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December 15, 2016

**Comments on ACGME Task Force Proposal to Revise Duty-Hour Requirements: “Section VI of the Common Program Requirements, The Learning and Working Environment (formerly, Resident Duty Hours in The Learning and Working Environment).”**

<http://www.acgme.org/What-We-Do/Accreditation/Review-and-Comment>

Lines 91-140

We broadly agree with the addition of guidelines for the reporting of adverse events and near misses. We would strongly encourage the Accreditation Council for Graduate Medical Education (ACGME) to insert additional wording on the need to train both residents and faculty in reporting adverse drug and medical device events to the Food and Drug Administration’s (FDA’s) MedWatch adverse drug and medical device reactions database.<sup>1</sup> It has been estimated that up to 90% of all adverse drug events and a large proportion of adverse medical device events go unreported to the FDA,<sup>2</sup> and it is thus essential that residents are trained in, and become accustomed to the practice of, reporting these events to the FDA once they become independent practitioners.

Lines 307-310

As with the 2011 program requirements, the current proposal continues to require programs to “educate residents and faculty members concerning the professional responsibilities of physicians, **including their obligation to be appropriately rested and fit to provide the care required by their patients.**” [Emphasis added] Requiring residents to be appropriately rested and fit is blatantly incompatible with allowing residents to work 28-hour or longer shifts without sleep every other shift and, like other provisions in the proposal, unreasonably places the burden squarely on overworked and exhausted residents to somehow remain functional enough to make critical patient decisions.

Lines 332-333, 342, and 348-350

As with the 2011 program requirements, the proposal states, “Residents and faculty members must demonstrate an understanding and acceptance of their personal role in the ... assurance of their fitness for work, including ... **recognition of impairment, including from ... fatigue ...** in themselves, their peers, and other members of the health care team.” [Emphasis added]

This proposal is nonsensical in that it assumes that only some residents would be impaired while working the 28-hour or longer shifts being proposed. In fact, all residents would suffer cognitive and motor impairment during the latter half of such shifts. Sleep deprivation studies in healthy adult subjects revealed objective impairment of working memory within 1 hour of their normal time of sleep onset<sup>3</sup> and

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<sup>1</sup> Food and Drug Administration. MedWatch: The FDA safety information and adverse event reporting program. <http://www.fda.gov/Safety/MedWatch/>. Accessed December 1, 2016.

<sup>2</sup> U.S. General Accounting Office. *Adverse Drug Events: Substantial Problem but Magnitude Uncertain*. February 1, 2000. <http://www.gao.gov/new.items/00053t.pdf>. Accessed December 1, 2016.

<sup>3</sup> Smith ME, McEvoy LK, Gevins A. The impact of moderate sleep loss on neurophysiologic signals during working-memory task performance. *Sleep*. 2002;25(7):784-794.

driving impairment after 18.5 and 21 hours without sleep that was comparable to the level of impairment seen with blood alcohol concentrations of 0.05% and 0.08%, respectively.<sup>4</sup> Likewise, sleep deprivation studies in residents have shown significant impairment in performing complex medical tasks. For example, sleep-deprived interns were significantly more likely to either miss arrhythmias or mistakenly label normal sinus rhythms as arrhythmias on electrocardiographic tasks;<sup>5</sup> surgical residents who were acutely sleep deprived after 24-hour call shifts had significantly increased technical error rates in the performance of simulated laparoscopic surgical procedures compared to rested residents.<sup>6</sup>

To require residents to not only work hours that are known to impair cognitive and motor function but, despite this, somehow recognize their impairment is implausible. As the Institute of Medicine, citing three studies, observed in its landmark 2009 report, *Resident Duty Hours: Enhancing Sleep, Supervision, and Safety*: “Although residents are at high risk for fatigue-related car crashes, they, like many other healthy but sleep-deprived adults, often fail to recognize their degree of impairment.”<sup>7</sup>

