 2003 limits.<sup>19,20,23–29</sup> A survey of residents in 1999 showed that residents averaging more than 80 hours per week were more likely to be involved in a personal accident or injury, or in a serious conflict with other staff members.<sup>30</sup> An anticipated effect of



the 2003 standards was improvement in resident mood and quality of life, which has been borne out by several studies across multiple specialties.<sup>31–37</sup> Finally, the Task Force entertained comment from a wide range of individual organizations in the profession and found broad-based support for maintaining the 80-hour weekly limit.

# **Duty Hour Exceptions**

A Review Committee may grant exceptions for up to 10%, or a maximum of 88 hours, to individual programs when based on a sound educational rationale.

In preparing a request for an exception, the program director must follow the duty hour exception policy from the "ACGME Manual on Policies and Procedures."

Before submitting the request to the Review Committee, the program director must obtain approval of the institution's Graduate Medical Education Committee and designated institutional official.

The Task Force retained this requirement unchanged from the 2003 standards. A major theme of the June 2009 ACGME Duty Hours Congress, was "one size does not fit all." This emphasizes that some academic and patient care settings may require an approved variance in weekly hours. Use of the exception will continue to require strict oversight by the program, the sponsoring institution, the Residency Review Committee, and the ACGME Monitoring Committee. Neurologic surgery is the only discipline that currently has a significant number of programs with an approved exception. All were reviewed and approved by the RRC, using criteria that have been approved by the ACGME. Support for maintaining this exception comes from research showing that in surgical specialties with very long operative procedures, duty hour limits may have a negative effect on residents' attainment of competence for independent practice.<sup>6</sup>

## Moonlighting

Moonlighting must not interfere with the ability of the resident to achieve the goals and objectives of the educational program. Time spent by residents in internal and external moonlighting (as defined in the "ACGME Glossary of Terms") must be counted toward the 80-hour maximum weekly hour limit. Postgraduate year–1 (PGY-1) residents are not permitted to moonlight.

The Task Force reviewed the benefits and drawbacks of resident moonlighting, including the Institute of Medicine position and the legal and logistic dimensions of inclusion of external moonlighting in the maximum hoursper-week calculation. It concluded that external moonlighting had a similar impact on overall resident fatigue as hours spent in the training program, and that for this reason, all moonlighting hours must be included in the calculation of weekly duty hours. PGY-1 residents are not permitted to moonlight because the necessary degree of supervision cannot be assured outside of their formal education program. In most states, first-year residents cannot moonlight because most state medical boards require at least 1 year of graduate medical training before residents are able to apply for an unrestricted license that would allow them to practice independently.<sup>38</sup>

One reason for including moonlighting under the duty hour limits is concern about the cumulative effect of an absence of supervision and the potential for fatigue. The lack of supervision may place patients seen by residents moonlighting at greater risk than patients seen by residents working the same number of hours under supervision. Also, because of the lack of supervision, moonlighting hours are less valuable for the acquisition of competence for independent practice than hours in the formal education program.



#### **MandatoryTime Free Of Duty**

Residents must be scheduled for a minimum of 1 day free of duty every week (when averaged over 4 weeks). Athome call cannot be assigned on these free days.

The Task Force left unchanged the requirement for 1 day in 7 free from duty to balance continuity of care with fostering resident recovery from fatigue and ensuring quality of life. The flexibility given by the option to average days off over 4 weeks allows residents a reasonable opportunity to participate in activities outside the hospital and ensures time for recuperation, while promoting continuity of care. Finally, an inpatient care team of any size can provide daily continuity of care because at least 1 member of the team will be present on every day.

## **Maximum Duty Period Length**

Duty periods of PGY-1 residents must not exceed 16 hours.

This group of requirements addresses the requests for some flexibility in the standards requested by the community. It takes into account the differences between PGY-1 residents and their more senior colleagues, and the consensus that very junior learners would benefit from a more

supported and regulated learning environment. PGY-1 residents may not have sufficient experience and skills to provide high-quality, safe patient care, while research indicates that under the current standards, this group works the longest hours of any cohort of residents,<sup>39</sup> as shown in FIGURE 2. All differences between first-year and other residents, with exception of home call and 1 day off in 7, are significant (P < .0001). In addition, PGY-1 residents make more errors when working longer consecutive hours.<sup>40,41</sup> Entrusting care to residents with inadequate experience is neither good education nor quality, safe patient care. PGY-1 residents must earn the right to remain with patients for 24 continuous hours, through demonstration of the competencies required, which are best learned under the direct supervision of upper-level residents, fellows, and faculty. The ideal is a first year of education with more protected hours, with hours and responsibilities gradually increasing over the years of residency, and the final year of residency beginning to emulate practice, while still under supervision.

Although limiting first-year residents to 16 continuous hours represents a significant shift in the scheduling patterns for PGY-1 residents, it should not diminish their overall contact time with patients. PGY-1 residents may still be scheduled for up to 80 hours per week, averaged over 4 weeks. Continuity of care
provided by PGY-1 residents may actually be enhanced by the new requirements because the typical amount of time the PGY-1 resident is ''away'' from his or her patients for a day off is decreased as compared to the usual practice of taking 18 hours off on the postcall day. Finally, these standards do not preclude PGY-1 residents from working at night and gaining experience that will prepare them for practice in the nighttime hospital setting.

Duty periods of PGY-2 residents and more senior residents may be scheduled to a maximum of 24 hours of continuous duty in the hospital. Programs must encourage residents to use alertness management strategies in the context of patient care responsibilities. Strategic napping, especially after 16 hours of continuous duty and between the hours of 10:00 PM and 8:00 AM, is strongly suggested.

Studies looking for an increased risk of errors among more advanced residents have not demonstrated significant differences in patient outcomes,<sup>42,43</sup> nor have they demonstrated any differences in patient outcomes based on the "sleep status" of the residents providing care.44-46 The Task Force asserted that observing the progression of illness and treatment in patients is critical in the development of clinical judgment. Although it is true that residents can learn about the preoperative, operative, and postoperative care by caring for 3 different patients, the experience is more effective when it involves the continuous care of a single person. In addition to providing for continuity of care, prolonged periods of duty more adequately replicate the actual practice of clinical medicine that residents will encounter after completing training and overcome senior residents' view of the duty hour restrictions as barriers to their education.47

The Task Force gave serious consideration to the recommendation by the IOM Committee on Resident Duty Hours to provide a 5-hour nap period for overnight call.<sup>1</sup> There is scientific evidence from other occupations with need for high performance that naps can restore alertness and cognitive function. However, sleep schedules tested and used in these settings generally consist of a brief "power nap,"<sup>48–50</sup> and longer naps of up to 1 hour may be associated with sleep inertia (difficulty waking up after sleep or a nap).<sup>51</sup> Studies of napping in teaching settings found that time for protected sleep enhanced sleep efficiency, but it did not affect measures of alertness.<sup>52</sup> One study found that interns who were given coverage for protected naps did not take the rest periods, owing to their desire to care for their patients and concerns about discontinuity of care.<sup>53</sup>

It is essential for patient safety and resident education that effective transitions in care occur. Residents may be allowed to remain on-site to accomplish these tasks; however, this period of time must be no longer than an additional 4 hours.

Residents must not be assigned additional clinical responsibilities after 24 hours of continuous in-house duty.

The Task Force learned that many programs had not used the 2003  $^{\prime\prime}24 + 6^{\prime\prime}$  hours, as was initially intended, and scheduled residents for 30 hours of continuous duty, sometimes caring for patients they had met previously owing to the broad definition of "new patient." To address this issue, the new standards define the 4 hours after the 24 hours of consecutive duty as time solely for transitions in care.

In unusual circumstances, residents, on their own initiative, may remain beyond their scheduled period of duty to continue to provide care to a single patient. Justifications for such extensions of duty are limited to reasons of required continuity for a severely ill or unstable patient, academic importance of the events transpiring, or humanistic attention to the needs of a patient or family. Under those circumstances, the resident must:

- appropriately hand over the care of all other patients to the team responsible for their continuing care; and
- document the reasons for remaining to care for the patient in question and submit that documentation in every circumstance to the program director.

The program director must review each submission of additional service and track both individual resident and program-wide episodes of additional duty.

One of the foremost concerns expressed in residents' testimony to the Task Force was the ethical dilemma the regulations caused them, because of the decision on whether to "break the rules" to do the right thing and remain at the bedside of a dying patient or to leave because of the time on the clock, while believing that their choice may be morally and professionally wrong. It was crucial that the Task Force address this concern by adding flexibility to the requirements, while promoting education and safety and maintaining the integrity of the standards. The flexibility offered by the new requirements allows residents to remain in the hospital caring for a single patient, satisfying the spirit of the requirements and the tenets of professionalism. Program directors are expected to monitor such occurrences, assuring that abuse of the privilege does not occur. This also offers a unique opportunity for reflection by the resident and the program director when such an extension occurs.

# Minimum Time Off Between Scheduled Duty Periods

PGY-1 residents should have 10 hours, and must have 8 hours, free of duty between scheduled duty periods.

Intermediate-level residents (as defined by the Review Committee) should have 10 hours free of duty and must have 8 hours between scheduled duty periods. They must have at least 14 hours free of duty after 24 hours of in-house duty.

Residents in the final years of education (as defined by the Review Committee) must be prepared to enter the unsupervised practice of medicine and care for patients over irregular or extended periods. This must occur within the context of the 80-hour maximum duty period length and 1-day-offin-7 standards. While it is desirable that residents in their final years of education have 8 hours free of duty between scheduled duty periods, there may be circumstances (as defined by the Review Committee) when these residents must stay on duty to care for their patients or return to the hospital with fewer than 8 hours free of duty.

Circumstances of return-to-hospital activities with fewer than 8 hours away from the hospital by residents in their final years of education must be monitored by the program director.

The aim of this requirement is to provide residents adequate time for recovery between shifts. According to the American Time Use Survey 2003–2005, adults 25 to 34 years of age slept an average of 8.2 hours each night,<sup>54</sup> and nearly two-thirds of employed respondents who participated in the National Health Interview Survey in 2004–2007 reported sleeping an average of 7 or 8 hours each night.<sup>55</sup> In consideration of this, the Task Force elected to set the minimum requirement for time off between shifts at 10 hours, unless programs were able to provide an acceptable educational justification for a briefer rest period of 8 hours between shifts.<sup>56</sup>

The increased flexibility for residents in the final years of training is intended to prepare them for the 24-hour world they will enter after completing training. The Task Force received extensive testimony from specialty societies and from senior residents and fellows that this degree of flexibility was essential in the final phases of preparation for independent clinical practice in many fields, most notably those where clinical responsibilities include surgical or invasive procedures. This requirement also decreases the likelihood of an ethical dilemma for senior level residents in the provision of care to their patients.

## **Maximum Frequency of In-House Night Float**

Residents must not be scheduled for more than 6 consecutive nights of night float. (The maximum number of consecutive weeks of night float, and maximum number of months of night float per year, may be further specified by the Review Committee.)

Sleep physiology studies have demonstrated that night shifts are more taxing than day shifts.<sup>57</sup> With this requirement, The Task Force ensured that any resident on night float would receive 1 day in 7 free from program responsibilities, and that the requirement for 1 day off in 7 must not be averaged during night float rotations. Although there is evidence that the deleterious effects of working night shifts or night float are cumulative,<sup>58–60</sup> no studies have identified a consistent number of days at which the effects warrant added limitation on the number of consecutive nights.

The Task Force recognized that the intensity and quality of the learning experience of night float varies both between specialties and between programs. Each Review Committee therefore was directed to consider further specificity regarding night float, including placing limits upon the maximum number of consecutive weeks of night float and maximum number of months of night float per year.

# **Maximum In-House On-Call Frequency**

PGY-2 and more senior residents must be scheduled for in-house call no more frequently than every third night (when averaged over a 4-week period). The Task Force considered the scientific literature and testimony by the medical community in deliberating this requirement. Studies have demonstrated that residents continue to experience effects of call beyond the first recovery night,<sup>57</sup> and that PGY-1 residents taking every-other-night call experienced more fatigue and stress than their counterparts taking call less frequently.<sup>61</sup> For these reasons, the Task Force initially recommended in-house call to be no more frequent than every third night, with no averaging permitted. During the period of public comment, however, resident groups and individuals pleaded for the flexibility averaging provides, with many comments coming from program directors and residents representing programs with a small resident complement, where averaging of call frequency is essential in providing residents with a weekend free from duty each month. The Task Force noted that PGY-1 residents are excluded from overnight call, and studies<sup>62</sup> have not found any difference in the actual number of errors per call when residents took every-other-night call, as compared to less frequently. The members also noted that the current standard is infrequently cited or identified as problematic in the ACGME Resident Survey. After careful consideration of all the factors involved, the Task Force affirmed the current standard, deciding that the trade-off of occasional every-other-night call (for residents beyond the PGY-1 year) for increased flexibility of scheduling, to allow residents to be scheduled for 1 weekend entirely free of duty per month. was acceptable. The discussion of this standard emphasized that frequent or routine scheduling of every-other-night call is unacceptable and should be cited by the Review Committees, even if the frequency of call is every third night or less when averaged over 4 weeks.

# **At-Home Call**

Time spent in the hospital by residents on at-home call must count toward the 80hour maximum weekly hour limit. The frequency of at-home call is not subject to the every-third-night limitation, but must satisfy the requirement for 1 day in 7 free of duty, when averaged over 4 weeks.

At-home call must not be so frequent or taxing to preclude rest or reasonable personal time for each resident.

Residents are permitted to return to the hospital while on at-home call to care for new or established patients. Each episode of this type of care, while it must be included in the 80-hour weekly maximum, will not initiate a new "off-duty period."

This requirement relates to the time residents spend at home but are available to provide care for patients should the need arise. The sleep physiology literature has affirmed that the most restorative sleep is fully uninterrupted. At the same time, medical practice in the United States requires physicians to be available to their patients and respond to their needs 24 hours a day.

Use of at-home call varies among specialties, as does the intensity of such coverage. At-home call provides the more senior resident or fellow with the opportunity to experience that actual practice with some degree of supervision. In many circumstances, the resident may not receive a call. In others, at-home call may result in remote supervision of more junior residents, or telephone counseling of patients or families. Finally, there may be instances in which at-home call frequently requires the resident to return to the hospital at night. These hours of return to the hospital continue to be included in the maximum weekly hour limit.

The Task Force attempted to further limit the impact at-home call would have on resident fatigue by including the time spent in the hospital while on at-home call in the 80-hour weekly maximum and by requiring that the resident have 1 day in 7 free of all duties including at-home call. In some specialties, the nuances of at-home call may require more specific oversight or guidance, and in those cases, individual Review Committees may make standards more stringent.

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# CHAPTER 6 New Supervision Standards:

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# **DISCUSSION AND JUSTIFICATION**

## Background

Supervision is a key concept in graduate medical education, with educational and clinical origins, and it is deeply rooted in traditional concepts of the education of physicians.<sup>1,2</sup> It is critical in ensuring safe and effective patient care.1,3,4 Research has shown lack of supervision as a cause or contributing factor in adverse events,<sup>5</sup> and good supervision has been associated with improved clinical outcomes.<sup>6–8</sup> Supervision and the resulting feedback are important to residents' acquisition of clinical skills and professional development and socialization into the profession.<sup>9,10</sup> Finally, faculty supervision is required for faculty to be compensated when residents participate in care.<sup>11,12</sup> Combined with gradually increasing authority and independence, supervision and feedback allow residents to make the transition from novice learner to proficient practitioner at the completion of residency training.<sup>13</sup> At the same time, excessive supervision without progressive independence, as residents acquire knowledge and skills, may hamper their progression from learner to competent practitioner in their discipline.13

The Institute of Medicine's report entitled "To Err Is Human"<sup>14</sup> did not focus on teaching settings or provide recommendations for enhancing supervision. However, much of the subsequent literature on supervision referenced the report for its alarming data on preventable health care errors that lead to adverse outcomes for patients, with calls for enhanced transparency, oversight, and attention to human factors.<sup>15,16</sup> The IOM's 2008 report entitled "Resident Duty Hours: Enhancing Sleep, Supervision, and Safety"<sup>17</sup> expressly recommended enhancing supervision in teaching settings.

### Empirical Evidence for the Supervision Standards

A systematic review of the literature on supervision in 2000 concluded that "current supervisory practice in medicine has very little empirical or theoretical basis'' and borrows from other disciplines such as nursing, education, and social work,<sup>9</sup> and much of the early practical guidance on supervision came from other disciplines.<sup>18</sup> Research over the past decade has developed a conceptual framework and guidance for supervision of medical residents. This includes research in the Department of Veterans Affairs,<sup>19–21</sup> single-site studies,<sup>22,23</sup> surveys of residents' perceptions of their supervision,<sup>24</sup> and studies that have explored the value of increasing on-site faculty presence and supervision after the institution of the 2003 duty hour limits.<sup>25,26</sup> Some studies developed models for supervision that seek to promote safety and resident learning.<sup>27</sup> Of particular value is the work by Tara Kennedy and colleagues, 13, 28-31 which explores the relationship between supervision and progressive independence and was used to develop the supervision framework on which the ACGME common standards are based.

# **Supervision and Patient Safety**

Appropriate supervision is critical to patient safety. To many, the advent of oversight and increasing regulation of the resident work environment resulted from the 1984 death of Libby Zion in a New York teaching hospital.<sup>32</sup> The inquiry that followed implicated the lack of supervision of the first- and second-year residents who provided most of her care and ultimately prompted the New York State Board of Health to establish regulations governing resident physician duty hours and the level of supervision provided to them.<sup>33,34</sup> Other accounts of adverse events in teaching institutions also implicate lack of adequate supervision. A study of nearly 4000 patients who presented with a variety of diagnoses that included asthma/chronic obstructive pulmonary disease, chest pain, abdominal pain, hand laceration, head trauma, and vaginal bleeding reported that the quality of care benefited from direct supervision regardless of the residents' level of training.<sup>3</sup> Research on the effect of admission during a weekend on hospital mortality found a larger "weekend effect" in major teaching hospitals compared with nonteaching hospitals and minor teaching hospitals, which may be attributable to reduced availability of faculty for supervision.<sup>35</sup> Other studies have also found that reduced availability of faculty supervision over the weekend was associated with increased mortality for patients whose treatment depended on rapid availability of services and personnel.<sup>36</sup> A longitudinal analysis of adverse events in teaching hospitals between 1979 and 2001 revealed that this prevalence of adverse events associated with problems with supervision may have declined, as clinical supervision has increased during the past 2 decades. The study found that improvements in supervision during the latter one-half of the study period (1993-2001) significantly reduced the frequency of events in which suboptimal supervision was a cause or contributing factor  $(61\% \text{ versus } 47\%; P = .01).^{5}$ 

#### Supervision and the Acquisition of Competence for Independent Practice

The importance of supervision to the acquisition of competence for independent practice is made prominent in the work of K. Anders Ericsson<sup>10</sup> and colleagues<sup>37</sup> on expert performance, which makes a strong case for ''deliberate practice'' in the acquisition of a high level of skill. Although residents may feel their learning benefits from the increased autonomy, this work has shown that guided practice is instrumental in the development of higher-order competence in complex cognitive and haptic tasks.<sup>10,37</sup>

A number of studies have explored supervision in graduate medical education during the past 2 decades, finding that residents who were more closely supervised through direct observation acquired primary-care skills more rapidly than those who were supervised after the fact.<sup>38</sup> Practice without adequate supervision also may result in learners failing to adopt the best models for care. A classic study<sup>4</sup> showed that when faculty physicians personally examined patients cared for by residents, they reached different conclusions about the severity of patients' illness, diagnosis, treatment and required follow-up and were more critical of the residents' assessment and care plan than when they provided remote supervision.

Supervision is important in allowing residents to receive guidance for giving and coordinating care, even as they progress toward independent practice. A commentary on the fallacies of common recommendations for residency education settings noted that the recommendation to "let residents run the teams," together with "mistakes are valuable learning opportunities," is used as a justification for absent faculty supervision, even for junior residents, and diminishes faculty oversight of care, along with faculty members' active practice of the science and art of supervision.<sup>39</sup>

Recent work has explored supervision from the perspective of those being supervised.<sup>22–27,40</sup> A qualitative study of residents and their supervising faculty revealed that an important aspect of the supervisory relationship entails recognizing and dealing with uncertainty and ensuring that residents know when to involve their supervising physician.<sup>27</sup> Two early studies also defined attributes of a functioning supervisor-supervisee relationship. Research in pediatrics showed that residents were able to evaluate supervision and distinguish between good and poor supervision, with positive characteristics including supervisors who are approachable, nonthreatening, enthusiastic, who provide clear explanations and feedback, and who give residents autonomy that is appropriate for their competence and clinical experience.<sup>40</sup> The same study found that

characteristics of poor supervision included lack of guidance, oversupervision, poor clinical decisions, and overuse of resources by faculty supervisors.<sup>40</sup> Helpful forms of supervision, as defined by supervisors and those being supervised, include linking theoretic concepts to actual practice; personal supervision and guidance on clinical tasks work, with residents reporting that it is more helpful when they are encouraged early to provide their thoughts on diagnosis and treatment; and opportunities for joint problem solving, and providing reassurance to learners.<sup>41</sup>

# Justification for the 2011 Common Supervision Requirements

Evidence shows that supervision contributes to high-quality clinical outcomes and resident learning and professional development, particularly when combined with focused feedback. The new Common Program Requirements include enhanced supervision standards that explicitly define the levels of supervision provided to residents for different stages of their training and for various levels of knowledge and skills, to create a seamless transition from highly supervised care during the early years of residency to progressive independence, culminating in a fully trained physician capable of independent, unsupervised practice.

In the clinical learning environment, each patient must have an identifiable, appropriately credentialed attending physician with privileges who is ultimately responsible for that patient's care. Supervision may be exercised through a variety of methods. Some activities require the physical presence of the supervising faculty member. Other portions of care provided by the resident can be adequately supervised by a more advanced resident or fellow. The program must demonstrate that the appropriate level of supervision is in place for all residents caring for patients. This preamble to the new, detailed supervision standards and the associated expectations for enhanced supervisory practices and oversight in residency programs and sponsoring institutions is in keeping with the overarching goal of the 2011 common duty hour standards of promoting a climate of patient safety. Levels of supervision:

Direct supervision: The supervising physician is physically present with the resident and patient.

Indirect supervision:

- With direct supervision immediately available: The supervising physician is physically within the hospital or other site of patient care and is immediately available to provide direct supervision.
- With direct supervision available: The supervising physician is not physically present within the hospital or other site of patient care, but is immediately available by means of telephonic and/or electronic modalities, and is available to provide direct supervision.

Oversight: The supervising physician is available to provide review of procedures/ encounters with feedback provided after care is delivered.

This section of the standards is based on the work by Tara Kennedy and colleagues, who conducted extensive observational field work and qualitative interviews of faculty physicians, residents, medical students, and other health care personnel to explore themes around supervision and faculty oversight of clinical care.<sup>28–31</sup> Their research produced the graded levels of supervision, with progressively increasing responsibility and autonomy used in the new standards, to ensure that supervision is commensurate with the residents' knowledge and clinical competence, and with patient severity of illness and intensity of care.

The privilege of progressive authority and responsibility, conditional independence,

and a supervisory role in patient care delegated to each resident must be assigned by the program director and faculty members.

The preceding section defines that the assignment of progressive responsibility must be made by the program director and faculty and must be based on an assessment of the given resident's ability to safely provide care and, ideally, with educational benefit from the level of autonomy that is being assigned. An early study of resident physicians found that they desire autonomy and that this is critical to their professional development.<sup>42</sup> Other studies similarly have shown that residents desire less supervision than attending physicians want to provide, although both groups agree on the patient care events that require direct supervision and/or involvement of the supervisory physician.23,27 Residents' selfassessments regarding their need for clinical supervision are problematic in light of research suggesting that self-monitoring or "reflection-inpractice'' requires high-quality data and the ability to distinguish high-quality data from projection, even in experienced clinicians.<sup>43</sup> In this context, proper balancing of supervision and autonomy, in measures appropriate to a given resident's developing capabilities, is the key to appropriate progressive assignment of independent responsibility. Farnan and colleagues<sup>44</sup> described this ongoing conversation and negotiation between the resident and the supervisor as "a 2-way street."

A study of the factors guiding clinical supervisors' decisions to trust residents with critical patient care tasks showed the importance of these faculty decisions and found that 4 sets of factors determined these ''entrustment'' decisions: characteristics of the resident, the attending physician, the clinical context, and the criticality of the task.<sup>45</sup> Kennedy and colleagues<sup>28</sup> found that faculty varied their degree of supervision from ''routine oversight'' to ''responsive oversight'' when routing monitoring revealed concerns. When supervisors' concerns or the situation warranted it (when clinical demands exceeded the resident's abilities), the supervisor would readily move from clinical oversight to "direct patient care."<sup>28</sup>

These findings suggest that the ideal set of standards is specific about the level of supervision and, at the same time, allows sufficient flexibility to be applicable to multiple specialties and over the continuum of multiple year levels. The standards were created to allow individual Residency Review Committees latitude in defining what the qualifications of the supervising physician are. The standards affirm that it is appropriate and, in many cases, educationally desirable, to have a senior resident provide supervision to a more junior resident.

Programs must set guidelines for circumstances and events in which residents must communicate with appropriate supervising faculty members, such as the transfer of a patient to an intensive care unit or end-of-life decisions.

Beyond allowing for flexibility for the individual RRCs, the responsibility for supervision can be individualized even further and more appropriately at the level of the training program when instances of significant changes in care arise. Components of an effective supervisory relationship include reassuring the residents that it is appropriate to call the supervisor and that there will be no negative consequences for seeking the attending physician; ready availability of the supervising attending physician, and sharing contact information and responding promptly to questions and requests for assistance; balancing supervision and resident decision autonomy; planning regular communication times; defining in advance the role each resident will play on the team; and setting clear expectations for the types of clinical scenarios that always warrant attending physician input (such as end-of-life and legal issues, transfers to the intensive care unit,

resuscitations, or assistance with navigating difficult systems-level issues).<sup>27</sup>

Each resident is responsible for knowing the limits of his or her scope of authority, and the circumstances under which he or she is permitted to act with conditional independence.

As adult learners and physicians, residents are expected to take responsibility in the area of supervision. By formally stating that residents are responsible for knowing their limits and the scope of their authority, the standards promote a culture that allows residents to seek assistance, and one in which faculty are trained to provide it. Concurrently, the program director and faculty are expected to assess the knowledge and skills of each resident and change the level of supervision when warranted.

In particular, during the PGY-1, residents should be supervised either directly or indirectly, with direct supervision immediately available. Each RRC must describe the achieved competencies that PGY-1 residents must possess to be supervised indirectly, with direct supervision available.

The standards establish that, as the least experienced residents, PGY-1 residents should always have direct supervision immediately available. They contain a provision that allows determination of competencies that a PGY-1 resident would need to demonstrate to allow supervision from home by a faculty physician or more senior resident.

# **Institutional Oversight for Supervision**

Creating the environment for appropriate supervision goes beyond setting and complying with supervision standards at the level of the individual residency program. The larger institutional environment, and how faculty are scheduled, rewarded, and developed for the process of teaching and supervising residents, are important in promoting appropriate supervision and faculty oversight of care. To ensure this, the ACGME will monitor sponsoring institutions for compliance with the Institutional Requirements that set forth expectations for institutional monitoring of resident supervision, to ensure that supervision is consistent with "a) [p]rovision of safe and effective patient care; b) [e]ducational needs of residents; c) [p]rogressive responsibility appropriate to residents' level of education, competence, and experience...."<sup>46</sup>

In addition, as defined in the Institutional Requirements, the designated institutional official is required to make an annual report for the sponsoring institution's and major participating site's Organized Medical Staff and governing body that, among other items, addresses resident supervision and resident clinical responsibilities.

# Preparing Faculty for their Role as Supervisors

The quality of the supervisory relationship is very important, as noted in a systematic review of the literature in supervision, which affirmed "that the quality of the relationship between supervisor and resident is probably the single most important factor for effective supervision."<sup>9</sup> A recent commentary on supervision called for enhancing faculty development for their role as supervisors of the residents, noting that "[a]vailable and involved master clinician-educators are integral to the delicate balance of effective supervision, clinical service, and learner autonomy," and also sought to dispel the notion that supervision and autonomy are mutually exclusive.<sup>39</sup>

Given the need for a balance between supervision and granting autonomy to facilitate residents' professional development, faculty should receive added training and professional development for their role as supervisors. However, current training for supervisors, when provided, often is not theoretically or empirically based. Guidance should come from studies of effective supervision, which have identified openness, availability, and clear feedback, including feedback about errors; on the other hand, ineffective supervision includes rigidity, low empathy, failure to offer support, and failure to follow the supervisees' concerns.<sup>27–31</sup> It is encouraging that residents may feel greater satisfaction with attending physicians who are more often present on the floors and may perceive better medical care and autonomy with them at the bedside.<sup>47</sup> A study comparing resident perceptions of the ideal clinical supervisor in 1994 and 2003 found that the supervisor role gained significant prominence in 2003 versus 1994, and the importance of the role of ''physician'' declined concurrently.<sup>48</sup>

Developing faculty as supervisors may require enhanced teaching of skills that residents consider as desirable components of their supervision—but report as being largely absent in many supervisors—including active coaching in clinical skills and procedures, effective communication skills, and clinical decision making that incorporates the principles of costappropriate care.<sup>39</sup>

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# CHAPTER 7 New Standards for Resident Professionalism: Discussion and Justification

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### Introduction

Professionalism forms the core of a good physician. There have been numerous efforts by medical educators, associations, and specialty boards to elevate the awareness of professionalism throughout all levels of training and into the lives of practicing physicians.<sup>1–3</sup> The Accreditation Council for Graduate Medical Education has long focused attention on the critical importance of professionalism in graduate medical education by incorporating it as 1 of the 6 core competencies.<sup>1</sup> There are many definitions for professionalism but one that is all inclusive is espoused by Stern<sup>4</sup> in his book titled *Measuring Medical Professionalism*:

Professionalism is demonstrated through a foundation of clinical competence, communication skills, and ethical understanding, upon which is built the aspiration to and wise application of the principles of professionalism: excellence, humanism, accountability and altruism.<sup>4</sup>

In the American Board of Internal Medicine's review of this topic in 2002, the working group,<sup>5</sup> led by Sax, created a physician charter and enumerated 3 core principles related to professionalism: (1) the primacy of patient welfare, (2) patient autonomy, and (3) social justice. The document further listed 10 professional responsibilities, including commitments to the following:

- Professional competence;
- Honesty with patients;
- Patient confidentiality;
- Maintaining appropriate relationships with patients;
- Improving quality of care;

- Improving access to care;
- Just distribution of finite resources;
- Scientific knowledge;
- Maintaining trust by managing conflicts of interest;
- Professional responsibilities.

This professionalism charter became an important bedrock in the ACGME deliberations and recommendations regarding the new standards on professionalism.

#### **Resident Professionalism**

The principal aim of graduate medical education in the United States is to prepare young doctors for the safe, independent practice of medicine on completion of residency or fellowship.6,7 An important part of graduate medical training is that it exposes residents to the demands of real-life practice, including the long work hours of physicians in practice (50 to 60 hours a week on average,<sup>8</sup> with a sizable percentage of physicians in a number of specialties working more than 80 hours a week).<sup>9,10</sup> In 1998, realizing the power of the "hidden curriculum" on the values that are being communicated to residents, members of the profession called for a significant change in the way residents were treated,<sup>11</sup> and in 2003 the ACGME adopted a set of duty hour regulations in a report about resident hours and conditions to optimize patient safety, which made prominent reference to supervision and other factors that collectively contribute to the quality and safety of care in teaching settings, which provide the setting for the development of resident professionalism.12

## **Professionalism and Duty Hours**

In considering a revision of the duty hour standards, the basic tenets of professionalism often were at the core of Task Force deliberations. Many individuals and professional organizations expressed concern that residents not be reduced to shift workers with resultant erosion of their sense of duty and professionalism. There was a strong belief among the members that a major factor in the professional development of residents is that they personally must take primary responsibility for how their hours are spent, to ensure their personal readiness to work and learn. Many advisors to the process also spoke passionately about how graduated physicians must efficiently manage their time and responsibilities and stressed that gaining facility with time management during their training years was important. Managing work and other life responsibilities is critical to the long-term success of physicians and can be directly linked to their job satisfaction and longevity in medical practice.

Studies and testimony heard by the Task Force showed that among residents there often was a stated conflict between issues of professional commitment—such as being with a needy patient in the hospital at a time past the allowed duty hours versus being at home to rest or study in preparation for the next day's work. This was a prominent finding in research on the effect of the regulation of duty hours in New York and in studies of resident perceptions of the effect of the national duty hour standards.<sup>13–16</sup> Resident sentiments regarding duty hours often were stated as 2 divergent positions:

Resident 1: Strict limitation of my duty hours is antiprofessional. I need to be with my patients when my patients need me. A professional should not punch a time clock.

Resident 2: Duty hours should be restricted. I need time to think, to rest, and to live my life. That will prepare me to come to work the next day and give it my all. Eighty hours is more than enough.

Both residents are making important and valid points and the position that each one is taking needs to be addressed. This diversity reflects the fact that professionalism, personal responsibility, and patient safety always are inseparable.<sup>17</sup> The Task Force focused on patient safety and recognized that, in a patient-centered model, graduate medical education must stress the personal responsibility physicians must have for their patients. Although professionalism is emphasized from the first day of medical school, increasing responsibility and skill during residency must be aligned with professional growth and a growing sense of individual responsibility as residents move through supervised, guided settings toward independent practice.

## Requirements for Duty Hours and Professionalism and their Rationale

The aim of the new requirements for professionalism is to ensure that residents understand their personal responsibility to their patients, including their responsibility for maintaining alertness and fitness for duty and the effect that all activities, including those outside of their educational program may have on this.

Programs and sponsoring institutions must educate residents and faculty members concerning the professional responsibilities of physicians to appear for duty appropriately rested and fit to provide the services required by their patients.

The program director and institution must ensure a culture of professionalism that supports patient safety and personal responsibility.

Residents and faculty members must demonstrate an understanding and acceptance of their personal role in the following:

- 1. assurance of the safety and welfare of patients entrusted to their care;
- 2. provision of patient- and family-centered care;

- 3. assurance of their fitness for duty;
- 4. management of their time before, during, and after clinical assignments;
- recognition of impairment, including illness and fatigue, in themselves and in their peers;
- 6. attention to lifelong learning;
- 7. the monitoring of their patient care performance improvement indicators; and,
- 8. honest and accurate reporting of duty hours, patient outcomes, and clinical experience data.

The Task Force recognized that responsibility for building professionalism is a collaborative process involving programs, program directors, institutions, and most important, the residents. All must be involved and have shared goals. Education of faculty (who may have trained under different standards) and residents/ fellows is the responsibility of programs and sponsoring institutions. The onus of responsibility extends beyond the individual program to the institution, to ensure that programs are provided appropriate resources and that education occurs in a suitable learning environment. This fosters both patient safety and resident well-being, which are important outcomes of quality graduate medical education.

To properly fulfill their professional responsibilities, residents must understand the systems in which they function, and the interprofessional nature of health care. Thus, the Task Force emphasized the regular, meaningful involvement of residents in program and institutional quality improvement and patient safety initiatives. Such an expansion of the educational model should have the benefit of an immediate focus on ensuring patient safety; it also sets the stage for lifelong behaviors directly toward enhancing patient care through improving the systems for health care delivery.

When designing learning objectives, programs in essence are creating the atmosphere of professionalism.<sup>6,11,17</sup> Residents learn by doing (patient care responsibilities), by being mentored (supervision during these patient care responsibilities), by observing and listening to those more senior in their level of competence (clinical learning), and by acquiring medical knowledge necessary for state-of-the-art management of disease and other conditions (didactic learning). To acquire the judgment to determine how various conditions resemble, yet differ, from one another, a balance must be achieved between the expertise gained by repetitive exposure to specific diseases and accrual of the didactic information covering the spectrum of presentations and findings in any particular diagnostic category.

Since residents have limited time to acquire medical experience and knowledge necessary to sharpen their judgment, programs must not allow service obligations to take precedence over activities that have true educational value. The new standards reemphasize this mandate, seeking to eliminate instances where residents are asked to perform tasks not normally relegated to physicians.

As part of a modern medical education environment, residents' involvement in patient care must continually focus on patient safety and individual responsibility. This should be accomplished by the program director and faculty leading by example, and by the institution providing a learning environment that emphasizes patient safety not only in policies but also through its actions. The optimal patient care environment stresses 7 principles:

1. Patient safety is at the core of all patient care. This simple statement requires support from all care providers and a seamless interaction among many hospital systems and policies. There should be adequate support staff; protocols for preventing wrong-side surgery or patient falls must be in place; quality laboratory testing and imaging must be readily available; and patients' rights must be clearly written and easily accessed by patients and their families. Patients are vulnerable, and must perceive the environment in which care is rendered as deserving of their trust.

- 2. Care must be patient centered and family centered. This key concept of the Institute of Medicine's report, "Crossing the Quality Chasm,"<sup>18</sup> is equally important in the teaching hospital environment, where research, education, or departmental needs may on occasion appear to take precedence over the needs of patients and their families. Such an emphasis is inappropriate and must be redirected. An excellent clinical learning milieu can be achieved without sacrificing focus on patients, and education in such an environment is likely to positively shape the future practice of graduates.
- 3. Physicians must be fit for duty. Physicians—whether faculty or resident must be fit for duty and able to effectively care for their patients. That "[p]atients have a right to expect a healthy, alert, responsible, and responsive physician''19 has been a key tenet of the dialogue about work hours since the American College of Surgeons formally issued this statement in 1994. Residents and faculty, even when "off duty," are still responsible for appropriately managing their time to enable them to report for their next scheduled duty well rested and alert. Program directors and supervising faculty cannot mandate that residents or other faculty members get sufficient rest at home, or place any other limitations on activity (other than external moonlighting for residents) away from work. They can, however, demand that resident physicians on duty are well rested and capable of performing their duties.
- Impaired physicians must be recognized and removed from patient care activities. Residents and faculty are human and on rare occasion are found to be impaired. Such impairment, which can be as serious as drug or alcohol addiction or as

temporary as a significantly fatigued resident, can adversely affect patient safety and must be recognized and addressed in a timely manner. It is the responsibility of anyone in the health care system observing impaired behavior to report it to a supervisor or other individual who can intervene.

- 5. Physicians must be committed to lifelong learning. In a time when medical knowledge is rapidly advancing, it is incumbent on faculty members to model the behaviors of ongoing critical review of the literature and to participate in programs that document ongoing medical competence (such as Maintenance of Certification and Maintenance of Licensure).
- 6. Patient care must be monitored for overall quality. Institutions must have in place quality and performance improvement initiatives, outcomes assessment, and peer review programs designed to constantly monitor patient safety, the quality of care rendered, and the competence of physicians. While these functions have long been the purview of the faculty and an essential element of self-regulation, it will now be required that residents participate actively in these processes as part of the new emphasis on patient-centered care.
- 7. There must be honest and accurate reporting of all elements of resident training and patient care. In the past, there has been concern that residents reported what they thought faculty wanted to hear when answering questions about duty hours, clinical experiences, and patient outcomes. The new requirements emphasize honesty in reporting as yet another essential element of professionalism. This applies to individuals, programs, and institutions.