#### Lines 357-359

As with the 2011 program requirements, the proposal requires residents to accurately report their work hours. This is a laudable goal, but one that is sure to continue to be unattainable due to several obvious factors. First, to our knowledge, the ACGME does not systematically enforce its duty-hour limits. In a 2010 *New England Journal of Medicine* commentary, ACGME Chief Executive Officer (CEO) Dr. Thomas Nasca identified a then-new ACGME program of annual site visits to sponsoring institutions, focusing, in part, on duty-hour compliance.<sup>8</sup> He declared the ACGME’s intent to release to the public the reports on those visits. Six years later, to the best of our knowledge, these reports have not been made public, and the ACGME has not provided the reports in response to an inquiry from our organization earlier this year.<sup>9</sup> The ACGME’s entire “enforcement” apparatus seemingly consists solely of resident self-reports, which are rarely if ever validated objectively by their programs, are, to our knowledge, never systematically inspected by the ACGME, and often are falsified. In a national survey published in 2013, nearly half (43%) of 6,202 residents stated that they had falsely reported their duty hours at some point, including 19% who did so at least once or twice a month.<sup>10</sup>

Second, both residents and programs have every incentive not to report duty-hour violations. Residents do not want to run afoul of their programs for habitually violating the ACGME’s restrictions, nor is it in their career interest to put their programs’ accreditation status at risk. Many programs, in turn, know that, in the absence of any objective verification by ACGME of residents’ reported hours, they stand to gain nothing by proactively seeking out violations of the duty-hour program requirements.

The ACGME must devise a robust enforcement apparatus, consisting of unannounced, random inspections of programs across the country at varying intervals. These inspections must include anonymous interviews with randomly selected residents, assuring these residents that they will not face

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<sup>4</sup> Arnedt JT, Wilde GJ, Munt PW, MacLean AW. How do prolonged wakefulness and alcohol compare in the decrements they produce on a simulated driving task? *Accid Anal Prev.* 2001;33(3):337-344.

<sup>5</sup> Friedman RC, Bigger JT, Kornfeld DS. The intern and sleep loss. *N Engl J Med.* 1971;285(4):201-203.

<sup>6</sup> Eastridge BJ, Hamilton EC, O’Keefe GE, et al. Effect of sleep deprivation on the performance of simulated laparoscopic surgical skill. *Am J Surg.* 2003;186(2):169-74.

<sup>7</sup> IOM (Institute of Medicine). *Resident Duty Hours: Enhancing Sleep, Supervision, and Safety.* Washington, DC: The National Academies Press; 2009. <http://www.nap.edu/catalog/12508/resident-duty-hours-enhancing-sleep-supervision-and-safety>. Accessed December 9, 2016.

<sup>8</sup> Nasca TJ, Day SH, Amis ES, ACGME Duty Hour Task Force. The new recommendations on duty hours from the ACGME Task Force. *N Engl J Med.* 2010;363(2):e3.

<sup>9</sup> Personal communication with the ACGME, email sent on August 29, 2016.

<sup>10</sup> Drolet BC, Schwede M, Bishop KD, Fischer SA. Compliance and falsification of duty hours: Reports from residents and program directors. *J Grad Med Educ.* 2013;5(3):368-373. Survey response rate: 23% of interns.

any consequences for revealing duty-hour violations that they did not report to their programs. Only through such proactive enforcement will there be a semblance of compliance with the ACGME's duty-hour program requirements.

Lines 367-434 (Section VI.C. "Well-Being")

The proposal's new, lengthy section purporting to address resident "well-being," while laudable on its face, is obviously intended, in part, to distract from the proposal's evisceration of the limited protections on the hours that residents can work without sleep. The section opens (lines 369-372) with an accurate characterization of the mental health risks incurred by residents during their training: "In the current health care environment, residents and faculty members are at increased risk for burnout and depression. Psychological, emotional, and physical well-being are critical in the development of the competent, caring, and resilient physician." However, the section goes on to state that programs have a responsibility to give "attention to **scheduling**, work intensity, and work compression that impacts resident well-being." [Emphasis added]

The proposal thus simultaneously allows and implicitly encourages programs to require interns and other residents to work shifts of 28 hours or longer that are known to harm residents' mental and physical well-being and safety, while claiming that programs must be attentive to "scheduling" that "impacts resident well-being." The section then goes on to require programs to be proactive in identifying cases of burnout, depression, suicidal ideation, and other adverse psychological conditions in residents and to provide access to self-screening tools and mental health services. Again, such provisions are a welcome addition to the ACGME's program requirements, but their intent is completely undermined by the proposal's simultaneous weakening of the resident duty-hour limits, which would increase the number of residents suffering from the mental health conditions focused on in this section on well-being.