The ACGME's emphasis on professionalism, evidenced by the development and

implementation of more detailed standards, reflects a belief that this core competency underpins many elements of residency training, especially in the arena of fitness for duty and compliance with duty hours. It is felt that these standards are in keeping with the broader principles already espoused by the medical profession. In addition to reasonable limits on resident work hours, there is a new emphasis on immersing residents in all aspects of patient care including diagnosis and treatment of disease, and inculcating in them a commitment to care for patients as human beings. This should result in a more altruistic physician and set the stage for a lifetime of highly professional behavior.

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# CHAPTER 8 New Standards for Teamwork: Discussion and Justification

The sum total of medical knowledge is now so great and wide-spreading that it would be futile for any one man...to assume that he has even a working knowledge of any part of the whole....The best interest of the patient is the only interest to be considered, and in order that the sick may have the benefit of advancing knowledge, union of forces is necessary....It has become necessary to develop medicine as a cooperative science; the clinician, the specialist, and the laboratory workers uniting for the good of the patient, each assisting in elucidation of the problem at hand, and each dependent upon the other for support.

William J. Mayo, 1910

#### The Study of Teamwork in Health Care

A growing interest in team approaches to health care has been fostered by trends in health care delivery, including changes in organization; increasing specialization and division of labor; a need for coordination of comprehensive, cost-effective, population-based, and patient-focused care; and a growing interest in prevention and ongoing management of chronic conditions.<sup>1–4</sup> For health professionals, teamwork offers the benefits of enhanced professional satisfaction and a change in emphasis from acute, episodic care to management and prevention. Teamwork also encourages innovation and quality improvement in health care.<sup>2–4</sup>

Teamwork in health care has been described and studied for several decades. In a classic study done in the 1970s, Bosk<sup>5</sup> described how surgical teams decentralize authority, make decisions, and develop value systems related to their work. Coordination of teamwork in health care settings often depends on direct communication and informal rules in the

immediate care environment. This contrasts with formal bureaucratic rules in other settings and makes teams vulnerable to changes in health care leadership and context.<sup>6,7</sup> In 1975, themes in the literature on teams in health care encompassed status, power and authority, roles and professional domains, and decision making and communication; and these still are dominant themes in the research on health care teams. Areas of emphasis more recently added include patient-centered approaches to care<sup>8-10</sup> and clinical microsystems as the organizing framework for health care delivery.<sup>11,12</sup> The term clinical microsystem refers to a small health care work unit that provides care to a defined group of patients. Microsystems consist of a small team of people, a local information system, and a set of work processes.<sup>11</sup>

#### **Benefits of Teamwork**

The 2001 Institute of Medicine report entitled "Crossing the Quality Chasm"<sup>13</sup> references the importance of teamwork in realizing 6 aims for the health care system. Those 6 aims call for care to be as follows:

- Safe: Avoid injuries to patients from the care that is intended to help them.
- Effective: Match care to science; avoid overuse of ineffective care and underuse of effective care.
- Patient-Centered: Honor the individual and respect choice.
- Timely: Reduce waiting for both patients and those who give care.
- Efficient: Reduce waste.
- Equitable: Close racial and ethnic gaps in health status.

A few empirical studies that have examined teamwork and clinical outcomes have found evidence of benefit. A Cochrane systematic

review<sup>14</sup> of the benefits of teamwork in 2007 found that practice-based interprofessional team interventions improve health care delivery and outcomes, but the small number of studies, small sample size, and challenges in measuring collaboration made it difficult to generalize about the elements of teamwork that were responsible for these positive effects. A review of the literature on the benefits of team approaches from 1985 through 2004 found that the diversity of clinical expertise involved in team decision making may account for improvements in patient care and organizational effectiveness, while collaboration, conflict resolution, participation, and cohesion may enhance team member satisfaction and perceptions of team effectiveness.<sup>15</sup> A study of safety factors and surgical outcomes in 52 teaching hospitals found that high levels of faculty and resident communication and collaboration were associated with lower risk-adjusted morbidity for surgical patients.<sup>16</sup> In another study,<sup>17</sup> intensive care unit nurses' reports of collaboration were associated positively with patient outcomes.

# **The NewTeamwork Standards**

The ACGME standards promote teamwork as beneficial to patient safety and to the professional development and formation of the resident. In addition to the standards below, the sections on transitions of care emphasize teamwork in transmitting information and collectively managing the care of patients.

[Residents are expected to] work effectively as a member or leader of a health care team or other professional group.

[Residents are expected to] work in interprofessional teams to enhance patient safety and improve patient care quality.

The first standard defines residents' roles as members or leaders of health care teams or similar groups, while the second section expands existing expectations for resident representation on hospital quality improvement committees to include active resident

participation on quality and safety teams. Systematic approaches to enhance quality and safety in health professions education, including changes in curricula and organizational culture, and assessing outcomes at the individual and program level, have been recommended for a number of years.<sup>18</sup> The literature on educational approaches to teach residents how to improve quality and safety has demonstrated that ongoing, active involvement in quality improvement efforts is superior to didactic methods and short-term quality or safety electives.<sup>18,19</sup> Popular approaches for applied teaching of quality improvement include incorporating quality improvement principles into morbidity and mortality conferences, morning report, and clinical case conferences.<sup>20-23</sup> Recent efforts have focused on closer integration between didactics and applied approaches to teaching practice-based learning and improvement and systems-based practice, with a particular emphasis on quality and safety.24-27

Residents must care for patients in an environment that maximizes effective communication. This must include the opportunity to work as a member of effective interprofessional teams that are appropriate to the delivery of care in the specialty.

The program director must ensure that residents are integrated and actively participate in interdisciplinary clinical quality improvement and patient safety programs.

These standards define attributes of the environment for resident teamwork and collaboration and cooperation, with the aim of creating a system in which residents manage information and care decisions collectively and with other health professionals.<sup>28</sup> Implementation of these standards will necessitate, and likely contribute, to a change in the culture in settings where residents participate in patient care.

# Implementing Teamwork in Teaching Settings: Models and Challenges

The IOM report "Crossing the Quality Chasm"<sup>13</sup> did not offer specific guidance for how to implement teamwork in patient care settings. Two exceptions are the reference to clinical microsystems<sup>9,10</sup> and the statement asserting that redesign of the immediate work units that provide care will be required to ensure that care is knowledge based, patient centered, and systems minded.<sup>11</sup> Practical interpretations and companion documents to the report also do not offer advice on how to make health care more team oriented, but rather offer visions of a new system in which cooperation among clinicians is a priority.<sup>29</sup> A theoretic discussion of physicians' education and professional development related to teamwork postulated that the knowledge, skills, and attitudes to enhance team work can be taught and assessed.<sup>30</sup> A review of team training interventions found that curricula used in team training for residents and medical students use sound educational principles and appear to be modestly effective and that the effectiveness of interventions is enhanced when curricula cover several dimensions of teamwork.<sup>31</sup>

Teams can be effective catalysts for organizational change.<sup>32</sup> In teaching settings, care teams are made more complex by professional role boundaries and interprofessional relations and by how team activities are influenced by technology and the care environment. An added challenge for teams that include residents is that much of the research on teams has focused on stable teams, yet many health care teams are temporary, coming together for brief periods, ranging from the time spent caring for a given patient to the 30-day time frame of a clinical rotation. The implementation of the new teamwork standards will need to be mindful of these teams' temporary nature.

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Continuity of care is an important aspect of quality, yet in the 24-hours-a-day, 7-days-a-week enterprise of the teaching hospital, which encompasses multiple specialties, clinical departments, and modalities of care, transitions of care between units and providers or provider teams (also called handoffs, handovers, or signouts) are a common and necessary occurrence. During these transitions, the physician or team handing over responsibility for care must accurately convey information about the patients under his or her care, and the physician accepting responsibility must receive, process, and interpret this information to make judgments about what actions must be taken in the immediate future.<sup>1</sup> In addition to ''task lists,'' this process frequently includes decisions about the degree of monitoring necessary for the patients' acuity of illness to allow for the appropriate allocation of time, attention, and other resources.<sup>1,2</sup> These attributes of transitions are addressed in the ACGME standards.

# **Transitions of Care**

Programs must design clinical assignments to minimize the number of transitions in patient care.

This standard seeks to reduce the number of handoffs to the minimum needed to ensure coverage, with the understanding that each transition creates the potential for information to be lost or distorted.<sup>3,4</sup> A study of closed malpractice claims attributed a high percentage of errors in teaching settings to teamwork problems, with handoff errors being disproportionately more common in teaching settings.<sup>5</sup> Communication failures were also implicated in 60% of the sentinel events reported to the Joint Commission on the Accreditation of Healthcare Organizations,<sup>6</sup> and the 2008 Institute of Medicine report<sup>7</sup> regarding resident hours and patient safety recommended that all residents receive education in patient handoffs.

Studies have shown that the frequency of transitions in patient care has increased since the 2003 institution of common duty hour standards. A consequence of the regulation of duty hours is that the responsibility for each patient may be transferred between 2 or more physicians 2 to 3 times during a 24-hour period. A study in the pediatrics inpatient setting found a small increase in medication errors after the institution of the duty hour limits and attributed this change to problems with patient handoffs.<sup>8</sup>

Sponsoring institutions and programs must ensure and monitor effective, structured handover processes to facilitate both continuity of care and patient safety. Programs must ensure that residents are competent in communicating with team members in the handover process.

In 2006 the Joint Commission added transitions in patient care to its National Patient Safety Goals, referencing the need for "a standardized approach to hand-off communications, including an opportunity to ask and respond to questions."9 Residents believe transitions are not adequately addressed in education and practice, noting that processes are haphazard, with no system of organized interaction.<sup>10,11</sup> Limits on resident hours have also increased the use of "cross-coverage," defined as residents outside of the primary care team providing care in the absence of the primary team. This increase has been associated with an increase in the likelihood of unplanned changes in care and errors attributed to problems with the transfer of information.<sup>12</sup> In some surgical

programs, the limits may have increased the number of asynchronous handoffs without person-to-person interactions, a practice that is associated with even greater potential for handoff errors.<sup>1,13</sup>

An important reason for instituting common duty hour limits was to reduce the potential for errors attributed to resident sleep deprivation and fatigue. Improving transitions in patient care is critical to ensure that the common duty hour limits realize this aim and that reductions in errors due to fatigue are not offset by increases in errors due to inadequate information transfer. Large scale studies of the effect of the 2003 duty hour limits have not found significant improvement of morbidity and mortality.14-16 Because these analyses have used administrative data, it is not possible to determine whether "technical problems" considered sensitive to improvements in resident alertness under reduced duty hours were offset by "communication errors" thought to result from lost information under more frequent care transfers.

The sponsoring institution must ensure the availability of schedules that inform all members of the health care team of attending physicians and residents currently responsible for each patient's care.

This standard addresses coordination of care, which has traditionally been an important concept in continuity, with classic definitions of continuity including an understanding of who is responsible for patient care and communicating this information to the patient.<sup>17,18</sup> An added benefit of enhanced coordination is that transitions of care and handoffs are complex clinical acts, which benefit from supervision and coaching, particularly for junior learners. In addition, recommendations for transferring practices from high-reliability organizations have focused on how redundancy can reduce the risk of errors in transmission and how feedback to the presenter contributes to enhanced accuracy and learning.<sup>1</sup> This approach is congruent with

the concept of high-reliability organizations' "preoccupation with failure" and may result in increased ability of the system to detect both deterioration of patients and errors and omissions in information transfer.<sup>19</sup> Other recent approaches for improving transitions have focused on supervision and provision of feedback for junior residents' handoffs<sup>1,20</sup> and on the use of objective skills-based examinations to allow residents to test and practice handoff skills.<sup>21</sup>

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# CHAPTER 10 New Standards Addressing Fitness for Duty, Alertness Management, and Fatigue Mitigation

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If sleep does not serve an absolutely vital process, it is the biggest mistake the evolutionary process ever made. Allan Rechtschaffen

#### Sleep and Its Effect on Performance: A Brief History

In 350 BCE Aristotle wrote about human sleep as "an inhibition of sense perception" for "conservation."<sup>1</sup> Studies on the effect of sleep and sleep loss began with animals in the 1800s and the 1920s. Kleitman and colleagues<sup>2</sup> explored how sleep and wakefulness relate to circadian rhythms and studied the effects of sleep deprivation. One of Kleitman's students, William Dement,<sup>3</sup> described the cyclic patterns of rapid eye movement (REM) and non-REM sleep in humans and later in other mammals. In 1968, Allan Rechtschaffen and Anthony Kales created "A Manual of Standardised Terminology, Techniques and Scoring System for Sleep Stages of Human Subjects,"<sup>4</sup> and in 1978, Mary Carskadon and colleagues<sup>5</sup> developed the first test to assess for sleepiness, known as the multiple sleep latency test. The first study in resident physicians, conducted by Friedman and colleagues<sup>6</sup> in 1971, showed that postcall residents made more errors in reading a standardized electrocardiogram than their rested colleagues.

In the ensuing 4 decades, individual studies and systematic reviews found that sleep deprivation had a negative effect on aspects of human performance important to physicians' work, including cognitive function, working memory, vigilance, fine motor skills, and mood.<sup>6–12</sup> Three meta-analyses<sup>13–15</sup> and 3 qualitative reviews<sup>16–18</sup> found that sleep deprivation reduced cognitive performance, mood, concentration, and effort. All subjects reported a decline in performance after 24 to 30 hours without sleep, and several highlighted chronic partial sleep loss, defined as sleep duration of fewer than 5 hours for several consecutive nights, as a significant cause of reduced performance. Chronic partial sleep loss is common in residents, and residents who reported sleeping 5 or fewer hours per night were more likely to report having worked in an "impaired condition" and having made medical errors.<sup>19</sup>

The meta-analyses also explored moderators in the effect of sleep loss on performance, including type of performance, as well as task duration and complexity. Research on type of performance found that vigilance appears to be affected first by sleep loss and to a higher degree than memory and cognitive function, with gross motor performance being quite resilient.<sup>14,15,20</sup> Hours without sleep influenced this effect, with long-term total sleep deprivation having the most pronounced negative consequences for performance.14,15 A metaanalysis with a large sample of physician participants reported a decline in clinical performance of 1.5 standard deviations in sleepdeprived individuals.<sup>15</sup> Finally, interindividual variation in the effect of sleep loss on performance may be a moderator. Some individuals appear to be profoundly affected, whereas others are minimally affected by the same number of hours without sleep<sup>21–23</sup>; others may require longer sleep on a regular basis to maintain wakefulness.<sup>24</sup> Recent research has identified a gene allele associated with individuals' high susceptibility to sleep loss.<sup>25</sup>

A number of commentaries about physicians and their performance while sleep deprived have suggested that individual selection may result in physicians as a group being more resistant to the performance effects of sleep loss. While

some selection undoubtedly is present, 2 other factors may explain why earlier studies have found that physicians are less affected by sleep loss. The first is that many residents experience chronic partial sleep loss owing to their working schedules; the second relates to differences in how studies were conducted.<sup>15</sup> Most research on sleep deprivation in nonphysicians has been conducted in highly controlled laboratory settings, while the common approach for studying residents involves field experiments that compare the performance of postcall residents to a "rested" comparison group or that study the same residents in a sleep deprived and a "rested" state. This approach results in studies with less rigid control on the number of sleep hours for the sleep-deprived group, which attenuates the effect size of sleep loss in these field studies.<sup>15</sup>

An important recent observation is that while older studies of the clinical implications of sleep loss have found it to be associated with greater complication rates,26 and increased errors and lower effectiveness on actual and simulated care tasks,<sup>27-29</sup> more recent studies conducted under the 2003 ACGME common duty hour standards or comparable limits and conditions in other nations, including 24-hour call, have failed to find a reduction in clinical performance in physicians.<sup>30–34</sup> A study of surgical residents<sup>35</sup> also found no worsening of mood under conditions of acute sleep loss. Its authors<sup>35</sup> and an unpublished meta-analysis of articles on the effect of work and sleep hours on clinical performance and medical errors hypothesized that by eliminating some of the chronic sleep debt, the duty hour limits may have reduced the negative effect of acute sleep loss in postcall individuals (Ingrid Philibert, unpublished metaanalysis, December 2010).

# **Fitness for Duty**

Standards and regulations to promote patient safety and resident alertness for the learning process traditionally have focused on the number of hours worked. This includes state regulation of resident hours in New York State and the ACGME's 2003 common duty hour standards. However, focusing predominantly on duty hours neglects much of the science about sleep and performance that may influence multiple human factors. The concept of "fatigue" extends beyond sleep status and views other factors. This concept recognizes that the performance effect of sleep loss on performance is more complex than a linear association with hours without sleep and is influenced by the time of day and its effect on circadian rhythm,<sup>36–39</sup> as well as the length and complexity of the test or task, and whether it is self-paced or performed at a pace that is externally dictated.<sup>14,40,41</sup>

Limits on resident duty hours, applied equally to all residents in all situations, cannot incorporate information about the amount and quality of the sleep the individual resident had before presenting for work on a given morning; about the biologic factors that may predispose an individual to be more susceptible to the performance effects of sleep loss; nor about questions about the intensity of the activities residents engage in during their nonduty hours.

Sleep experts who have advocated for further restrictions in resident hours acknowledge that a host of factors, both genetic and adaptive, contributes to different individual responses to the amount and quality of sleep obtained.<sup>22,42</sup>

Without the ability to consider some of these attributes of individuals, tasks or contexts, the concern is that further restrictions in resident hours may reduce professional socialization and preparation for some of the demands of independent practice,<sup>43</sup> but still may not guarantee a rested and alert resident.

The ACGME Task Force asked the advice of experts in exploring whether tests existed that could determine an individual resident's fitness for duty. The ideal would be a quick, reliable, easy to administer, and inexpensive assessment tool that could accurately predict the ability to safely provide care, effectively participate in the learning process, and ensure the safety of the resident on activities such as driving home. To date, no reliable mechanism exists that would be feasible and practical for application in residency programs. Research in this area has been conducted for the past 2 decades and continues to focus on the development of a model of alertness and performance by using 3 relatively simple inputs: the time of day, the time since awakening, and the duration of prior sleep.<sup>44</sup> This has shown some success in predicting motor vehicle accidents.<sup>45</sup>

# **Alertness Management/Fatigue Mitigation**

There has been considerable research on the assessment of sleep for the past several decades, which has produced a number of methodologies, both investigational and clinical, including polysomnography, wrist actigraphy, sleep latency tests, and others.<sup>1,3–5</sup> These can be used to measure the amount of sleep, its quality, and the desire for sleep, with some of these providing information that can be used to make inferences about alertness. There also is an emerging science of how to maintain and manage alertness by identifying and addressing various factors that assist in maintaining wakefulness and alertness.

Alertness management strategies can minimize the adverse effects of sleep loss and circadian disruption and promote optimal alertness and performance in operational settings. Sleep and circadian physiology are complex, individuals are different, the task demands of settings are different, and schedules are extremely diverse; therefore, no single strategy will fully address the fatigue, sleepiness and performance vulnerabilities engendered by 24-hour operational demands. Rather than attempt to eliminate fatigue, it may be more useful to consider the critical factors that can promote and optimize alertness management.46

The belief that there should be systematic attempts to manage alertness for individuals who need to work and function under stressful conditions for prolonged periods of time is not unique to medicine.<sup>47</sup> Physicians, nurses, police, firefighters, emergency personnel, fighter pilots, naval crews, and transportation workers all operate in environments where the timing of work is not always conveniently matched to the human circadian rhythm, and the length of the work may challenge individuals' ability to function effectively.48 While to date few trials of alertness management strategies have been undertaken with resident physicians in clinical settings, a sizable body of research has addressed the effectiveness of alertness management strategies in pilots, air traffic controllers, shift workers, and adults in laboratory settings, with much of this work done at the NASA Ames Jet Lag and Fatigue Countermeasure Groups.49-51

# Rationale for the Standards on Alertness Management/Fatigue Mitigation

The 2011 ACGME common duty hour standards expand the 2003 requirements that included a requirement for educating residents and faculty about recognizing and responding to the signs of fatigue and sleep deprivation. In addition, they include new standards for education in alertness management and fatigue mitigation, and for programs to adopt fatigue mitigation strategies such as naps or backup schedules. The standards call for each program to do the following:

- Educate all faculty members and residents to recognize the signs of fatigue and sleep deprivation;
- Educate all faculty members and residents in alertness management and fatigue mitigation processes; and,
- Adopt fatigue mitigation processes, such as naps or backup call schedules, to manage the potential negative effects of fatigue on patient care and learning.