Lines 390-391

The proposal includes a requirement that programs evaluate "safety data" and address "the safety of residents and faculty members in the learning and working environment." The "Background and Intent" box then explains that one of the issues to be addressed is "vehicle collisions." Allowing interns to drive home after working 28 hours or longer without sleep clearly contradicts this rather vague provision regarding "the safety of residents."

A 1996 study found that 23% of pediatric residents at Johns Hopkins Hospital reported falling asleep while driving, with 71% of the incidents happening after shifts averaging 33 hours.<sup>11</sup> Forty-four percent of pediatric residents reported falling asleep while stopped at a traffic light, with all such incidents occurring post-call. One resident reported that she "routinely used her emergency brakes when stopped at a light because of her sleepiness post-call."

In a 2005 *New England Journal of Medicine* study, the Harvard Work Hours, Health, and Safety Group collected monthly data from 2,737 interns across the U.S. to investigate the relationship between hours worked and motor vehicle accidents, near misses, and incidents involving involuntary sleeping while driving.<sup>12</sup> Interns' risk of a motor vehicle crash increased more than twofold (odds ratio [OR] 2.3; 95% confidence interval [CI]: 1.6-3.3) and the risk of a near-miss driving event increased nearly sixfold (OR 5.9; 95% CI: 5.4-6.3) after shifts of 24 hours or greater compared with shifts of less than 24 hours. Interns were also significantly more likely to fall asleep while driving during months with one to four (OR 1.82;

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<sup>11</sup> Marcus CL, Loughlin GM. Effect of sleep deprivation on driving safety in housestaff. *Sleep*. 1996;19(10):763-766. Survey response rate: 87% of residents.

<sup>12</sup> Barger LK, Cade BE, Ayas NT, et al. Extended work shifts and the risk of motor vehicle crashes among interns. *N Engl J Med*. 2005;352(2):125-134. Survey response rate: 80% of interns who volunteered to participate.

95% CI: 1.73-1.93) and five or more (OR 2.39; 95% CI: 2.31-2.46) extended shifts than during months with no extended shifts. Each extra extended shift scheduled per month increased the monthly rate of any motor vehicle accident by 9.1% (95% CI: 3.4-14.7%) and increased the monthly rate of an accident on the commute from work by 16.2% (95% CI: 7.8-24.7%). The study authors concluded that “scheduling physicians to work such extended shifts, which our group has recently shown to increase the risk of failures of attention and serious medical errors, poses a serious and preventable safety hazard for them and other motorists.”

A 2006 study of 19 residents’ performance on a driving simulator found that male residents displayed greater impairment, as measured by increased lane deviations and crash frequency, after a 15-hour overnight call shift and an extra four hours of patient-care duties, compared with driving simulation testing after a night spent at home without call responsibility.<sup>13</sup> The authors concluded that “[c]ollectively, results of this study and others suggest that medical residents are at risk when driving after a night on call.”

#### Line 403

The proposal also mentions the need for attention to the widely recognized, serious problem of resident depression and suicide.<sup>14</sup>

Ironically, on December 1, 2016, the ACGME, the American Foundation for Suicide Prevention, and Mayo Clinic launched an initiative to prevent physician and medical trainee suicides.<sup>15</sup> The announcement for this initiative cited an increasing rate of fatigue as one of the factors fueling concern about physician well-being. Commenting on the initiative, ACGME CEO Nasca stated, “We want to be part of a national dialogue that addresses physician well-being and leads to transformational change — to a more humane learning environment for all medical education and a healthier culture for all physicians.” This initiative, like much of the other rhetoric on physician well-being in the proposed program requirements, seems to be a calculated attempt to **distract** from the proposed requirements’ dramatic rollback of (already insufficient) limits on residents’ duty hours. Forcing interns to work shifts of 28 hours or longer, with no minimum time off after shifts of less than 24 hours, is clearly incompatible with a “humane learning environment” and a “healthier culture,” and will only lead to increased fatigue, decreased well-being, and a greater risk of depression and suicide.

The first year of medical residency is known to be a time of high stress, and such residents are at a higher risk for major depression than the general population.<sup>16</sup> A 1991 study of 61 pediatric residents (34 first-year residents and 27 second-year residents) found that scores on mood and anxiety questionnaires were significantly worsen following a 24-hour call shift compared with those on questionnaires completed following 24 hours without a call shift.<sup>17</sup> A 1993 study found that internal medicine residents working 32-hour shifts every fourth night reported significantly higher rates of depression symptoms than those working 16-hour shifts under a night float system, as indicated on a post-shift questionnaire (although

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<sup>13</sup> Ware JC, Risser MR, Manser T, Karlson KH. Medical resident driving simulator performance following a night on call. *Behav Sleep Med*. 2006;4(1):1-12.