The underlying evidence indicates that while research has shown that self-assessment of fatigue by individuals is poor,<sup>48</sup> individuals can plan in advance to deal with fatigue and institute appropriate countermeasures.<sup>47</sup> Allowing for naps at opportune times during actual work conditions

TABLE	EFFECTIVE ALERTNESS MANAGEMENT
Fatigue prevention strategies	
Obtain adequate sleep before presenting for duty	
Treat all sleep-related illnesses (insomnia, OSA)	
Obtain adequate exercise and nutrition	
Reduce use of alcohol or hypnotics for sleep when not on duty, if avoidable	
Fatigue mitigation strategies	
10- to 45-minute naps	
1- and 2-hour naps also increase efficacy, but may result in sleep inertia	
Caffeine when sleepy (and not when awake)	
Exercise/activity during duty	
Bright light	

Abbreviation: OSA - obstructive sleep apnea

has been tested in pilots on long-haul flights,<sup>52</sup> nurses,<sup>53</sup> and air traffic controllers,<sup>54</sup> with improved postnap performance found across this range of occupations, with performance dimensions relevant to the work of physicians. Preventive strategies (coming to work rested and ready for duty), in addition to operational strategies (napping, use of caffeine) have been assessed and have proved effective.<sup>55</sup>

The program director and institution must ensure a culture of professionalism that supports patient safety and personal responsibility.

Residents and faculty members must demonstrate an understanding and acceptance of their personal role in the following: assurance of the safety and welfare of patients entrusted to their care; provision of patient- and family-centered care; assurance of their fitness for duty; management of their time before, during, and after clinical assignments; recognition of impairment, including illness and fatigue, in themselves and in their peers.

The 2011 ACGME common program requirements for the first time mention attention to being rested and fit for duty as an element of residents' personal and professional obligations. This is based on research showing that obtaining appropriate rest between duty periods greatly improves operational effectiveness in several occupational sectors.49-55 Maintaining good sleep hygiene when not at work can include regular bedtimes, use of the bedroom for sleep, eating only lightly (or not at all) before sleep, avoiding alcohol or caffeine before sleep, and getting out of bed if not asleep in 30 minutes.<sup>56–61</sup> Operational alertness management strategies must allow for individual, workload, and task variation and are best when several strategies are used collectively. What is important is to be aware of which strategies work. Strategic napping, use of selected stimulants,62 physical activity,63 and eating properly have been shown to be of benefit. The use of stimulants has been studied in shift workers; of these stimulants, caffeine is the safest and easiest to use (TABLE).<sup>62,64,65</sup> To obtain the best effect in managing alertness, caffeine should not be used as a "food," but rather as a drug to be taken when one is most fatigued, and not taken before sleep periods or when waking from a nap.

Naps in the workplace have been tested in some occupations, with beneficial effects on alertness.<sup>52–54</sup> Scientific studies suggest that a minimum of 2 hours is required for completion of 1 "cycle" through the various stages of sleep.<sup>66,67</sup> Longer naps of up to 1 hour have been associated with sleep inertia, or difficulty waking up after napping.<sup>46,68,69</sup> In some contexts, very brief naps have been demonstrated to improve alertness and reduce errors in laboratory experiments, with nap length ranging from 10 or 20 minutes, but also 30 seconds and 90 seconds.<sup>54,70–73</sup>

The 2008 Institute of Medicine report<sup>74</sup> on resident duty hours included a recommendation for 5-hour naps. However, the only 2 studies of a prolonged nap period for residents found them ineffective in improving alertness.<sup>75,76</sup> An early formal study of a 4-hour protected sleep period showed that sign-out to night-float residents for

4 hours did not significantly change total sleep time (it did increase slow-wave sleep) nor did it have significant effect measures of alertness and performance.<sup>75</sup> In the second study, residents rarely fully used the nap period provided to them, owing to an unwillingness to sign out the pager for their own patients, and the study also found that residents with shorter nap periods felt more rested.<sup>76</sup>

Making fitness for duty part of residents' professional obligations recognizes both its important contribution to managing alertness for patient care and the learning process; it also responds to comments the Task Force received that indicated some confusion in the graduate medical education community about the extent to which program leaders can influence the activities and behavior of residents during their hours outside of the educational program. Other standards, which promote alertness management in the clinical setting, include a reiteration of the importance of appropriate space conducive to sleep and rest in the hospital. Included are enhanced standards that formally make residents and faculty collectively responsible for the safety and welfare of patients and that call for a transfer of responsibility for the patient to another rested provider; the standard for appropriate backup to maintain continuity of care when a resident is too fatigued to perform his or her patient care responsibilities; and the new standard for provision of safe transport home for residents too fatigued to drive safely.

All residents and faculty members must demonstrate responsiveness to patient needs that supersedes self-interest. Physicians must recognize that under certain circumstances, the best interests of the patient may be served by transitioning that patient's care to another qualified and rested provider.

Each program must have a process to ensure continuity of patient care in the event that a resident may be unable to perform his or her patient care duties. The sponsoring institution must provide adequate sleep facilities and/or safe transportation options for residents who may be too fatigued to safely return home.

In addition to continued education of residents and faculty about sleep, performance, and alertness management, the requirements expand the role of program directors, faculty, and resident colleagues in identifying and intervening in instances when residents exhibit signs of fatigue. Fully meeting the intent of these standards may necessitate change in the culture of some programs and sponsoring institutions, with faculty taking an active role in supporting residents' decision to leave when fatigued; counseling residents who appear fatigued but are reluctant to leave; and assisting residents in making appropriate decisions about the circumstances when patient care and learning are served by staying beyond the limits and when patients benefit from transferring the care to a rested resident or team. To avail themselves of something as simple as safe transportation home, residents need to recognize their own limits and request it, knowing their safety may be compromised by driving. Programs will need to institute the necessary changes in their learning environment to allow residents to make these decisions.

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# CHAPTER 11 GOING BEYOND DUTY HOURS: A Focus on Patient Safety

Much of the public focus on resident hours has been in the context of a perception of long hours and fatigue as performance-shaping factors and contributing causes in errors and adverse events in teaching settings. Yet, early in the debate on duty hours and safety, it was noted that limits on resident hours cannot guarantee safety in teaching hospitals, that "[i]t would be unrealistic to expect residents to absorb the realities of caring for their equally fragile and needy patients if their working hours were fixed according to an arbitrary schedule, however well-intended''(F. Davidoff, MD, testimony to the 1986 Ad Hoc Committee charged with the inquiry into the Libby Zion's death). As an educational accreditor, the ACGME focuses on resident duty hours in the context of the patient care environment and learning, mindful that resident education and patient safety are influenced by multiple factors. No single intervention, including the imposition of strict limits on standards for resident duty hours, by itself can ensure the safety of patients in teaching settings.

#### "To Err is Human"

In 1999, the Institute of Medicine's report "To Err Is Human: Building a Safer Health System''1 focused public attention on the findings that in the United States medical errors may be responsible for 44000 to 98000 deaths annually. The estimate is based on 2 studies of adverse events in hospitals in the 1980s: a study in Colorado and Utah, which showed that 2.9% of hospitalized patients experienced an adverse event (of which 8.8% were fatal), and a study in New York State, showing that 3.7% of hospitalizations were associated with an adverse event. More than one-half of the adverse events in both studies were deemed preventable, and the total cost to society of these preventable adverse events was estimated at \$17 billion to \$29 billion, with one-half of this total

representing health care costs.<sup>1</sup> The release of the IOM report prompted the ACGME to begin a process of exploring errors in teaching settings. While the report did not implicate resident hours as a cause or contributing factor, it was one factor in the ACGME's implementing duty hour limits in 2003.

The 2008 IOM report on resident hours referenced this earlier work and concluded that 8 years after the publication of "To Err Is Human,"<sup>1</sup> patient safety remained a problem that went "well beyond the subset of hospitals that train residents."<sup>2</sup> In developing the ACGME duty hour standards, the Task Force applied a broad-based approach to promote safe and effective patient care, high-quality education, and resident safety. The 2011 duty hour standards include provisions for enhanced supervision and graduated responsibility, limits on patient load, improvements in the process for transitions in care, increased education about alertness management, and enhancement of teamwork in clinical settings.

### Causes and Contributing Factors of Errors in Teaching Settings

To many, the advent of oversight and increasing regulation of resident hours was prompted by the 1984 death of Libby Zion in a major New York teaching hospital.<sup>3</sup> While much of the investigation into her death focused on the 36-hour duty periods worked by the resident physicians who had cared for her, lack of supervision by an attending physician was a key contributing factor in her death,<sup>4,5</sup> and the 1986 grand jury investigation into her death ultimately led to New York's state regulation establishing duty hour limits and requirements for resident supervision.<sup>6</sup>

Residents function in a health care system in which the financial and human costs of errors are significant. Their role as learners, with short tenure and lack of familiarity with settings, may make them more vulnerable to errors. That efforts to explore the role of human factors in health care lag behind those in other industries becomes evident in reviews of the literature on the causes of errors and adverse events in teaching settings.<sup>7,8</sup> A number of studies that have analyzed long hours as a contributing factor have found a link between resident fatigue and error.<sup>9-12</sup> At the same time duty hours are by no means the sole or even the leading cause of errors. A study of nearly 700 residents conducted in 2004 found that one-half of respondents had cared for patients with adverse events, with the common types of events related to the procedures and drugs. Residents attributed nearly one-fourth of the adverse events to "mistakes." Working more than 80 hours during the preceding week was associated with a higher likelihood of reporting an error (odds ratio 1.8).9 The same study found that during a 1-week period, 18% of the respondents had cared for a patient who had experienced an adverse event, and 37% of the respondents in this group reported they considered themselves responsible for the error.<sup>9</sup> While these are important findings, there are methodologic problems with studies that associate resident self-reports of working long hours with higher rates of errors (without the ability to temporally associate incidents of errors with extended shifts). There are also more general attribution problems when individuals are asked to assign causes and contributing factors to errors they have committeed.10,11

The 2008 IOM Committee on Resident Duty Hours reported that the percentage of errors attributed to long hours and fatigue varied by type of study. It found that error rates in self-attribution studies ranged from 19% to 41%, with data for the lower percentage collected in 2003,<sup>11</sup> shortly after the implementation of the ACGME common duty hour limits, and the higher estimate resulting from a study of internal medicine residents in 1989.<sup>10</sup> In contrast, there are much lower percentages of work hours and fatigue in root cause analyses. Root cause analyses of errors in Veterans Affairs hospitals mention fatigue as an associated factor in 4.5% and a cause in 0.7% of serious errors.<sup>13</sup> A comparable analysis for less serious safety incidents mentioned fatigue as a contributing factor in 1.0% to 3.3% of the cases.<sup>13</sup> In addition to methodologic differences, the self-report studies assessed solely residents, while the Veterans Affairs studies include all types of providers (including those who work hours much below the weekly and continuous duty hour limits worked by residents), as the Veterans Affairs does not routinely identify resident status in its analyses.<sup>13</sup>

## Nonduty Hour Causes of Errors in Teaching Settings

A study of closed malpractice claims data between 1979 and 2001 found higher error rates in teaching than nonteaching settings, but it does not allow the calculation of a percentage of patients that experienced an error during their care.<sup>14</sup> The study found 240 errors in teaching settings during the 22-year period.<sup>14</sup> Of these, the most prevalent contributing factors were errors in judgment in 72% of the 240 cases, problems with teamwork in 70%, and lack of technical competence in 58%.14 Lack of supervision and handoff problems were the most prevalent teamwork problems, and both were disproportionately more common among errors that involved residents than those that did not.14 Studies based on resident self-reports also find that factors such as "job overload" and suboptimal working conditions contribute to errors and adverse events.<sup>10–12,15</sup> In a large study of residents and errors, residents offered inadequate supervision ahead of duty hours, problems with handoffs, large patient loads, and cross-covering patients as common causes or contributing factors to error, along with long work hours.9 A cross-sectional survey of 125 internal medicine residents immediately before the implementation of the ACGME 2003 duty hour limits found that suboptimal working conditions (fatigue and work compression and errors during handovers) were the most common contributing conditions reported by the residents.<sup>12</sup> Personal factors and lack of support for noneducational and administrative tasks also played a role, with

residents who felt overwhelmed with work (P = .02) and who reported spending more than 50% of their time in nonphysician tasks (P = .002) more likely to report suboptimal care practices, which was associated with a higher self-reports of errors.<sup>12</sup>

The most common event during which failures of technical competence or attention occurred involved diagnostic decision making and monitoring of the patient.<sup>14</sup> This is consistent with studies of instances of "failure to rescue" as a cause or contributing factor in adverse outcomes, and with publicized errors in settings where residents participate in care, such as the death of a live liver donor in a New York teaching institution after the state implemented limits on resident hours,<sup>16</sup> or the postoperative death of a young patient from a perforated ulcer due to a high dose of pain medication.<sup>17</sup> An analysis of closed malpractice claims found that errors involving residents also were more complex than errors for other practitioners (with a mean of 3.8 contributing factors versus 2.5 [P < .001]), suggesting that 1 factor may be complexity of the teaching environment.14

# Impact of the 2003 Duty Hour Limits

Data collected soon after the 2003 implementation of the ACGME common standards found resident self-reports of factors contributing to errors for programs did not differ for residents in programs that had made significant reductions in weekly hours and those that had made no changes under the new limits.<sup>15</sup> Both groups implicated poor handoff practices, caring for too many patients, and inadequate supervision, though all percentages were somewhat lower for residents in programs that reduced duty hours.<sup>15</sup> A study that explored the effect of duty hour limits on patient safety implicated problems with handoffs in a slight increase in errors in the pediatrics inpatient setting,18 and a systematic review found that effort to reduce resident hours failed to have a clear positive effect on patient safety indicators, with some unchanged and others worsening.<sup>19</sup> However, many were single-site studies with

interventions entailing informal schedule changes, and the analysis was limited by study factors, small sample sizes, and the range of interventions included in the analysis.<sup>19</sup>

In an important research article about the patient safety benefits of limits on residents' continuous duty period, Landrigan and colleagues<sup>20</sup> reported on error rates for 21 firstyear residents in an intensive care unit. The study compared error rates across first-year residents and unit-wide, as well as residents working a 14-hour shift versus a schedule pattern that included overnight call, and found that errors per 1000 patient-days unit-wide were 193 for serious errors and 39 for preventable adverse events. First-year residents working on call every third night accounted for a substantial portion of the reported errors (136 serious errors and 20 preventable events per 1000 patientdays). Working a schedule limited to no more than 16 continuous hours reduced errors and adverse events involving first-year residents.<sup>20</sup> A third-party observer collected errors, increasing the methodologic robustness of this study. However, although unit-wide collection of information on errors was within the range identified by other studies, the "data on interns were more detailed due to the presence of the observers."21 It is important to note that none of the studies answer the question of whether there is an increased prevalence of errors in teaching hospitals, as none compare error rates for teaching and nonteaching hospitals. A single analysis of the classic studies of adverse event rates for Utah and Colorado, which underlie the estimates of errors in the 1999 IOM report,1 found adverse event rates of 4.0% for major teaching hospitals, 3.9% for minor teaching hospitals, and 2.5% for nonteaching and private hospitals, though the data are not adjusted for differences in severity of illness or intensity of service among the 3 types of hospitals.<sup>22</sup>

# The 2011 Standards and Safety as a Systems Property

Experts have estimated that 80% of medical errors occur as a result of systems failures.<sup>23,p. 5</sup>

This suggests that the resolve of individuals residents, faculty physicians, and other professionals-to work harder and avoid errors will be insufficient to improve the quality and safety of care. The IOM's 2008 report on resident hours noted that a culture of safety in hospitals and enhanced teamwork in patient care can also contribute to safety, and the examples of this culture of safety exist from highreliability organizations.<sup>2</sup> High-reliability organizations function in high-risk domains and produce "nearly accident-free performance"24 or function in a "nearly error-free fashion."<sup>25</sup> Examples include flight deck operations on aircraft carriers, the US air traffic control system, and nuclear power plants. All of these settings emphasize teamwork and training in and for teams.<sup>26,27</sup> The IOM's 2001 report "Crossing the Quality Chasm'' emphasized coordination across multiple professionals responsible for the care of the patient, stating that "[c]linicians and institutions should actively collaborate and communicate to ensure an appropriate exchange of information and coordination of care."28

The 2011 standards address various aspects of patient safety, including (1) efforts to enhance the quality and safety of care through residents' participation in interprofessional quality improvements teams; (2) enhancements to the handover process; (3) promotion of patient safety as an element of physician professionalism; and (4) residency program and sponsoring institution commitment to creating an environment and systems focus on patient safety.

[Residents are expected to] work in interprofessional teams to enhance patient safety and improve patient care quality.

The program must be committed to and responsible for promoting patient safety and resident well-being in a supportive educational environment.

The program director must ensure that residents are integrated and actively participate in interdisciplinary clinical quality improvement and patient safety programs.

The program director and institution must ensure a culture of professionalism that supports patient safety and personal responsibility.

Residents and faculty members must demonstrate an understanding and acceptance of their personal role in...[the] assurance of the safety and welfare of patients entrusted to their care.

Sponsoring institutions and programs must ensure and monitor effective, structured handover processes to facilitate both continuity of care and patient safety.

Collectively, these standards promote a focus on patient safety as a property of the learning and patient care environment in which residents function. Safety as a systems property is important because individuals, including residents and faculty, can positively influence practices and processes to promote safe practices and a focus on safety and quality. Studies across a range of industries show that the most important marker of safety is an organizational effort to create a culture of safety at the system level,<sup>29–31</sup> and that an organizational culture of safety is associated with fewer adverse events. The focus on safety at the systems level includes research on a safety focus at the level of the clinical microsystem.<sup>32</sup> Finally, such an organizational focus on patient safety requires the commitment of the organizational leadership by setting expectations, ensuring organizational focus and, as needed, providing resources to enhance the safety of patient care.30,33,34

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# CHAPTER 12 THE NEED FOR FLEXIBILITY IN THE NEW STANDARDS

#### Background

In 2003, the Accreditation Council for Graduate Medical Education approved accreditation standards for duty hours for all residency and fellowship programs.<sup>1</sup> At the time, the decision to implement common standards was based on 3 factors: (1) change in the spectrum of hospitalized patients, with higher levels of acuity and intensity of services and shorter lengths of stay; (2) the emergence of a significant body of scientific data on the effects of sleep loss on cognitive and neurobehavioral performance; and (3) a growing interest in the amount of time residents worked each week, including the length of their continuous duty period. The last was prompted by the death of Libby Zion in a New York teaching hospital in 1984 and the subsequent regulation of duty hours in New York State,<sup>2</sup> and a 1999 report by the Institute of Medicine, entitled "To Err is Human."<sup>3</sup> Unlike the findings of the Bell Commission that led to the establishment of New York State's duty hour regulations, the IOM report<sup>3</sup> did not directly implicate sleep loss in residents, but discussed the role of a host of "human factors," including fatigue, as contributors to medical errors responsible for a large number of preventable deaths annually.