<sup>14</sup> Goldman ML, Shah RN, Bernstein CA. Depression and suicide among physician trainees: Recommendations for a national response. *JAMA Psychiatry*. 2015;72(5):411-412.

<sup>15</sup> American Foundation for Suicide Prevention. 3 leading health organizations aim to reduce suicides by physicians, medical trainees. December 1, 2016. <http://www.prnewswire.com/news-releases/3-leading-health-organizations-aim-to-reduce-suicides-by-physicians-medical-trainees-300371426.html>. Accessed December 2, 2016.

<sup>16</sup> Sen S, Kranzler HR, Krystal JH, et al. A prospective cohort study investigating factors associated with depression during medical internship. *Arch Gen Psychiatry*. 2010;67(6):557-565.

<sup>17</sup> Berkoff K, Rusin W. Pediatric house staff’s psychological response to call duty. *J Dev Behav Pediatr*. 1991;12(1):6-10.

scores on anxiety and hostility questionnaires did not differ between the two groups).<sup>18</sup> A 2015 systematic review found that the overall estimated prevalence of depression or depressive symptoms in resident physicians was 29% (95% CI: 25%-33%).<sup>19</sup>

A 2010 prospective cohort study administered depression questionnaires to 740 interns at 13 U.S. hospitals during the 2007-2008 and 2008-2009 academic years.<sup>20</sup> Surveys were administered at one to two months prior to beginning their first year of residency training and at months 3, 6, 9, and 12 of the first year. A total of 58% (740 of 1271) of the interns who could be contacted agreed to participate, and, of these, 88% (651 of 740) completed at least one follow-up study survey. Just 4% of interns met the criteria for major depression at the beginning of their internship, but 27% reached this threshold both at month 3 and at the end of the year. The prevalence of moderately severe depression increased from 0.7% at baseline to 7.6% by the end of the year. A greater number of hours worked was significantly associated with an increase in depressive symptoms ( $p < 0.001$ ).

A second prospective cohort study published in 2013 that used the same design and involved 1,289 interns during the 2009-2010 and 2010-2011 academic years found similar results, with all depression symptoms (as measured by the nine-item depression scale of the Patient Health Questionnaire-9), including suicidal ideation, increasing significantly during the internship year.<sup>21</sup> On average, symptoms increased by 169% over baseline.

A 2016 online survey of 1,888 medical residents conducted by Medscape found that 69% reported that they were “always, mostly, or sometimes too tired to function well owing to long shifts.”<sup>22</sup> Disturbingly, 10% of residents reported feeling depressed always or most of the time (compared with 6.7% of all U.S. adults), 33% reported depression sometimes, and 9% reported having considered suicide (compared with 2.9% of all adults 18 years and older who had completed college).<sup>23</sup>

#### Line 448

We strongly oppose the removal of language concerning napping to the section on fatigue mitigation strategies. The removal of the suggestion to nap within the text of the proposed program requirements, while at the same time permitting interns to work shifts of 28 hours or longer, is dangerously misguided. In fact, napping is now nowhere to be found in the text of the newly proposed program requirements. We note, however, that brief naps (in the likely rare instances in which the current “suggestion” to allow naps during 28-hour shifts has even been adopted) are not sufficient to mitigate the hazards of 28-hour shifts.

#### Lines 457-459

We agree with the decision to require programs to provide *both* “adequate sleep facilities and safe transportation options for residents who may be too fatigued to safely return home.” However, while the intent of the requirement is laudable, in practice, this provision, like so many others in the proposed

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<sup>18</sup> Gottlieb DJ, Peterson CA, Parenti CM, Lofgren RP. Effects of a night float system on housestaff neuropsychologic function. *J Gen Intern Med.* 1993;8(3):146-148.

<sup>19</sup> Mata DA, Ramos MA, Bansal N, et al. Prevalence of depression and depressive symptoms among resident physicians: A systematic review and meta-analysis. *JAMA.* 2015;314(22):2373-2383.

<sup>20</sup> Sen S, Kranzler HR, Krystal JH, et al. A prospective cohort study investigating factors associated with depression during medical internship. *Arch Gen Psychiatry.* 2010;67(6):557-565.

<sup>21</sup> Fried EI, Nesse RM, Zivin K, et al. Depression is more than the sum score of its parts: individual DSM symptoms have different risk factors. *Psychol Med.* 2014;44(10):2067-2076.

<sup>22</sup> Medscape. Residents Lifestyle and Happiness Report 2016. August 17, 2016.

[http://www.medscape.com/features/slideshow/residentslifestylereport2016?src=wnl\\_physrep\\_160817\\_mscpedit\\_md\\_V2&uac=126316PN&impID=1180021&faf=1#page=12](http://www.medscape.com/features/slideshow/residentslifestylereport2016?src=wnl_physrep_160817_mscpedit_md_V2&uac=126316PN&impID=1180021&faf=1#page=12). Accessed December 13, 2016. See slide 12.

<sup>23</sup> *Ibid.* See slides 5-6.

program requirements, will likely go unheeded — and unenforced — when 28-hour or longer shifts are routine. At the end of a 28-hour or longer shift, few residents would opt to spend their little time off in a hospital call room. And many residents who choose to return home after their shifts are likely highly reluctant to ask their program to repeatedly pay for transportation to and from home after every shift of longer than 16 consecutive hours (when, as described above, evidence shows that driving impairment occurs<sup>24</sup>).

Lines 504-507

The proposed program requirements' new language that “each program must ensure continuity of patient care, consistent with the program’s policy and procedures referenced in VI.C.2, **in the event that a resident may be unable to perform their patient care responsibilities due to excessive fatigue or illness**” [emphasis added] is, as with many other provisions, superficially laudable but patently unworkable. The provision raises the question: How will residents themselves or their supervisors be able to distinguish fatigued residents from those supposedly alert enough to deliver patient care? The short answer, based on evidence on sleep-deprivation-induced cognitive impairment, is that all residents are unable to adequately “perform their patient care responsibilities due to excessive fatigue” in the latter half of a 28-hour or longer shift. Yet, few, if any, will be able or willing to recognize their cognitive impairment, and, in fact, most will likely be discouraged from doing so within a residency culture that values working through fatigue for the perceived (but only perceived) good of the patient and the profession. For this reason, the provisions in the proposed requirements that purport to address fatigue mitigation are merely another diversion from the overarching thread of the proposal: to force interns and residents to work longer hours without sleep.

Lines 516-521

This comment does not concern the text of the proposed section VI.F.1., but rather addresses the Background and Intent explanatory language. The ACGME states that its “Review Committees will strictly monitor and enforce compliance with the 80-hour requirement. Where violations of the 80-hour requirement are identified, programs will be subject to citation and at risk for adverse accreditation action.” As indicated in the comment to lines 347-359, the ACGME does not systematically enforce its own work-hour program requirements, which contradicts its claim that it will “strictly monitor and enforce” its new duty-hour limits. Furthermore, the proposal makes no mention of any enforcement plan and whether it would include objective validation of residents’ self-reported work-hour logs. Such validation is necessary for effective oversight.

Lines 568-571

The removal of the 16-consecutive-hour limit on interns’ shifts, allowing them to work the 28-hour or longer shifts to which upper-level residents have long been subjected, would be a dangerous setback for the safety of both interns and their patients. What follows is a review of the peer-reviewed literature on the harmful effects of shifts longer than 16 consecutive hours on both resident and patient safety outcomes. The section concludes with a reminder that 16-hour shifts are feasible and, in fact, already implemented (for much, if not most, of every academic year) in the vast majority of internal medicine and general surgery residency programs across the country through night float systems.

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<sup>24</sup> Arnedt JT, Wilde GJ, Munt PW, MacLean AW. How do prolonged wakefulness and alcohol compare in the decrements they produce on a simulated driving task? *Accid Anal Prev.* 2001;33(3):337-44.

## Risks to Residents of Long Shifts

There is a substantial body of evidence that an increased duration of duty shifts and the resulting sleep deprivation pose significant risks to medical residents' health and well-being. Three serious outcomes have been studied extensively: motor vehicle accidents, percutaneous injuries and exposure to bloodborne pathogens, and depression. The evidence on motor vehicle accidents and depression associated with long work shifts is presented above in the comments on lines 390-391 and line 403, respectively.