The 2003 standards were written to maintain a balance between the need for ACGME to ensure the high quality of education in all ACGME training programs and the need for institutions to provide high-quality round-the-clock patient care. The original duty hour standards were also designed to incorporate the rapidly enlarging body of scientific knowledge on the effects of sleep deprivation. Except for a few specialties like emergency medicine and anesthesiology, which previously had established standards more restrictive than the 2003 common duty hour requirements, and the option for programs to extend weekly duty hours by 10% under an educationally justified

exception, the duty hour standards were identical across specialties, essentially espousing a notion of "one size fits all."

The ACGME Task Force on Quality Care and Professionalism approached the need to revise the duty hour standards from a different vantage point. It reviewed the evidence supporting a maximum weekly and continuous duty period, including data showing the effect of sleep deprivation on cognitive and neurobehavioral performance. It also considered the strongly emphasized view of the graduate medical education community that flexibility in duty hours and supervision were needed both vertically (from postgraduate year-1 [PGY-1] to higher levels of residents/fellows) and horizontally (surgical, medical, and hospital-based specialties) to allow graduated responsibility as residents progress to independent practice.

### The Need for Flexibility and Graduated Responsibility

The 2008 publication of the Institute of Medicine's report on duty hours,<sup>4</sup> among other restrictions, recommended reduced limits on continuous duty hours for all residents and fellows. The publication of the report coincided with the ACGME's promised plan to reexamine and refine the common duty hour requirements that were implemented in 2003. Recognizing the importance of the IOM recommendations and the views of the GME community that differed from the IOM recommendations on a number of matters, the Task Force strove for a balanced view that invited the perspective of the GME community and specialties into the discussion. In June 2009, the Task Force received written position papers from more than 140 medical organizations and during 1.5 days, heard formal testimony from more than 70 national organizations representing all domains of medicine and medical education.

A recurring point in the testimony and the written positions from members of the graduate medical education community was the need for flexibility in the duty hour standards across specialties and levels of training. The American College of Physicians stated that "rigid guidelines may unduly prohibit creativity in program design, strip residents of their ability to make the best decisions that impact them as well as their patients, and actually be counterproductive in achieving one or more of the goals. Providing flexibility in this regard is essential to allow the appropriate level of learning to occur."<sup>5</sup> The American College of Surgeons (ACS) presented the results of a survey of the members of the ACS Resident and Associate Council, in which 41% of 599 respondents indicated that the current inflexible duty hour restrictions were a considerable or moderate barrier to their education.<sup>6</sup>

The official positions of major organizations in medicine showed a high degree of correlation between level of training and a perception that the 2003 limits had a negative effect on learning, with senior residents more likely to report that duty hours significantly impeded their education, compromising the time in the operating room necessary to increase their technical skills and the time spent to maintain continuity of patient care as they approached entering independent practice. There also was strong sentiment on the part of senior residents that they were inhibited from participating in rare and educationally valuable clinical scenarios; this may cause some graduating residents to feel less than fully prepared for independent practice. The ACS reported that this perception was supported by the fact that 77% of surgical chief residents in 2005 and 76% in 2008 chose to pursue fellowships for increased specific training, in lieu of entering general surgery practice.7,8

Although Task Force deliberations had considered a system of standards that would offer flexibility by specialty and level of training, the ultimate recommendations for the 2011 standards focused on flexibility by level of

training, owing to the availability of scientific data supporting this approach and to reduce the danger of fragmentation and undue complexity in the new standards. There was no question about the need for maintaining the 80-hour weekly limit, which also had been supported in the recommendations of the IOM report on duty hours.<sup>4</sup> In contrast, there were questions of whether the 24 + up-to-6-hour limit on the continuous duty period was optimal, with the IOM report having recommended a more restrictive 16-hour limit. The positions presented to the Task Force by the academic community voiced strong support for flexibility in the continuous duty period and in the required hours of time off between scheduled duty periods. The positions also emphasized the benefits of a system that would take into account the level of training and competence of the resident, the level of supervision, the anticipated workload, and, perhaps most important, the value of graduated responsibility to prepare residents to function independently after graduation.

The need for flexibility across specialties is further emphasized by the fact that some specialties, such as dermatology, pathology, and radiology, have not been significantly affected by the 2003 duty hour standards, typically because they never reached 2003 duty hour limits even before their implementation. Others, such as surgical specialties and the inpatient experiences in many medical disciplines, needed to be revised significantly to comply with the current limits. Flexibility also is beneficial because of emergent care needs; the educational benefit of seeing rare diagnoses or treatment; the benefits to patient care of continuity, particularly in difficult or emotionally stressful circumstances; and the overlapping involvement of several specialties in the acute care setting. With the 2003 common duty hour standards, which espoused a "one-size fits-all" approach, residents occasionally face an ethical dilemma between their professional desire to remain beyond proscribed duty hour limits to provide the best care for their patients (in the process gaining new medical knowledge and

clinical skills) or leaving the institution in order to comply with regulations and not put their institution at risk for a citation. The Task Force felt that more flexibility in the 2011 standards would reduce the incidence and severity of these situations.

# Evidence Supporting More Restrictive Limits for PGY-1 Residents

The Task Force considered 3 reviews of the relevant literature commissioned by the ACGME,<sup>9-11</sup> and also heard expert testimony on sleep physiology. On the basis of this information, the Task Force concluded there is physiologic data demonstrating that a statistically significant dip in performance on psychomotor vigilance tasks occurs between 16 and 24 hours of wakefulness.12 The extent of the decline in performance varies among individuals and is most likely substantially worse for some residents.<sup>13</sup> The practical and clinical significance of these findings were less clear, particularly the effect on medical decision making. In addition, there was concern about the impact that added transitions of care (handoffs), under greater restrictions on the continuous duty period, may have on patient safety.

The 3 literature reviews also explored various other factors, such as resident quality of life, and the effect of sleep loss and duty hour limits on resident education and patient safety and quality of care. Most studies demonstrated an improvement in resident quality of life, but they involved only a single cohort and did not stratify by levels of training. In addition, many studies that assessed the effect of sleep loss on performance used general tasks assessing vigilance and cognitive function, or narrow taskrelated performance on laparoscopy-training devices, and their validity related to performance on clinical tasks may be limited. A recent systematic review of the literature<sup>14</sup> ranked studies that reduced the length of the continuous duty and those that reduced the frequency of overnight call of 24 to 30 hours, by using the United States Preventive Services Task Force methodology. It found that only 1 study, examining the quality of patient care after

implementation of the 2003 duty hour standards, reached level I, defined as evidence obtained from at least 1 properly designed randomized trial;<sup>15</sup> and only 2 added studies reached a level II-1, defined as evidence obtained from well-designed controlled trials without randomization studies.<sup>16,17</sup> The study reaching level I had a sample size of 21 first-year residents, with a reduction in errors under a 16hour limit on the continuous duty period.<sup>15</sup> Of the studies reaching level II-1, one was a prospective study that showed no difference in the number of errors per call shift.<sup>16</sup> The other was a retrospective controlled trial with both concurrent and historical controls that demonstrated a decrease in intensive care unit admissions and pharmacist interventions to prevent drug errors after the 2003 standards were instituted.17 While the data showing a decline in performance after 16 hours of wakefulness is scientifically important,12 its generalizability and practical significance is less clear, given the redundant safety and educational oversight systems of patient care in teaching hospitals in the United States. However, the limited data from highquality studies performed within the medical environment indicated that despite the presence of these systems, PGY-1 residents made fewer errors when their continuous duty period was limited to no more than 16 hours.<sup>15,18</sup> The Task Force further heard evidence that PGY-1 residents work the longest hours of any resident cohort. FIGURE 1 presenting data from the ACGME Resident Survey, collected under the 2003 standards, shows this, particularly for first-year residents in specialties with a preliminary year.<sup>19</sup> Differences for all duty hour parameters, with the exception of home call and 1 day off in 7, are significant (P < .0001). The findings suggest that the current patterns of resident hours are counter to an ideal of first-year residents having more protected hours, with hours and responsibilities gradually increasing over the years of residency, and the final year beginning to emulate practice, while still under faculty supervision.

The long hours currently worked by PGY-1 residents, linked with 2 studies showing the

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negative effect of long hours (greater than 16 hours of wakefulness) on their performance, resulted in the Task Force adopting the standard that this group of residents (PGY-1s) must be limited to a maximum of 16 continuous hours on duty. The training paradigm adopted by the Task Force is predicated on better preparation and supervision of PGY-1 residents, followed by progressive liberalization of the duty hour standards as the resident demonstrates additional competency and is delegated greater degrees of conditional independence in the care of patients.

### **Evidence Supporting Levels of Supervision and Graduated Responsibility**

The Task Force believed that data from laboratory sleep studies were only 1 factor in the design of educational standards, yet the Task Force members agreed that the clinical care environment has become much more complex, and novice residents need to be more directly and explicitly supervised to promote both patient safety and resident learning, and that supervision is likely the more important factor in preventing errors.

The concept of graduated or progressive responsibility is the cornerstone of medical training in the United States. Many participants at the 2009 Duty Hour Congress testified to the need for preparing residents for the transition from conditional independence during their years of training to independence upon graduation. In an open letter to the GME community Thomas Nasca noted that this graduated independence paradigm can be shifted in 2 ways.<sup>20</sup> First, the most inexperienced resident can be given a high level of authority with too little supervision (FIGURE 2), or second, too much supervision can be given throughout training (FIGURE 3), causing a lack of preparedness at the time of graduation from training, or "falling off the cliff into practice."<sup>20</sup> The ideal model is the balance of independence and supervision illustrated in FIGURE 4.20

The United States model of graduate medical education is different from the training paradigm in other countries, notably in Europe, where





2nd+yr Always / Usually compliant with requirement

1st yr Always / Usually compliant with requirement

graduates may remain in the institution where they trained under indirect supervision by their mentors as they enter practice, particularly in subspecialty areas. The training paradigm adopted by the Task Force is predicated on better preparation and supervision of PGY-1 residents during more normalized work hours,



Figure adapted from T. Nasca, MD, Open Letter to the GME Community, October 2009.



Figure adapted from T. Nasca, MD, Open Letter to the GME Community, October 2009.

followed by progressive liberalization of the duty hour standards as the resident demonstrates competencies that can be used as the basis for granting them greater conditional independence in the care of patients. This progression of responsibility to unsupervised independence is primarily based on the level of training in the new standards, but the ACGME Review Committees will have some latitude in modifying the



### GRADUATED RESPONSIBILITY

Figure adapted from T. Nasca, MD, Open Letter to the GME Community, October 2009.

standards to meet more specific specialty needs. It will be aided significantly by the development of the educational "milestones," which is already underway in internal medicine,<sup>21</sup> pediatrics,<sup>22,23</sup> general surgery, urology, and obstetrics-gynecology, and will be initiated in the remaining specialties during the next few years. The milestones will provide a more solid and individualized basis for charting residents' road to independent practice.

### Conclusion

The Task Force developed the new standards in the context of an expanded awareness and emphasis on professionalism, a long recognized need for more defined supervision of residents, and a widely expressed desire for greater flexibility in duty hours to facilitate the education of residents who must be prepared to enter the unsupervised practice of medicine at the completion of training.

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### CHAPTER 13 THE GRADUATE MEDICAL EDUCATION COMMUNITY'S RESPONSIBILITY FOR PRODUCING A FULLY TRAINED PHYSICIAN

### **The Aim of Graduate Medical Education**

Today's patients are sicker, and diagnostic and therapeutic options are more numerous, complex, and costly than a generation ago. In response, graduate medical education continues to evolve to educate physicians who can effectively function in this environment. Graduate medical education programs and the institutions sponsoring them are held accountable for ensuring that their graduates have achieved all appropriate competencies by the time that their residency/fellowship training is completed. In a commentary published in June 2003, entitled "Trust, Accountability, and Other Common Denominators in Modernizing Medical Training," Thomas Nasca, MD, MACP, and Jeanne Heard, MD, PhD, FACP described this responsibility of the GME community:

In medical education, we have a greater responsibility than do most other disciplines to not only ensure that our graduates have been exposed to a curriculum that meets national standards for breadth and depth of experience but also to demonstrate that our graduates can actually perform the duties of a specialist in their chosen discipline. Prior to graduation, each resident must demonstrate that he or she is capable of practicing independently.<sup>1</sup>

The commentary underscores that as a professional obligation and a consequence of increased public scrutiny, programs and sponsoring institutions must make patient safety their first priority. A concurrent aim of GME accreditation is to ensure that training programs produce fully trained physicians capable of functioning independently in their chosen field. This is central to the mission of graduate medical

education, and the ACGME Common Program Requirements (Section V.A.2.b)<sup>2</sup> stipulate that programs enter a summative evaluation in each resident's file verifying that he or she has "demonstrated sufficient competence to enter practice without direct supervision." An expected outcome of residency is that graduates will be eligible for initial certification and entry into Maintenance of Certification programs by a member board of the American Board of Medical Specialties. All ACGME Review Committees track board-certification rates of graduates of residency programs as a measure of quality of the programs, and some have as specific requirement that a certain percentage of graduates achieve board certification.<sup>3,4</sup> These measures are useful but may not present a complete picture of a program's graduates' ability to practice competently and independently.

### Hours and the Attainment of Clinical Competence

A critical element of producing a fully competent physician will entail preserving and promoting educationally valuable hours and experiences under the new, more restrictive standards, and using the milestones to ensure that residents are attaining the competencies for independent clinical practice in the specialty. A 2005 systematic review of the literature regarding the effect of interventions to reduce resident work hours on residents' education and quality of life found that that these interventions produced a mixed effect on both experience and on perceived educational quality.<sup>5</sup>

Since the ACGME implemented the common duty hour standards in 2003, questions have arisen about the number of hours required to train a fully competent physician. This is particularly true for surgical programs, which experienced sizable reductions in duty hours under the 2003 ACGME common standards. To date, relatively little research has assessed the role of operative volume and time on competence for independent medical practice, and proxies from other fields, such as concert pianists, professional athletes, and chess players are being referenced in the literature. These have suggested that it takes approximately 10 000 hours of practice to produce "world class" performance.<sup>6</sup> A study that applied these concepts to graduate medical education estimated the hours residents spend to complete the procedures required for eligibility for certification by the American Board of Surgery; it found that only 20.6% of the approximately 19 200 maximally available hours for a surgery residency (5 years at 80 hours/week) were spent as a chief surgeon, an assistant, or in preoperative and postoperative care.<sup>7</sup>

While commentaries and early studies after the implementation of the 2003 common duty hour standards postulated a reduction in operative experience under the limits, most studies of programs in surgical specialties have found no decline in operative volume.<sup>8-11</sup> One study found both a decline in first-assistant experience and in perioperative continuity of care,<sup>12</sup> and experts have commented that preservation of operative volume has come at the expense of resident involvement in perioperative care. In some surgical disciplines, educators have voiced concern about reduced competency and performance in recent graduates, and a study of neurosurgical residents' board performance on self-assessments and for actual scoring has shown a sizable decline for the cohort sitting for the examination in 2008, as compared to the 2000 cohort.13

A critique of this approach to assessing the effect of duty hours on the attainment of skills for independent practice is that it fails to consider the proportion of hours residents may currently spend on activities with comparably low educational value. For more than a decade, the ACGME Institutional Requirements have required that institutions provide transport and

messenger and test retrieval services that reduce resident hours spent on these activities.<sup>14</sup> Analyses conducted during the late 1990s and in the early years of the 21st century have found that a significant proportion of resident time, including time on overnight call, was spent on activities that did not require a physician, did not include direct contact with patients, and may not contribute to the competence for clinical practice.<sup>15–20</sup> Tasks included charting, other documentation and clerical tasks, time spent waiting and dealing with delays in test results,15-19 and time in transit among the clinical areas of the inpatient hospital.<sup>20</sup> The findings suggest that institutions have largely eliminated resident time spent in transport of patients and specimens. However, it is not clear to what degree programs and institutions have enhanced the educational value of resident hours by reducing these other more subtle and difficult-to-address areas of work with lower relevance to the acquisition of competence.

Problems with reducing activities of lower educational value and preserving formal education contract hours are reported from the European Community, which has functioned for more than 15 years under restrictions on work hours for all physicians.<sup>21–24</sup> Some studies have reported declines in experience and in the comfort level of residents and faculty for graduates' preparedness for independent practice, yet viewed collectively, the findings are not conclusive in allowing an assessment of the educational effect of the European duty hour limits.<sup>25–30</sup> However, a recent study<sup>31</sup> suggested comparably lower competence in medical decision making and patient management skills for physicians recently entering practice in the Netherlands, compared to their Canadian counterparts, who were educated under duty hour limits similar to those in the United States.

### Assessing Acquisition of Competence and Readiness for Practice

Concerns about the effect of duty hour limits on the acquisition of competence for practice has further heightened interest in competency-based education and assessment.<sup>32</sup> Competence in the realm of medical knowledge has long been determined by using standardized examinations (ie, in-service and board-certification examinations).<sup>33</sup> For the 5 other competencies, expectations for competence and methods of assessment are not as clearly defined, and written or computer-based examinations are not the ideal means to asses professionalism, interpersonal and communication skills, practicebased learning and improvement, or systemsbased practice.<sup>34–37</sup> These assessment mechanisms also are not well suited to the assessment of haptic, higher-order, or integrated skills that must be fully developed before a physician is able to practice independently.<sup>33</sup>

The ACGME formally implemented the Outcome Project in 2002, to expand the formal assessment of resident physicians to all 6 competencies, with the aim of assuring the public that graduate medical education is meeting its societal obligation of producing fully trained physicians capable of providing independent patient care.<sup>38</sup> While the Outcome Project significantly advanced teaching of all 6 competencies, evaluation of residents to date largely has been limited to formative assessment using relatively simple, locally developed tools that frequently have undergone little or no validation, or using global "cross-competency" faculty ratings of residents after major rotations. The lack of nationally applied and validated assessment tools makes it impossible to conduct national comparisons of resident performance with the aim of identifying best practices and benchmarks.

### **The Milestone Project**

To enhance the systems for tracking the development of residents as they aim to become fully competent physicians, the ACGME in 2008 initiated the Milestone Project as a major effort to move toward competency-based education.<sup>39</sup> Under the Project, the ACGME is working with its Review Committees and specialty boards to develop specialty milestones—clear, specific

accomplishments relevant to the specialty that residents must achieve at specific times during their education.<sup>40,41</sup> The measure of a fully competent physician ready for entry into practice would be the completion of all education milestones in the specialty.

The goal of the Milestone Project is to set discipline-specific standards for performance over the course of the required years of training by using the progression from beginner to proficient/expert as defined by Drevfus and Dreyfus.<sup>42</sup> The timing of these assessments will be the biannual, more formal evaluations of resident progress, which are already required by the ACGME for all programs and are an accepted approach in residency education. The approach is justified by educational research and will improve the quality and consistency of the assessment of residents in all competencies and, through this, their education and preparation for practice. By having discrete and clearly outlined milestones in place, programs will be able to better plan the major curricular elements of the program, thus ensuring that residents have more uniform, and yet tailored, educational experiences. It also is thought that the milestones will offer clearer guidance for assessment of residents' readiness to be declared "competent" in given domains.<sup>40,42</sup> By offering national comparisons, programs will be able to benchmark their achievements, and sharing of best practices by high-performing programs may accelerate the pace of innovation and improvement in GME. Finally, the Milestone Project incorporates the understanding that learners' pace of acquisition of competence may differ and, moreover, that by being able to identify learners who require additional experience in a given area at various predetermined times during the course of training, programs can more easily provide such experiences.42

At the time of writing, 5 specialties (internal medicine, pediatrics, surgery, obstetricsgynecology, and urology) are nearing completion or have initiated the development of specialty-specific milestones. Other ACGME Review Committees are slated to commence with development of milestones in the near future, and plans call for the completion of this effort for all core specialties in 3 to 5 years. With the implementation of the Milestone measures, programs and institutions will be able to demonstrate with greater confidence and credibility that their graduates have mastered required goals and are competent to enter independent practice.