Regarding percutaneous injuries and exposure to bloodborne pathogens, a 2000 retrospective review analyzed 745 accidental exposures (involving both percutaneous injuries and superficial skin or mucous membrane contact from splashes) to bloodborne pathogens reported by residents and medical students while on duty.<sup>25</sup> The rate of such incidents was 50% higher during night shifts than during day shifts ( $p < 0.04$ ), and first- and second-year residents reported considerably more such incidents than more-senior residents. The authors concluded, "Presumably, the fatigue of the 24h-36h work schedules with little or no sleep for on-call medical students and residents plus circadian rhythms in human cognitive performance and eye-hand coordination contribute to the observed day-night pattern in accidental exposures to bloodborne pathogens described herein."

In addition, a 2006 prospective cohort study analyzed reported percutaneous injuries in 2,737 interns from July 2002 through June 2003.<sup>26</sup> Interns most commonly reported lapses in concentration (64% of injuries) and fatigue (31%) as contributing factors for the injuries. Injuries were significantly more likely to occur during extended shifts than non-extended shifts (OR 1.61; 95% CI: 1.46-1.78). Injuries following extended shifts occurred after an average of 29 consecutive hours of work, while those occurring on days not preceded by an overnight shift occurred after an average of six hours of consecutive work. The authors concluded, "The association of these injuries with extended work duration is likely due to the adverse cognitive effects of the sleep deprivation associated with such extended work."

## Risks to Patients of Long Shifts

### *Medical Errors During Shifts Greater Than 16 Hours*

The long shifts that second-year-and-above residents are allowed to work also put their patients in danger. A number of studies have confirmed that tired residents make more medical errors the longer they go without sleep, which can lead to patient injury and death.

The Intern Sleep and Patient Safety Study, published in 2004 by experts in patient safety and sleep medicine at Harvard, remains the most rigorous study of the effects of different resident shift lengths on the rate of medical errors.<sup>27</sup> Over the course of the 2002-2003 academic year, the authors randomized interns working in intensive care units to one of two arms: a) maximum workweeks of 60-63 hours, with maximum shift lengths of 16 consecutive hours; or b) average workweeks of 77-81 hours, with shifts of up to 34 consecutive hours. The study included 634 admissions and 2,203 patient-days. Interns working shifts of 24 hours or longer made 36% more serious medical errors, including 21% more serious medication errors and 460% more serious diagnostic errors, than interns working shifts of 16 hours or less.

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<sup>25</sup> Parks DK, Yetman RJ, McNeese MC, et al. Day-night pattern in accidental exposures to blood-borne pathogens among medical students and residents. *Chronobiol Int.* 2000;17(1):61-70.

<sup>26</sup> Ayas NT, Barger LK, Cade BE, et al. Extended work duration and the risk of self-reported percutaneous injuries in interns. *JAMA.* 2006;296(9):1055-1062.

<sup>27</sup> Landrigan CP, Rothschild CM, Cronin JW, et al. Effect of reducing interns' work hours on serious medical errors in intensive care units. *N Engl J Med.* 2004;351(18): 1838-1848.

In 2010, Reed et al. published a systematic review of all studies published up to May 2010 that examined the association between shift length and patient health, among other outcomes.<sup>28</sup> The review found that, of the six studies evaluating the relationship between shift length and medical errors, all showed statistically significant decreases in error rates with shorter shifts. The Intern Sleep and Patient Safety Study was the only randomized trial and therefore deemed the highest-quality study. Of the other five studies, one showed a decreased rate of potentially serious medication errors by residents working 16-hour shifts (plus two additional hours after the shift ends to finish work) once per week compared with those working 32-hour shifts every fourth (interns) or eighth (second-year-and-above residents) day.<sup>29</sup> A national survey study found that interns who worked from one to four extended-duration shifts of 24 hours or longer within a one-month period were 3.5 (95% CI: 3.3-3.7) times more likely to report at least one significant medical error due to fatigue compared to interns who did not work such long shifts, and residents working five or more extended-duration shifts in a month were 7.5 (95% CI: 7.2-7.8) times more likely to do so.<sup>30</sup>