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### CHAPTER 14 PROMOTING COMPLIANCE WITH THE Standards to Advance Patient Safety and Physician Competence

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The ACGME 2011 common duty hour standards emphasize that professionalism and supervision are overarching and necessary companions to the duty hour standards, to promote patient safety in settings where residents participate in care and in the care they will provide after completing their training.<sup>1</sup> This is in keeping with ACGME's role as the accrediting organization for graduate medical education, and the importance of accreditation as a measure of the quality for residency programs and their sponsoring institutions.

### The ACGME's Approach to Promoting Compliance

The ACGME monitors compliance with the duty hour standards through a combination of approaches that include the following:

- 1. Monitoring through an annual ACGME Resident Survey, with follow-up for programs with responses suggesting potential areas of noncompliance;
- 2. Implementing an accreditation review with onsite visits and interviews with residents, program directors, and faculty;
- Responding to complaints about potential duty hour violations;
- Promoting sponsoring institutions' oversight and monitoring of resident hours; and
- 5. Increasing residents' and the education community's knowledge of the adverse consequences of sleep loss, and of preventive and operational countermeasures, and through the 2011 standards, affirming residents' responsibility for managing alertness and fitness for practice as a component of their professional obligations as physicians.<sup>1</sup>

The ACGME uses a concept of substantial compliance, in which residency programs and sponsoring institutions are expected to essentially meet the spirit of all program and Institutional Requirements, including those pertaining to resident hours. Substantial compliance distinguishes between individual residents in a program working beyond the duty hour standards and instances in which several residents report they exceed the limits. The ACGME promotes compliance by using external assessments and an increasingly data-driven approach, which uses submission of data at regular intervals between site visits and contributes to ushering in a new model of accreditation, with longer cycle lengths and added focus on residents' meeting specialtyspecific educational milestones.<sup>2</sup>

The 27 Review Committees that have accreditation authority in the 26 accredited core specialties and the transitional year (a year of preparatory education for specialties that accept residents at the second postgraduate year) annually review 40% to 45% of all accredited programs. Review Committees monitor and cite programs that fail to meet the standards and take adverse actions when programs fail to comply substantially with the requirements, after appropriate due process. At present, the percentage of programs annually cited for duty hour noncompliance hovers around 7%, with evidence that citations lead to improvements in most programs.<sup>3</sup> The first step in promoting compliance with the duty hour standards entails collecting detailed, accurate information about residents' hours.

When it implemented the common duty hour standards in 2003, the ACGME's aim was to advance compliance with the new standards by broadening the data sources.<sup>3</sup> Soon after the 2003 implementation, the ACMGE incorporated

direct input from residents via the ACGME Resident Survey.<sup>4</sup> After piloting a Resident Survey in 2003, the ACGME surveyed all programs between 2004 and 2006.<sup>4</sup> It again surveyed all programs between 2007 and 2008, and since 2009 it has annually surveyed all core programs and all subspecialty programs with 4 or more fellows. For the approximately 5% of programs for which responses suggest a noncompliance with several standards, the ACGME follows up by requesting information on how the problem is being addressed, and in serious cases, conducting site visits of the programs with annually recurring ("continuous") and multiyear ("significant") noncompliance.<sup>4</sup> The validity of the Resident Survey has been demonstrated, although significant correlations with site-visit findings warrant added scrutiny for programs meeting the thresholds of potential noncompliance found in the group targeted for follow-up.<sup>5</sup>

The ACGME assigned oversight of compliance to its Monitoring Committee, which tracks duty hour citations issued by Review Committees, and monitors programs with potential duty hour problems identified via the Resident Survey.<sup>4</sup> Follow-up activities for multiyear, potentially serious noncompliance identified via the Resident Survey may include a "targeted" site visit.<sup>4</sup>

Accreditation site visits continue to be an important component of the compliance assessment process. During their site visits, the members of the ACGME field staff annually interview 12 000 to 15 000 residents about their educational experience, including duty hours, supervision, and other elements of their program. Together with the site visit, both the ACGME Resident Survey and a planned faculty survey are critical for assessing compliance with the duty hour, supervision, and related standards. A trained "site visitor" visits the program and confirms the information submitted by the program in the program information form. The Review Committee's assessment of the program is based on the information contained in the site visitor's report, the program

information form, and history and other relevant information, such as case and experience logs for residents. Areas of noncompliance with the common or specialty-specific requirements are cited after discussion and concurrence by the entire Review Committee. The Review Committee sets the accreditation status of the program (full accreditation or a proposed adverse action) by the number and severity of citations, the accreditation cycle, and next survey date.

The ACGME also receives and follows up on complaints related to alleged noncompliance with the Institutional and Program Requirements, including the requirements for duty hours. Complaints may originate from residents, program staff, and others with knowledge of the residency program. Experience with these complaints has shown that duty hours are often a symptom of inadequate attention to the educational demands of residency, as complaints often pertain to the interface between duty hours and the learning environment for residents.

Key elements of enhancing compliance with the duty hour standards entail requesting progress reports and action plans from programs that have been cited and involving their sponsoring institution. Because institutional support will often be critical to a program's ability to address these citations, the sponsoring institution is involved in formulating the progress report and needs to sign off on the document. Simultaneously, the Institutional Review Committee reviews sponsoring institutions for patterns of duty hour noncompliance. The Review Committees and the Institutional Review Committee may conduct repeated surveys and/ or focused reviews to reevaluate compliance. The aim is to foster compliance and program improvement, while allowing correction of citations made in error.

### **The Effectiveness of Accreditation**

The Institute of Medicine's report, "Resident Duty Hours: Enhancing Sleep, Supervision, and Safety,"<sup>6(p.4)</sup> included a critique of the ACGME's effectiveness in enforcing the duty hour standards implemented in 2003. Independent of the IOM report, the ACGME identified the need for enhanced compliance monitoring, along with inherent challenges of enhancing the frequency and intensity of duty hour surveillance at the program level, given the nearly 9000 programs it accredits. Out of this rose a plan for enhanced measures to promote compliance at the institutional level and for annual site visits to sponsoring institutions, focusing on duty hour compliance, supervision, and provision of a safe and effective environment for care and learning. The dual aim of the planned sponsor visit is (1) to promote enhanced institutional oversight of duty hours and of the ability of the learning environment to provide safe high-quality health care; and (2) to assess the institution's effectiveness in involving residents in institutional efforts to enhance safety and quality in their learning environment and to benefit their professional development and future practice.

The ACGME has convened experts in safety, sleep medicine, and graduate medical education to suggest data elements for the institutional site visit and to ensure the data collected will provide a thorough and realistic analysis of institutions' ability to provide a safe and effective learning environment. Using a set of data elements suggested by this group, the ACGME will gather data from all sponsoring institutions and will conduct onsite visits for institutions with 4 or more core residency programs. Interpretation of the data also will involve experts in patient safety, sleep medicine, and graduate medical education, and the ACGME plans to provide each institution with a report that details its compliance status and identifies noncompliance issues for timely resolution. In addition to institutional reports, the monitoring process will generate aggregated reports (national, regional, hospital type) with 3 objectives: (1) public release of data on institutions' achievements to assure the public of teaching hospitals' adherence to practices important to safe and effective care; (2) dissemination of best practices for adoption and

adaptation; and (3) through the aggregation of deidentified data, identification of common safety threats and risks in settings where residents learn and participate in care. ACGME information-sharing activities may include safety alerts, sharing of information on best practices and, potentially, enhancements to its standards in selected areas. The expert panel will provide ongoing guidance to refine the process and ensure currency with scientific evidence and state-of-the-art practice. Once the institutional site visit program is established, data from the process will be available to the public.

A comparison of the approaches to address patient safety by the Agency for Healthcare Research and Quality (AHRQ)—by highlighting their respective advantages and drawbacks when compared to legislation, regulation, and accreditation-finds that accreditation has the advantages of greater flexibility and input and opportunities for implementation at the organizational level.<sup>7</sup> One drawback cited—the fact that participation in the accreditation process is voluntary—is not entirely true for the accreditation of graduate medical education, because the American Board of Medical Specialties requires completion of an ACGMEaccredited program as a prerequisite for board certification in all basic specialties; moreover, programs must be accredited to receive federal support for graduate medical education, which creates additional strong incentives. Finally, another drawback of accreditation mentioned by AHRQ—infrequent assessments—also applies to existing regulatory solutions to address duty hours.

The data for individual states show that noncompliance with the duty hour standards is distributed approximately equally among all states, including New York State, which has an 18-year history of state regulation of resident hours, and Puerto Rico, the only other jurisdiction that regulates resident physician hours. ACGME data show that compliance for programs in New York State is comparable to that in other states. New York State accounts for 9% of sponsoring institutions and accounts for approximately 9% of institutions cited for duty hour noncompliance, and 9% of all duty hour citations between 2003 and 2009. Institutions in New York State account for 11.4% of institutions whose programs meet criteria for Review Committee follow-up on Resident Survey results that suggest duty hour violations.<sup>8</sup>

# The Responsibility of Programs and Sponsoring Institutions

The ACGME traditionally has emphasized the responsibilities of programs and sponsoring institutions for creating an environment that promotes safe patient care and high-quality resident education.<sup>3</sup> During the past decade, the ACGME's standards have expanded to include new important areas of focus, including competency-based education, development and codification of the role of the designated institutional official, more rigorous common program requirements that include the duty hour limits, efforts to minimize resident hours spent on activities that do not contribute to the acquisition of competence for independent clinical practice, and a more data-based approach to accreditation with web-based reporting and tracking systems.

The Outcome Project and the Milestone Project have further affirmed that the obligation of residency education programs and sponsoring institutions goes beyond the safety of patients in teaching hospitals, where residents participate in providing care, and includes the safety of patients that residents will care for in independent practice after completing their formal education.<sup>2,9</sup> This requires further attention to the curriculum and experiences that maximize resident education and to meaningful assessment with feedback for all residents, to maximize the educational value of the hours in the program, and to ensure residents meet all educational milestone expectations by the time they complete their training.

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### CHAPTER 15 A RESEARCH AGENDA TO ASSESS THE IMPACT OF THE 2011 STANDARDS AND TO IDENTIFY OPPORTUNITIES FOR REFINEMENT

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After the establishment of common duty hour standards in 2003, the ACGME affirmed that future refinements should be based on scientific information on the effect of duty hour limits on patient safety, quality of care, and resident learning and well-being. Basing standards on scientific data promotes acceptance and is important in justifying revisions to members of the profession who may have concerns about the effect of duty hour limits on graduates' preparedness for independent practice. It is equally important to public stakeholders, who need assurance that patient care in teaching hospitals is safe and effective and who may be less aware of the possible negative effect of severe cuts in duty hours on resident learning and acquisition of clinical skills.

In developing the 2011 standards, the Task Force used the available scientific data, including 3 detailed reviews of the literature commissioned by the ACGME.1-3 This revealed a lack of scientific data in many areas, while in others, the findings were equivocal about the benefits and drawbacks of duty hour limits. The Institute of Medicine's report entitled "Resident Duty Hours: Enhancing Sleep, Supervision, and Safety,"<sup>4</sup> released in 2008, summarized the available evidence on the effect of duty hour limits and noted a lack of clear evidence in some key areas. This included a lack of evidence of a relationship between negative effects of sleep loss on performance with the causes of error identified in closed claims studies and root cause analyses. The report also could not answer the question of whether duty hour limits would have a negative effect on competence for independent practice. The Task Force and the literature reviews identified additional areas where empirical data are lacking. Consequently, the debate about the 2011 duty hour standards

echoed many of the concerns about the potential diminished clinical competence and professionalism of graduating cohorts as the discussions that preceded the implementation of common standards in 2003.

The review of the literature by the University of Illinois at Chicago identified additional gaps, including how to conceptualize the balance between education and service required by the ACGME standards; other gaps included the benefits and risks associated with different ways of organizing resident work periods and shifts, the cost of duty hour reductions (to programs and society), the effect on quality of life for resident and attending physicians, and the value society may place on trade-offs among these outcomes.<sup>1</sup> This chapter lays out a research agenda for the medical education community and the ACGME for the rigorous analysis of the 2011 standards for duty hours and related areas such as supervision, transitions of care, teamwork, and alertness management.

### Research on the Effect on Resident Competency and Professional Development

In 2003, the debate about the effect of the common standards was influenced by the number of duty hours that needed to be reduced so that residents in a given specialty could comply with the new standards. Although research on the effect of duty hour limits in different clinical specialties remains a priority, added aspects of the 2011 standards that require further investigation include the benefits and drawbacks of the new limits for first-year residents and the impact of added flexibility for senior residents.

Research into the effect of hours of practice on the acquisition of competence remains a high priority, as the lack of empirical data in this area has made it difficult to justify, to the public and opinion leaders, that resident physicians' long hours are necessary for their clinical and professional development. Of particular interest are studies that assess the role of practice, repetition, and time in the acquisition of competence for independent practice. While there is a body of scientific evidence about the role of volume in the maintenance of competence at the institutional and individual level, scientific evidence on the role of time, volume, and repetition in the initial acquisition is lacking. As a consequence, the medical community adopted proxies from other disciplines.<sup>5</sup> These may not be the most appropriate in defining the effect of duty hour limits on the preparation of residents at graduation from training, and well-designed studies that seek to replicate the approaches used in other domains of competence clearly are needed. Research is also needed to offer added scientific evidence on the competency benefits of simulation. While accepted for its benefits to patient safety, use of simulation to facilitate the acquisition of clinical skills is still limited by the skills that lend themselves to current simulation models and by the financial and opportunity costs of its broad application in resident education.

In the nearly 10 years since the ACGME began its deliberations on common duty hour standards, several articles have commented on reduction in residents' ''professionalism''-their willingness to put patients' interests above their own. However, it is difficult to separate the extent to which this may be a consequence of the limits or whether interest in the limits resulted in part from residents' desire for a balance between their personal and professional lives, as compared to prior generations of physicians. Further research is needed to explore new models that do not equate professionalism with unlimited hours but that seek to provide residents with better guidance for how to put patients' expectations first, while promoting safe and effective care and maintaining an appropriate balance between the professional and personal pursuits.

### **Research on "Work Intensity" and "Work Compression"**

There are many indications that resident work has not diminished proportionately to the reductions in hours and that work intensity has increased in the past decade. This is not solely due to the duty hour standards, and one reason for the institution of common duty hour limits in 2003 was growing acuity and intensity of service in the inpatient setting. However, since the implementation of duty hour limits in 2003, financial pressures have forced many hospitals to preserve residents' significant role in the care of patients in teaching hospitals.<sup>6</sup> At present, few studies have sought to quantify the degree of work intensity that residents experience in their shortened hours, though some exploratory studies suggest that added reductions result in compression of activities. This may hamper learning by contributing work and cognitive overload, particularly for junior learners.

### Research on the Effect on Patient Safety and Quality of Care

One reason for the public demand for duty hour limits in the United States was to reduce excessive duty hours and fatigue as potential performance-shaping factors and contributing causes in health care errors. Yet the literature on the effect of duty hour reductions on quality and safety has not produced unequivocal findings. Despite large sample sizes and the power to detect minute differences, studies of the effect of the common duty hour limits found little change in patient mortality during the early years after the implementation of the 2003 standards.<sup>7–10</sup> Minor gains in patient safety and quality indicators were not associated with teaching status, suggesting that other factors accounted for these improvements and that the duty hour limits did not have a positive or negative effect.

These observations suggest the need for further research to analyze the patient safety benefits associated with the larger changes under the 2011 standards, including the enhanced standards for supervision, resident professionalism, transitions of care, and alertness management. Supervision of resident physicians is an important area that, except for a few recent high-quality studies, is underdescribed in the literature. An important area requiring additional work is that of resident attitudes toward supervision and behaviors (on the part of learners and supervisors) that impede learning or negatively affect patient safety. Another important area for research is assessing the effectiveness of supervision and exploring the educational needs of faculty and resident physicians entrusted with supervisory responsibilities.<sup>1</sup>

Other aspects of the duty hour limits that have not been fully researched include differences among specialties and among different years of training, the effects of replacing residents with other providers, and whether there may be trade-offs under which duty hour limits reduce errors related to fatigue, but increase errors attributed to problems with transitions and continuity of care.

Residents' role as learners and their lack of familiarity with clinical settings may make them vulnerable to errors. Duty hour limits fit among other systems approaches that seek to reduce sources of errors by addressing sleep loss, which may add to residents' vulnerability. At the same time, research in the determinants of patient safety suggests that safety results require broader attention at the system level, including multiprofessional engagement and communication, routine monitoring of care processes, and the ability to evaluate the impact of changes in work systems.<sup>11</sup> How these efforts interact in a given clinical setting with residents' limited hours and relatively short tenure is an important area for future investigative work.

### Research in Alertness Management and Predicting the Effects of Sleep Loss

To date, few trials of alertness management strategies have been undertaken with resident physicians in real-life clinical settings. The military and the transportation industry have designed fatigue management studies that could be adapted for residents in clinical settings. The results gleaned from such studies could foster a better understanding of the proper use and benefits of short nap periods, physical activity, and the judicious use of caffeine as fatigue management strategies in the clinical environment. Research is also needed to explore how the more controlled learning environment during residency will affect performance in situations of fatigue and stress in practice, to asses whether experiencing these situations in training is vital to the development of coping skills for handling demanding situations. Finally, the Task Force has reviewed early, yet promising research into predictive models of alertness and performance. This is an area where further study would significantly benefit residents and practicing physicians.

### Innovative Approaches to Learning and Clinical Care

A significant body of research and several commentaries have focused on the added clinical pressures on faculty under reduced resident hours and concurrent expectations for clinical productivity. These pressures may contribute to less time for resident teaching at the bedside, in the clinic, and in the operating room, where opportunity to observe and assist in procedures before performing them under supervision may be becoming the exception rather than the norm. Research is needed on approaches that decouple educational goals and patient service demands, including expedited learning through use of standardized patients, objective skills-based clinical examinations, and simulation with extensive debriefing and feedback. Concurrent research needs to explore how to free up faculty physicians for teaching and reward them for their teaching role. Some promising programs and institutional initiatives have been found, but added study is needed to evaluate these practices before dissemination for adoption or adaptation in other settings. Knowledge about how institutions and programs create a better learning environment will allow others to learn from these models.

### **Local Implementation**

A challenging aspect of research on the effect of the new standards on patient care and resident

learning is that the duty hour and related standards, while significant, are one set of inputs in a system with multiple other inputs. Studies of the effect of the 2003 standards have shown that it is difficult to separate the effect of the limits from other factors in the learning environment, and that it may be equally difficult to isolate their effect on resident competence.

Research on other large-scale changes has highlighted differences in implementation among settings due to variation in context and organizational preparedness, suggesting it is influenced by local factors. Study designs must be sensitive to complex variation by using multiple qualitative and quantitative measures, collecting data over time to understand change, and capturing interactions between national standards and the local contexts under which they are implemented.<sup>12</sup>

### Conclusion

As the ACGME Task Force was formulating the new duty hour standards in 2009 and early 2010, the body of knowledge to assess the effect of the common duty hour limits on patient care and resident learning was still emerging. Some surgical specialties with longer training periods had graduated just 1 or 2 resident cohorts educated entirely under duty hour limits. As a result, some of the knowledge about the educational and patient effects of the resident duty hour limits is just emerging and other areas have not been studied. The areas discussed above are a starting point for a research agenda to assess the effect of the 2011 standards and to provide the scientific undergirding for future refinements.

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### APPENDIX A **POTENTIAL COST IMPLICATIONS OF CHANGES TO RESIDENT DUTY HOURS AND RELATED CHANGES TO THE TRAINING ENVIRONMENT**

TERYL NUCKOLS, MD, MSHS José J. Escarce, MD, PhD

### **Executive Summary**

The principal objective of this analysis was to estimate the potential direct costs of changes to resident duty hours and the training environment planned by the Accreditation Council for Graduate Medical Education. A secondary objective was to estimate the net costs at major teaching hospitals, that is, costs incurred after accounting for any savings that might occur through reductions in preventable adverse events (injuries due to medical errors).

To estimate the direct costs of the planned changes, we first reviewed recent literature pertaining to duty hours. Next, we examined the ACGME's revised Common Program Requirements and selected requirements for inclusion in the cost analysis, based on 2 criteria: (1) the requirement appears to differ from practices in most residency programs today and (2) the requirement would generate quantifiable costs. The planned changes that met these criteria included a maximum shift duration of 16 hours for PGY-1 residents, a maximum shift duration of 28 hours for specialty and subspecialty residents above the PGY-1 year, several requirements to educate residents and faculty members about fatigue and safety issues, the requirement for standardized procedures for handing over patient care, the requirement that programs offer sleep facilities or transportation after residents have overnight shifts, and the requirement for annual site visits by the ACGME to assess the implementation of the planned changes.

We estimated costs by determining the resources involved in adhering to each of the planned changes and then multiplying by the cost per unit of each resource. To determine the cost of the planned changes to duty hours, we considered residents' baseline working patterns, the hours of work that they would transfer to other providers after the planned changes are implemented, and the cost of the other providers per hour. In our base-case analysis, we made several important assumptions pertaining to the extended shift requirements:

- 1. PGY residents at small programs would transfer 14 or more hours of work per extended shift to a mixture of attending physicians and nurses;
- 2. PGY-1 residents at larger programs would continue to work the same number of hours as they do now through a reorganization of those hours rather than a transfer of hours to other providers;
- Specialty residents above the PGY-1 year would transfer 2 or more hours of work per extended shift to other specialty residents; and
- 4. Subspecialty residents would transfer 2 or more hours of work per extended shift to attending physicians.

These assumptions were based on how the ACGME anticipates that the reforms will be implemented. One set of sensitivity analyses examined the effect of uncertainty in model parameters. A second set of sensitivity analyses examined the effect of uncertainty in how the changes might be implemented, such as whether more residents would need to transfer work to alternative providers, or whether alternative types of substitutes might be used.

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For the cost of the planned changes to the training environment, little published literature was available. Consequently, we made assumptions about resource use in conjunction with ACGME representatives and then obtained published estimates of the cost per unit of each resource.

We found that the total direct annual cost of the planned changes (including both recurring costs and amortized start-up costs) would be \$380 766 262 nationwide (in 2008 dollars). In the sensitivity analysis reflecting uncertainty in model parameters, such as the frequency of extended shifts and the number of weeks with extended shifts, total direct annual costs ranged from \$226 463 205 to \$694 274 461.

Uncertainty in how the reforms may be implemented had a much greater effect on the cost estimates. If all PGY-1 residents transferred work to a mixture of attending physicians and nurses, the cost would reach \$1187014278. If only PGY-1 residents at small programs transfer work, but all other work beyond the current extended shift limits is transferred to substitute providers, the cost would be \$817 388 224 when using all attending physicians; \$561 769 401 when using all midlevel practitioners; and \$335141689 to \$739 503 992 when using an expanded population of residents (depending on whether the cost of hiring additional residents is based on wages and benefits or on average per resident expenditures on graduate medical education from all sources, respectively). The efficiency of the substitutes relative to the residents whose work they are assuming is another factor that could affect the cost.

To estimate net costs at major teaching hospitals (defined as members of the Council of Teaching Hospitals), we developed a probability model representing direct costs as well as costs associated with preventable adverse events. The model simulated hypothetic changes in preventable adverse events, ranging from a 10%

increase to a 10% decrease. We considered this range because reductions in fatigue, improved handover procedures, and other changes could reduce preventable adverse events, but the effect of the planned changes on preventable adverse events is not yet known and, if discontinuities of care rise, preventable adverse events might also. Two different versions of the model represented the hospital and societal perspectives; the teaching-hospital version included event costs that are absorbed by hospitals, whereas the societal version included all preventable adverse event costs. Both versions included the portion of the total direct annual costs associated with residents' training at major teaching hospitals (members of the Council of Teaching Hospitals). We found that, under the base-case analysis assumptions pertaining to direct annual costs, the revised policy would be cost saving for society if it reduced preventable adverse events by 2.4%, and costsaving for major teaching hospitals if it reduced preventable adverse events by 10.9%. If the direct annual costs are higher, greater reductions in preventable adverse events would be required for the change to be cost saving from both the majorteaching-hospital and societal perspectives.

This analysis has several limitations, including the fact that data on the baseline working patterns of residents are somewhat sparse and data relevant to the resources and costs associated with the planned changes to the training environment are minimal. Our methods of estimating costs may yield different results from the expenditures that programs ultimately incur when hiring other providers or additional residents because programs may implement the changes in a manner that differs from what the ACGME anticipates. However, we addressed limitations to available data through the use of numerous sensitivity analyses, which offer insight into the effect of model parameters on the direct annual costs.

### APPENDIX B SYSTEMATIC REVIEW OF THE LITERATURE: Resident Duty Hours and Related Topics

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### **Executive Summary**

In 2003, the Accreditation Council for Graduate Medical Education mandated duty hour restrictions, with a goal to reduce resident sleep loss and fatigue and improve patient safety.<sup>1</sup> This decision was fueled in part by public concerns that physicians-in-training are overworked and that the resulting fatigue contributes to medical errors. Research from the sleep community, which demonstrates that sleep deprivation impairs performance, also raised concerns. With little data to guide these decisions, the shift limits were largely based on New York State's experiments with duty hour regulations, which began in 1998 and limited hours to 80 per week. The New York State code 405 regulations were a result of the examination of graduate medical education by the Bell Commission<sup>2</sup> in the wake of Libby Zion's death and were based on the best opinions of experts, but not on strict science.

Since 2003, several articles examining the effects of the ACGME duty hour regulations on a variety of relevant outcomes (including patient safety, resident education and well-being, and working conditions) have been published.<sup>3,4</sup> In addition, research studies examining sleep deprivation and neurocognitive outcomes in physicians and nonphysicians have been reviewed.<sup>5</sup> Systematic examination of this literature is of utmost importance 5 years after the implementation of duty hour reform owing to the recent recommendations for further restrictions in duty hours put forth in December

2008 in the Institute of Medicine's report on duty hours, supervision, and patient safety.<sup>6</sup> The ACGME has launched a formal process to refine and revise duty hours. Reviewing the literature and the strength of the evidence is a critical first step in designing evidence-based policy changes to the current proposed rules.<sup>7</sup> Specific attention to field studies examining the impact of duty hour reductions, and related interventions, among residents in actual practice are particularly relevant, given the concerns regarding implementation of the Institute of Medicine recommendations.<sup>8</sup> Reviewing the evidence is also important to inform the current debate and to highlight gaps in the literature from which to direct the design and conduct of future studies in this area.

In response to the request for proposals from the ACGME for thorough reviews of the literature relevant to a broad array of topics in graduate medical education during the past 20 years, our aims were to perform a systematic review to investigate the effect of the 2003 resident duty hours on resident education and well-being and on patient care (see FIGURE 1). In addition, the body of literature of the past 20 years was reviewed to understand the impact of various staffing and scheduling models, such as appropriate shift length, implementation of night float, and moonlighting. Lastly, stand-alone reviews on supervision and workload, although not specifically related to duty hours, were performed because of their central role in the resident work environment.

It is important to note that certain types of literature were not considered the focus of this review. Specifically, this review does not cover sleep literature that focuses on neurocognitive outcomes or the myriad studies that assesses the generic topic of "learning environment." While important to consider in the debate on residency duty hours, sleep deprivation and

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2. Workload (including scope of work, etc)

FIGURE 1

SCOPE OF THE SYSTEMATIC REVIEW

neurocognitive outcomes in residents have been covered in a prior review.<sup>5</sup> Owing to the expansive nature of the learning environment, which includes topics such as curricular evaluation, professionalism, and burnout to name a few, we restricted the focus of this review to studies of learning environment that relate to duty hour restrictions directly or through our focus areas (ie, workload, supervision). In addition, literature that evaluated the impact of duty hour restrictions before 2003 were covered in prior systematic reviews<sup>3,4</sup> and was not repeated in our review. Finally, our focus was predominantly limited to studies that took place in the United States. While our initial search strategy did not eliminate articles from other countries, the uniqueness of the US medical system/graduate medical education system convinced us to narrow our scope. Synthesizing the volume of data that exists for studies done in the United States was daunting, but including the rest of the world's experience would have been nearly impossible.

A comprehensive search strategy was developed in consultation with a reference librarian to ensure capture of the target literature. Using this search strategy, MEDLINE, PreMEDLINE, and Embase were searched with a focus on studies relating to graduate medical education. Abstracts were reviewed by the 3 investigators (see FIGURE 2). Articles were excluded if they did not describe original research or if they did not address one of the topics in the review. For those articles that were included in this review, data were abstracted into a structured data abstraction tool in a database called Research Electronic Data Capture (REDCap), which is a secure Internet-based program that allows multiple users at different sites to access it at any time. It is maintained by the Medical College of Wisconsin's Clinical Translational Science Institute.<sup>9</sup>

To assess study quality, the Medical Education Research Quality Index (MERSQI) was used. The MERSQI, developed by Reed and colleagues,<sup>10,11</sup> has been shown to have content validity; interrater, intrarater, and internal consistency reliability; criterion validity; and predictive validity. The MERQSI evaluates 6 domains of study quality: design, sampling, type of data, validity, data analysis, and outcomes. Items are scored on an ordinal scale with a maximum of 18 allowable points. Another major advantage of the MERSQI is that it is easily applied to any medical education study, regardless of design, method, or outcome. Previous work by Reed et al<sup>11</sup> has demonstrated that a MERSQI score of 9.95 is average for medical education research studies overall.

The article reflects the major areas of work from this systematic review that are relevant to the current debate on resident duty hours, specifically addressing questions surrounding the impact of the current ACGME duty hour rules, the optimal shift length, what is known about night float systems, workload, supervision, and moonlighting. The areas of the report are as follows:

- Review of studies examining the impact of the 2003 ACGME duty hour rules on resident health, education (ie, test scores, operative experience), and patient safety;
- Review of studies examining the impact of consecutive work hours (shift length) on resident or patient outcomes;
- Review of studies examining the impact of night float/night work on resident or patient outcomes;



- Review of studies examining the type of work residents do, in addition to the impact of resident workload on resident and patient outcomes, and interventions that have been tested to reduce workload;
- 5. Review of studies related to moonlighting; and
- 6. Review of studies related to supervision.

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### APPENDIX C SYSTEMATIC REVIEW OF THE LITERATURE ON THE IMPACT OF VARIATION IN RESIDENTS' DUTY HOUR SCHEDULES ON PATIENT SAFETY

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### **Executive Summary**

The review was conducted by a multidisciplinary group of 7 physicians (internal medicine, pediatrics, and surgery) and 3 nonphysicians. No member of the review group was affiliated with the Accreditation Council for Graduate Medical Education. The review focuses on duty hours and patient safety.

### Important Concepts Identified in Previous Reviews

Veasey et al (2002) Literature Review

- Ascertain the impact of both acute and chronic sleep deprivation in any scheduling intervention or experiment.
- Evaluate interventions for control of additional factors, including circadian nadir, stimulant intake, and ambient conditions in testing environment.
- Napping and occasional low-dose caffeine may provide safe countermeasures for prolonged shifts.

### Fletcher et al (2005) Systematic Review

 Noted variability in interventions, even within the same category (ie, differing models of "night float" rotations between programs).

- Most studies analyzed did not adjust for differences outside of duty hour interventions, raising concern for unmeasured confounding.
- Different staffing models had different effects on patient continuity.

# Philibert (2005) Meta-analysis of Sleep Loss and Performance

- Reduction in cognitive performance of approximately 1 standard deviation in subjects with sleep loss.
- The effect of sleep loss appeared to be greater in nonphysicians.
- Model proposed suggested that detrimental effects of fatigue are larger for vigilance and clinical performance than memory and cognitive function.
- Incremental effect showed sleep loss greater than 54 hours as having a larger effect than sleep loss of 30 hours.

### **Research Question**

• What is known about the relationship between variation in residents' duty hour schedules and patient safety?

### Methods

The group developed the protocol in June 2009, using their prior experience with this format for conducting systematic reviews. The review included a search of OvidSP MEDLINE, PubMed, Scopus, CINAHL, ERIC, PsycINFO, Campbell Collaboration Library, and Cochrane Database of

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Systematic Reviews. One of the authors (M.G.) screened the title and abstract of citations identified in searches and classified these for further action. A total of 110 articles passed primary screening and secondary screening by a second member of the group.

### Data Extraction

Data extraction used a 3-page structured coding form. Two members of the Review Group independently read each article and completed a coding form

### Studies Included in the Analysis

A total of 48 studies were included in the final analysis. The remainder was excluded for a host of reasons, including the following:

- Twenty-four studies were excluded for small samples with no supporting analysis of statistical power, limited measurement of clinical outcomes or residents' performance, and data collection over a brief period.
- Twenty articles were excluded because they did not directly study duty hours and a variable related to patient safety.
- Five articles were excluded owing to the presence of confounding variables.
- Thirteen articles were excluded for miscellaneous reasons.

### Study Design: Dependent Variables

The most important feature differentiating these studies was how the dependent variable was defined and selected. This process identified the following:

- Thirty-two studies that used clinical measures of patient care quality such as patient outcomes and clinical process indicators (*clinical studies*).
- Sixteen studies that examined residents' performance in laboratory settings as a proxy for safety measures using simulators or tests of cognitive and fine motor skills (laboratory studies).
- These 2 study types generally involved different units of analysis, with resulting

implications for sample size, study design, and findings.

• A consensus was reached that it would be valuable to differentiate the findings of the clinical and laboratory studies.

### Thirty-two Clinical Studies Using Direct Measures of Patient Safety

### Dependent/Outcome Variables

- Thirteen studies examined mortality and/or major indicators of morbidity.
- Seven studies analyzed mortality and morbidity and also other indicators, such as readmission, length of stay, or number of tests ordered.

### Independent Variables

- Studies assessed the conditions before and after a major system change, such as implementation of 2003 ACGME duty hour regulations.
- Others analyzed scheduling option or set of options designed to reduce sleep deprivation, as compared to some conventional schedule.

### Study Design

- More than 50% of the studies were timeseries analyses in which the authors examined measures of patient safety at different time periods.
- Another group consisted of cohort studies in which the authors tracked details of hospitalization for samples of patients as they related to the duty hour schedule in effect for these patients' physicians.

### Timing, Setting, and Duration

- The largest number of studies (21) involved data collected before and after the implementation of the 2003 ACGME duty hour regulations.
- Seven studies collected data on the effect of implementation of duty hour limits in New York State.

• Nearly all had been published since 2004.

### Sampling

- Seventeen of the clinical studies reported data from a single residency program.
- Nine were large studies based on data for national samples of patients and involving residents in 1 or more specialty, and lasting 1 year or more.
- Most studies involved sample sizes of 30 to 100.

### Sixteen Laboratory Studies of Proxy Measures of Resident Performance

Dependent/Outcome Variables

- More than three-fourths of these studies analyzed measures of cognitive and fine motor skills.
- Only 3 studies involved resident performance in clinical simulations. The 3 studies with clinical simulations used 1 device, the minimally invasive surgery trainer (MIST-VR).

### Independent Variables

• Sleep status defined either by self-report or before and after a scheduled overnight call.

### Study Design

• Three-fourths were cross-over studies in which authors measured residents rotating under different schedules.

### Timing, Setting, and Duration

- More than three-fourths involved data collected before the 2003 ACGME duty hour restrictions.
- The median year of publication (2002) was earlier (P < .01) than that for the clinical studies (2006).
- Nearly all studies were based on data from a single residency program.

• Most of these studies lasted less than 1 year.

### Sampling

- Fourteen of 16 studies reported data from a single residency program.
- The median number of residents studied was 30.

### Effect of Duty Hour Schedules on Patient Safety

- Most of the 48 studies reported either a positive effect (27) or no clear effect (17) of duty hour limits on patient safety.
- Only 4 studies reported negative effects.
- Of the clinical studies, approximately onethird reported positive effects.
- Positive effects were more likely found in smaller studies in narrow, tightly controlled settings, or limited measurements of patient safety. The median number of subjects in studies demonstrating positive effects was 11 402.
- Sixteen studies reported no effect or mixed effects of duty hour limits on patient care. The median number of subjects in these studies was more than 4 million patients.
- Four clinical studies concluded that limits on duty hours have had a negative impact on patient safety.
- There were no reports of negative effects among laboratory studies, and nearly all of the laboratory studies (94%) reported positive effects of duty hour limits on patient safety.

### Comments

- There is little evidence in the literature indicating that duty hour restrictions have compromised patient safety.
- There is a significant contribution to the overall pattern of positive results by the laboratory studies.
- If the laboratory studies are removed from the review, the trend is changed from one of

significantly positive results to one where mixed or neutral results predominate.

- There are 2 potentially offsetting weaknesses of the laboratory designs:
  - The question surrounding the acceptability of the proxies that authors have substituted for patient care outcomes;
  - The evidence they produce can only lead to inferential, rather than deductive, decisions about how their results apply to the real world of patient safety.
- The design of most of the laboratory investigations presented little support for using a blinded approach with the subjects.
- A concern raised by this review group regards the external validity of studies using cognitive and fine motor skill tests and medical simulators.
  - There are many "layers" between tasks being assayed and the final and complex process of provision of care to patients;
  - A review of this nature cannot quantify this difference, or extrapolate the meaning of such data to actual patient care.
- While the strength of the clinical studies rested on the fact that they measured actual metrics of patient safety, their perspective tended to be from a "higher altitude," where many confounders common in such investigations were typically in play.
- The review group proposed potential explanations for the difference between smaller positive trials and large trials with neutral or ambiguous results. These included the fact that competing influences address the consequences of reductions in the duty hours of a particular resident, such as:
  - Decrease in continuity of care (or increase in patient ''handoffs'');
  - Increase in work intensity of residents remaining on duty.
- Studies that are sufficiently large to provide statistical power to make conclusions

about meaningful patient care events cannot prove individual compliance with the duty hour reduction under study or the actual amount of sleep obtained by the residents in the study.

- Layered supervision and increasing use of "care teams" may have adapted to and become more protective of fatigue-induced errors, as this issue has gained national prominence.
- It is difficult to isolate the individual components of the duty hour limits, and most large studies analyzed the sum of changes implemented under the standards or state regulations.
- The highest proportion of studies, where an individual component was able to be isolated, researched modifications of overnight call shift duration.

The review identified several important gaps.

- There were no studies of napping as a fatigue-mitigating process for prolonged duty periods.
- There was a lack of depth of studies involving long duty periods and probable fatigue in some specialties (obstetrics and gynecology, pediatrics).
- Few studies compared differential methods of complying with duty hour requirements.
- The timing of this review in relation to the ACGME 2003 regulations does not permit analysis of any long-term data.

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### APPENDIX D CONCEPTUAL FRAMEWORKS IN THE STUDY OF DUTY HOUR CHANGES IN GRADUATE MEDICAL EDUCATION: AN INTEGRATIVE REVIEW

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### **Executive Summary**

Resident physicians bear an enormous burden of responsibility for the nature and quality of patient care in the hospitals in which they are employed, and residency training has traditionally been a period of demanding and rigorous service. In 2003, the Accreditation Council for Graduate Medical Education instituted duty hour regulations in which residents of all specialties were limited to 80 hours per week.<sup>1</sup> In 2008, the Institute of Medicine issued a report, "Resident Duty Hours: Enhancing Sleep, Supervision, and Safety."<sup>2</sup> Despite noting a lack of empirical evidence, the report recommended additional changes to duty hour regulations, including protected sleep periods and additional time off.