### *Post-2011 Studies and the FIRST Trial's Methodological Flaws*

An updated systematic review of the effect of duty-hour restrictions on patient safety, resident well-being, and resident education, published in 2015 by Bolster et al., claimed that the 2011 duty-hour reforms had no significant impact on patient outcomes.<sup>31</sup> The review encompassed 27 studies published since the cutoff date for the 2010 Reed et al. review. Seven new studies on shortened shift duration and patient outcomes were analyzed; three were deemed by the authors of the systematic review to show a positive effect,<sup>32,33,34</sup> one a negative effect,<sup>35</sup> and three no effect.<sup>36,37,38</sup> The studies were of varying quality and design, and none were prospective, randomized trials. Two studies involved focus groups or surveys that did not directly measure patient outcomes.<sup>39,40</sup>

<sup>28</sup> Reed DA, Fletcher KE, Arora VM. Systematic review: Association of shift length, protected sleep time, and night float with patient care, residents' health, and education. *Ann Intern Med.* 2010;153(12):829-842.

<sup>29</sup> *Ibid.* Citing: Gottlieb DJ, Parenti CM, Peterson CA, Lofgren RP. Effect of a change in house staff work schedule on resource utilization and patient care. *Arch Intern Med.* 1991;151(10):2065-2070.

<sup>30</sup> *Ibid.* Citing: Barger LK, Ayas NT, Cade BE, et al. Impact of extended-duration shifts on medical errors, adverse events, and attentional failures. *PLoS Med.* 2006;3(12):e487.

<sup>31</sup> Bolster L, Rourke L. The effect of restricting residents' duty hours on patient safety, resident well-being, and resident education: An updated systematic review. *J Grad Med Educ.* 2015;7(3):349-363.

<sup>32</sup> Emler LL, Al-Khafaji A, Kim YH, et al. Trial of shift scheduling with standardized sign-out to improve continuity of care in intensive care units. *Crit Care Med.* 2012;40(12):3129-3134. Note that this study was of fellows, not residents.

<sup>33</sup> Rosenbluth G, Fiore DM, Maselli JH, et al. Association between adaptations to ACGME duty hour requirements, length of stay, and costs. *Sleep.* 2013;36(2):245-248.

<sup>34</sup> Stroud L, Oulanova O, Szecket N, Ginsburg S. "The benefits make up for whatever is lost": Altruism and accountability in a new call system. *Acad Med.* 2012;87(10):1421-1427.

<sup>35</sup> Sen S, Kranzler HR, Didwania AK, et al. Effects of the 2011 duty hour reforms on interns and their patients: A prospective longitudinal cohort study. *JAMA Intern Med.* 2013;173(8):657-662.

<sup>36</sup> Choma NN, Vasilevskis EE, Sponsler KC, et al. Effect of the ACGME 16-hour rule on efficiency and quality of care: Duty hours 2.0. *JAMA Intern Med.* 2013;173(9):819-821.

<sup>37</sup> Yaghoubian A, Kaji AH, Ishaque B, et al. Acute care surgery performed by sleep deprived residents: Are outcomes affected? *J Surg Res.* 2010;163(2):192-196.

<sup>38</sup> Yaghoubian A, Kaji AH, Putnam B, de Virgilio C. Trauma surgery performed by "sleep deprived" residents: Are outcomes affected? *J Surg Educ.* 2010;67(6):449-451.

<sup>39</sup> Stroud L, Oulanova O, Szecket N, Ginsburg S. "The benefits make up for whatever is lost": Altruism and accountability in a new call system. *Acad Med.* 2012;87(10):1421-1427.

<sup>40</sup> Sen S, Kranzler HR, Didwania AK, et al. Effects of the 2011 duty hour reforms on interns and their patients: A prospective longitudinal cohort study. *JAMA Intern Med.* 2013;173(8):657-662. Survey response rate: 58% of interns.

The largest study by far included in the Bolster et al. review that attempted to examine the effect of resident shift length on patient outcomes was published in 2013.<sup>41</sup> Cohorts of interns in 51 residency training programs were surveyed in 2009 (714 interns), 2010 (772 interns), and 2011 (837 interns). The interns were asked in quarterly surveys, among other questions, whether they were concerned that they made any major medical errors in the preceding three months. Significantly more interns in the 2011 cohort — the first group subject to the ACGME's 16-hour shift limit — reported concerns about making major medical errors than interns in the combined 2009-2010 cohort (23.3% vs. 19.9%;  $p = 0.007$ ). However, the study had several weaknesses. First, there was no objective assessment of actual medical errors. Second, self-reports by interns of concern about making medical errors may have been biased by the fact that most residency program directors had opposed the ACGME's 16-hour shift cap for interns, both before<sup>42</sup> and after<sup>43</sup> implementation, a view that filtered down to, and was shared by, nearly half of residents in a 2012 national survey.<sup>44</sup> Finally, the study was restricted to just the first year of the new 2011 duty-hour limits, possibly before many programs had adjusted adequately to the new program requirements by, among other measures, reducing interns' workload to accommodate the shortened 16-hour shift. The study authors alluded to the lack of such adjustment as a possible reason for the finding of increased concern about medical errors.