In choosing which outcomes of duty hours to describe and how to study them, researchers and others advance arguments that use conceptual frameworks, which represent simplified representations of the complex relationships between duty hours and outcomes to patients, residents, faculty, institutions, and other health professionals. These frameworks may be based on theories (evidence based, explanatory, and predictive), best practices (evidence-based observations), or models (presumptive relationships).<sup>3</sup>

The goal of this study was to identify and specify the conceptual frameworks used in the development, implementation, and study of duty hour regulations in the Institute of Medicine report and publications since the report.

Articles were searched across multiple bibliographic databases in July 2009, with additional articles through September 2009 located through automated alerts. Websites and conference proceedings for organizations involved in graduate medical education in the primary care specialties were also searched. Articles were reviewed to identify outcomes of duty hour changes, and to describe and critique conceptual frameworks used explicitly or implicitly to argue for the relationship between duty hour changes and outcomes.

Frameworks identified were reviewed by the 7member project team to confirm their structure, and disagreements were resolved by discussion and consensus.

We reviewed 203 publications in full and identified 83 outcomes of duty hour changes that have been studied or discussed. Twentythree conceptual frameworks were identified and described. The frameworks vary both in their theoretic basis and the amount of empirical evidence supporting the hypothesized relationships. Many of the frameworks are in opposition, some even making directly opposite predictions about the impact of a change in duty hours on such important outcomes as patient welfare and resident quality of life. On the whole, much of the discussion, both in the IOM report and by organizations responding to it, is characterized by strongly held positions and limited evidence.

Several gaps in the literature were identified as a result of the critique of conceptual frameworks. The concept of ''duty hours'' itself is contested, and long-standing questions about

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the balance of education and service for house staff have yet to be explicitly resolved. Too little attention has been paid to the nature and intensity of the activities that occupy those hours. Reflection on the European experience with 48-hour limits has rarely been given serious attention by US authors despite considerable European work on the scientific study of fatigue and risk associated with particular shift configurations, schedules, and rotations at the ward or service level.

Most of the literature to date focuses on isolated outcomes of changes in duty hours. Few conceptual frameworks have explicitly posited tests of mediators or moderators. Another, and related, critical gap in the literature is the dearth of studies that investigate the net tradeoffs between such key outcomes as patient safety, resident safety, resident education, resource costs (to society and programs), and quality of life for resident and attending physicians; even less study has been directed to the *value* society places on such tradeoffs.

Conceptual frameworks underlie arguments made about the impact of duty hour changes and frame assumptions about research hypotheses and necessary research designs to provide evidence about the impact of changes. We encourage researchers and advocates to make their conceptual frameworks explicit and to detail their bases, workings, and implications.

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### APPENDIX E COMPARISON OF THE ACGME 2003 Standards, the Institute of Medicine Recommended Limits, and the ACGME 2011 Standards

Standard	2003 Standards	2011 Standards	IOM Recommendations
Principles and introduction	<ol> <li>Principles</li> <li>The program must be committed to and be responsible for promoting patient safety and resident well-being and to providing a supportive educational environment.</li> <li>The learning objectives of the program must not be compromised by excessive reliance on residents to fulfill service obligations.</li> <li>Didactic and clinical education must have priority in the allotment of residents' time and energy.</li> <li>Duty hour assignments must recognize that faculty and residents collectively have responsibility for the safety and welfare of patients.</li> </ol>	Introduction Residency is an essential dimension of the transformation of the medical student to the independent practitioner along the continuum of medical education. It is physically, emotionally, and intellectually demanding and requires longitudinally concentrated effort on the part of the resident. The specialty education of physicians to practice independently is experiential and necessarily occurs within the context of the health care delivery system. Developing the skills, knowledge, and attitudes leading to proficiency in all the domains of clinical competency requires that the resident physician assume personal responsibility for the care of individual patients. For the resident, the essential learning activity is interaction with patients under the guidance and supervision of faculty members who give value, context, and meaning to those interactions. As residents gain experience and demonstrate growth in their ability to care for patients, they assume roles that permit them to exercise those skills with greater independence. This concept—graded and progressive responsibility—is one of the core tenets of American graduate medical education. Supervision in the setting of graduate medical education has the goals of assuring the provision of safe and effective care to the individual patient; assuring each resident's development of the skills, knowledge, and attitudes required to enter the unsupervised practice of medicine; and establishing a foundation for continued professional growth.	
Professionalism, personal responsibility, and patient safety		<ul> <li>VI.A.1. Programs and sponsoring institutions must educate residents and faculty members concerning the professional responsibilities of physicians to appear for duty appropriately rested and fit to provide the services required by their patients.</li> <li>VI.A.2. The program must be committed to and responsible for promoting patient safety and resident well-being in a supportive educational environment.</li> <li>VI.A.3. The program director must ensure that residents are integrated and actively participate in interdisciplinary clinical quality improvement and patient safety programs.</li> <li>VI.A.4. The learning objectives of the program must: VI.A.4. a. be accomplished through an appropriate blend of supervised patient care responsibilities, clinical teaching, and didactic educational events; and, VI.A.4. The program director and institution must ensure a culture of professionalism that supports patients afety and personal responsibility. Residents and faculty members must demonstrate an understanding and acceptance of their personal role in the following:</li> </ul>	
## The ACGME 2011 Duty Hour Standards

T A B L E CO	TABLE <b>CONTINUED</b>		
Standard	2003 Standards	2011 Standards	IOM Recommendations
		VI.A.5.a. assurance of the safety and welfare of patients entrusted to their care; VI.A.5.b. provision of patient- and family-centered care; VI.A.5.c. assurance of their fitness for duty; VI.A.5.d. management of their time before, during, and after clinical assignments; VI.A.5.e. recognition of impairment, including illness and fatigue, in themselves and in their peers; VI.A.5.f. attention to lifelong learning; VI.A.5.g. the monitoring of their patient care performance improvement indicators; and, VI.A.5.h. honest and accurate reporting of duty hours, patient outcomes, and clinical experience data. VI.A.6. All residents and faculty members must demonstrate responsiveness to patient needs that supersedes self-interest. Physicians must recognize that under certain circumstances, the best interests of the patient may be served by transitioning that patient's care to another qualified and rested provider.	
Transitions of care		<ul> <li>VI.B.1. Programs must design clinical assignments to minimize the number of transitions in patient care.</li> <li>VI.B.2. Sponsoring institutions and programs must ensure and monitor effective, structured handover processes to facilitate both continuity of care and patient safety.</li> <li>VI.B.3. Programs must ensure that residents are competent in communicating with team members in the handover process.</li> <li>VI.B.4. The sponsoring institution must ensure the availability of schedules that inform all members of the health care team of attending physicians and residents currently responsible for each patient's care.</li> </ul>	Teaching hospitals should design, implement, and institutionalize structured handover processes to ensure the continuity of care and patient safety. Programs should train residents and teams in effective communication and handover processes. Programs should schedule an overlap in time for transitioning on and off duty. The process should include a system that quickly provides staff and patients with the name of the resident currently responsible, in addition to the name of the attending physician.
Alertness management/ fatigue mitigation	Faculty and residents must be educated to recognize the signs of fatigue and sleep deprivation and must adopt and apply policies to prevent and counteract their potential negative effects on patient care and learning.	<ul> <li>VI.C.1. The program must:</li> <li>VI.C.1.a. educate all faculty members and residents to recognize the signs of fatigue and sleep deprivation;</li> <li>VI.C.1.b. educate all faculty members and residents in alertness management and fatigue mitigation processes; and,</li> <li>VI.C.1.c. adopt fatigue mitigation processes, such as naps or backup call schedules, to manage the potential negative effects of fatigue on patient care and learning.</li> <li>VI.C.2. Each program must have a process to ensure continuity of patient care in the event that a resident may be unable to perform his or her patient care duties.</li> <li>VI.C.3. The sponsoring institution must provide adequate sleep facilities and/or safe transportation options for residents who may be too fatigued to safely return home.</li> </ul>	ACGME should adopt and enforce requirements that adhere to the following principles: duty hour limits that promote prevention of sleep loss; additional measures that mitigate fatigue; and schedules that provide for predictable, protected, and sufficient uninterrupted recovery sleep to relieve acute and chronic sleep loss, promote resident well-being, and balance learning requirements. Programs should provide formal education for residents and staff on fatigue/sleep loss. Sponsoring institutions and programs should ensure that their practices promote that residents take the required sleep during extended duty periods.
Supervision of residents	The program must ensure that qualified faculty provide appropriate supervision of residents in patient care activities.	VI.D.1. In the clinical learning environment, each patient must have an identifiable, appropriately credentialed attending physician with privileges (or licensed independent practitioner as approved by each Review Committee), who is ultimately responsible for that patient's care. VI.D.1.a. This information should be available to residents, faculty members, and patients. VI.D.1.b. Residents and faculty members should inform patients of their respective roles in each patient's care.	Each RRC should establish measurable standards of supervision for each level of doctor in training, according to their specialty First-year residents should not be on duty without having immediate access to a residency program– approved supervisory physician in- house.

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Standard	2003 Standards	2011 Standards	IOM Recommendations	
		<ul> <li>VI.D.2. The program must demonstrate that the appropriate level of supervision is in place for all residents who care for patients.</li> <li>Supervision may be exercised through a variety of methods. Some activities require the physical presence of the supervising faculty member. For many aspects of patient care, the supervising physician may be a more advanced resident or fellow. Other portions of care provided by the resident can be adequately supervised by the immediate availability of the supervising faculty member or resident physician, either in the institution, or by means of telephonic and/or electronic modalities. In some circumstances, supervision may include post hoc review of resident-delivered care with feedback as to the appropriateness of that care.</li> <li>VI.D.3. Levels of supervision</li> <li>To ensure oversight of resident supervision and graded authority and responsibility, the program must use the following classification of supervision:</li> <li>VI.D.3.b. Indirect supervision:</li> <li>VI.D.3.b. Indirect supervision immediately available to provide direct supervision.</li> <li>VI.D.3.b.(1). with direct supervision available—the supervising physician is physical, or other site of patient care, and is immediately available to provide direct supervision.</li> <li>VI.D.3.b.(2). with direct supervision available—the supervising physician is available to provide direct supervision.</li> <li>VI.D.3.c. Oversight: The supervising physician is available to provide review of procedures/ encounters, with feedback provided after care is delivered.</li> <li>VI.D.4. The program director must evaluate each resident's abilities based on specific criteria. When available, evaluation should be guided by specific national standards-based criteria.</li> <li>VI.D.4. The program director must evaluate each residents abilities based on the needs of the patient care is delivered.</li> <li>VI.D.4. The program director must evaluate each residents abilities b</li></ul>		

## The ACGME 2011 Duty Hour Standards

TABLE CONTINUED			
Standard	2003 Standards	2011 Standards	IOM Recommendations
		VI.D.5.a.(1). In particular, PGY-1 residents should be supervised either directly or indirectly with direct supervision immediately available. [Each Review Committee will describe the achieved competencies under which PGY-1 residents progress to be supervised indirectly, with direct supervision available.] VI.D.6. Faculty supervision assignments should be of sufficient duration to assess the knowledge and skills of each resident and delegate to him/her the appropriate level of patient care authority and responsibility.	
Clinical responsibilities		VI.E. The clinical responsibilities for each resident must be based on PGY level, patient safety, resident education, severity and complexity of patient illness/condition, and available support services. (Optimal clinical workload will be further specified by each Review Committee.)	ACGME should require that sponsoring institutions appropriately adjust resident workload. Minimize the level of residents' work that is of limited or no educational value. Provide residents with adequate time for patient care and reflection time. ACGME should require RRCs to define and require appropriate limits on caseload, taking into consideration complexity of patient illness and level of residents' competency.
Teamwork		VI.F. Residents must care for patients in an environment that maximizes effective communication. This must include the opportunity to work as a member of effective interprofessional teams that are appropriate to the delivery of care in the specialty. (Each Review Committee will define the elements that must be present in each specialty.)	
Maximum hours of work per week	Duty hours must be limited to 80 h/ wk, averaged over a 4-week period, inclusive of all in-house call activities.	VI.G.1. Duty hours must be limited to 80 h/wk, averaged over a 4-week period, inclusive of all in- house call activities and all moonlighting.	80 h/wk, averaged over 4 weeks
Duty hour exceptions	A Review Committee may grant exceptions for up to 10%, or a maximum of 88 hours, to individual programs, based on a sound educational rationale. Before submitting the request to the Review Committee, the program director must obtain approval of the institution's GMEC and DIO.	VI.G.1.a. A Review Committee may grant exceptions for up to 10%, or a maximum of 88 hours, to individual programs, based on a sound educational rationale. VI.G.1.a.(1). In preparing a request for an exception, the program director must follow the duty hour exception policy from the "ACGME Manual on Policies and Procedures." VI.G.1.a.(2). Before submitting the request to the Review Committee, the program director must obtain approval of the institution's GMEC and DIO.	A Review Committee may grant exceptions for up to 10%, or a maximum of 88 hours, to individual programs, based on a sound educational rationale.
Moonlighting	<ol> <li>Moonlighting must not interfere with the ability of the resident to achieve the goals and objectives of the educational program.</li> <li>Internal moonlighting must be considered part of the 8o-hour weekly limit on duty hours.</li> </ol>	VI.G.2.a. Moonlighting must not interfere with the ability of the resident to achieve the goals and objectives of the educational program. VI.G.2.b. Time spent by residents in internal and external moonlighting (as defined in the ACGME "Glossary of Terms") must be counted toward the 80-hour maximum weekly hour limit. VI.G.2.c. PGY-1 residents are not permitted to moonlight.	Internal and external moonlighting count as part of the 8o-hour limit. Require sponsoring institutions to include provisions in resident contracts that residents must receive permission from the program director to moonlight, and resident performance will be monitored to ensure no adverse effects from moonlighting.

Standard	2002 Standards	2011 Standards	IOM Perommendations
Mandatory time free of duty	Residents must be provided with 1 day in 7 free from all educational and clinical responsibilities, averaged over a 4-week period, inclusive of call.	VI.G.3. Residents must be scheduled for a minimum of 1 day free of duty every week (when averaged over 4 weeks). At-home call cannot be assigned on these free days.	24 hours off per 7-day period. No averaging. One "golden weekend" per month.
Maximum duty period length	Continuous on-site duty, including in-house call, must not exceed 24 consecutive hours. Residents may remain on duty for up to 6 additional hours to participate in didactic activities, transfer care of patients, conduct outpatient clinics, and maintain continuity of medical and surgical care.	VI.G.4.a. Duty periods of PGY-1 residents must not exceed 16 hours. VI.G.4.b. Duty periods of PGY-2 residents and more senior residents may be scheduled to a maximum of 24 hours of continuous duty in the hospital. Programs must encourage residents to use alertness management strategies in the context of patient care responsibilities. Strategic napping, especially after 16 hours of continuous duty, and between the hours of 10:00 PM and 8:00 AM, is strongly suggested.	Extended duty must not exceed 16 hours, unless a 5-hour nap is provided between 10:00 PM and 8:00 AM. The 5-hour nap must be included in the 80-hour limit. After a 5-hour nap, resident may continue for up to 9 more hours for a total of 30 hours.
Maximum duty period length	No new patients may be accepted after 24 hours of continuous duty.	VI.G.4.b.(1). It is essential for patient safety and resident education that effective transitions in care occur. Residents may be allowed to remain on-site in order to accomplish these tasks; however, this period of time must be no longer than an additional 4 hours. VI.G.4.b.(2). Residents must not be assigned additional clinical responsibilities after 24 hours of continuous in-house duty. VI.G.4.b.(3). In unusual circumstances, residents, on their own initiative, may remain beyond their scheduled period of duty to continue to provide care to a single patient. Justifications for such extensions of duty are limited to reasons of required continuity for a severely ill or unstable patient, academic importance of the events transpiring, or humanistic attention to the needs of a patient or family. VI.G.4.b.(3).(a). Under those circumstances, the resident must: VI.G.4.b.(3).(a).(i). appropriately hand over the care of all other patients to the team responsible for their continuing care; and, VI.G.4.b.(3).(a).(i). document the reasons for remaining to care for the patient in question and submit that documentation in every circumstance to the program director. VI.G.4.b.(3).(b). The program director must review each submission of additional service and track both individual resident and program-wide episodes of additional duty.	No new patients after 16 hours. Extended duty (eg, 30 hours with a 5-hour nap) must not occur more frequently than every third night. No averaging.
Minimum time off between scheduled duty periods	Adequate time for rest and personal activities must be provided. This should consist of a 10-hour time period provided between all daily duty periods and after in-house call.	VI.G.5.a. PGY-1 residents should have 10 hours, and must have 8 hours, free of duty between scheduled duty periods. VI.G.5.b. Intermediate-level residents (as defined by the Review Committee) should have 10 hours free of duty, and must have 8 hours between scheduled duty periods. They must have at least 14 hours free of duty after 24 hours of in-house duty. VI.G.5.c. Residents in the final years of education (as defined by the Review Committee) must be prepared to enter the unsupervised practice of medicine and care for patients over irregular or extended periods. VI.G.5.c.(1). This preparation must occur within the context of the 80-hour maximum duty period length, and 1-day-off-in-7 standards. While it is desirable that residents in their final years of education have 8 hours free of duty between scheduled duty periods, there may be circumstances (as defined by the Review Committee) when these residents must stay on duty to care for their patients or return to the hospital with fewer than 8 hours free of duty.	Residents must have: 10 hours off after a regular daytime duty period; 12 hours off after night duty; 14 hours off after an extended duty period and not return earlier than 6 AM the next day.

The ACGME 2011 Duty	/ Hour Standards
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T A B L E CO	Continued		
Standard	2003 Standards	2011 Standards	IOM Recommendations
		VI.G.5.c.(1).(a). Circumstances of return-to- hospital activities with fewer than 8 hours away from the hospital by residents in their final years of education must be monitored by the program director.	
Maximum frequency of in- house night float		VI.G.6. Residents must not be scheduled for more than 6 consecutive nights of night float. (The maximum number of consecutive weeks of night float, and maximum number of months of night float per year, may be further specified by the Review Committee.)	Night duty must not exceed 4 consecutive nights and must be followed by a minimum of 48 continuous hours off (after 3 or 4 consecutive nights)
Maximum in- house on-call frequency	In-house call must occur no more frequently than every third night, averaged over a 4-week period.	VI.G.7. PGY-2 residents and more senior residents must be scheduled for in-house call no more frequently than every third night (when averaged over a 4-week period).	Every third night, no averaging
At-home call	<ol> <li>The frequency of at-home call is not subject to the every-third- night, or 24 + 6 limitation. However, at-home call must not be so frequent as to preclude rest and reasonable personal time for each resident.</li> <li>Residents taking at-home call must be provided with 1 day in 7 completely free from all educational and clinical responsibilities, averaged over a 4-week period.</li> <li>When residents are called into the hospital from home, the hours that residents spend in- house are counted toward the 8o-hour limit.</li> </ol>	VI.G.8.a. Time spent in the hospital by residents on at-home call must count toward the 8o-hour maximum weekly hour limit. The frequency of at- home call is not subject to the every-third-night limitation but must satisfy the requirement for 1 day in 7 free of duty, when averaged over 4 weeks. VI.G.8.a.(1). At-home call must not be so frequent or taxing as to preclude rest or reasonable personal time for each resident. VI.G.8.b. Residents are permitted to return to the hospital while on at-home call to care for new or established patients. Each episode of this type of care, while it must be included in the 8o-hour weekly maximum, will not initiate a new "off-duty period."	

Abbreviations: ACGME, Accreditation Council for Graduate Medical Education; DIO, designated institutional official; GMEC, Graduate Medical Education Committee; PGY, postgraduate year; RRC, Resident Review Committee.