The central flaw in the seven studies included in the Bolster et al. 2015 systematic review that examined the effect of resident shift length on patient outcomes is that none used objective patient outcome measures specific to the residents working varying shift lengths, such as medical errors committed by the residents.

A 2014 systematic review of the effect of 16-hour shifts for surgery residents included just one study that assessed the impact of such shifts on objective patient measures.<sup>45</sup> The 2013 randomized, crossover trial compared the effects of assigning interns on general internal medicine teams at a single university hospital to either 16-hour or 30-hour shifts on length of stay and 30-day readmissions.<sup>46</sup> Shift length was not associated with a significant effect on either outcome. However, the study was not adequately powered to assess such outcomes, with just 834 hospital admissions.<sup>47</sup> Nor did it utilize an objective, rigorous procedure for detecting medical errors, as was used in the Intern Sleep and Patient Safety Study, further diminishing its ability to detect any actual change.

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<sup>41</sup> *Ibid.*

<sup>42</sup> Antiel RM, Thompson SM, Reed DA, et al. ACGME duty-hour recommendations — a national survey of residency program directors. *N Engl J Med.* 2010;363(8):e12.

<sup>43</sup> Drolet BC, Khokhar MT, Fischer SA. The 2011 duty-hour requirements — a survey of residency program directors. *N Engl J Med.* 2013;368(8):694-697.

<sup>44</sup> Drolet BC, Christopher DA, Fischer SA. Residents' response to duty-hour regulations—a follow-up national survey. *N Engl J Med.* 2012;366(24):e35.

<sup>45</sup> Ahmed N, Devitt KS, Keshet I, et al. A systematic review of the effects of resident duty hour restrictions in surgery: Impact on resident wellness, training, and patient outcomes. *Ann Surg.* 2014;259(6):1041-1053.

<sup>46</sup> Desai SV, Feldman L, Brown L, et al. Effect of the 2011 vs 2003 duty hour regulation-compliant models on sleep duration, trainee education, and continuity of patient care among internal medicine house staff: A randomized trial. *JAMA Intern Med.* 2013;173(8):649-655.

<sup>47</sup> By way of reference, the 2004 Intern Sleep and Patient Safety Study (Landrigan et al.), detailed above, did not find a significant difference in patient outcomes (serious adverse events, patient length of stay, or overall mortality) in 634 admissions between intern shifts of 16 hours or less and shifts of up to 34 consecutive hours, despite a significantly increased rate of serious medical errors. This demonstrates that the number of admissions necessary to detect an effect of serious medical errors by residents (which, as demonstrated by Landrigan et al., increase with increased shift length) on patient outcomes is likely far higher than the number included in either the 2004 (Landrigan et al.) or 2013 (Desai et al.) randomized trials. Citation for 2004 study: Landrigan CP, Rothschild CM, Cronin JW, et al. Effect of reducing interns' work hours on serious medical errors in intensive care units. *N Engl J Med.* 2004;351(18): 1838-1848.

A 2014 observational study found that, compared with the two years (2009-2011) prior to implementation of the 2011 ACGME resident duty-hour restrictions, there was no increase in patient mortality or serious morbidity during the two years after the program requirements took effect (2011-2013) among more than 204,000 surgical patients in 54 hospitals.<sup>48</sup> In addition, the concern raised by some residency directors in 2011<sup>49</sup> that duty-hour limits could lead to less knowledgeable residents was countered by the study's finding that resident examination performance did not decrease following implementation of the duty-hour restrictions.<sup>50</sup>

Since 2015, two randomized, controlled trials have attempted to assess the effect of resident shift lengths on medical errors and patient outcomes. In 2015, Parshuram et al. published a randomized, controlled trial that assessed the effects of three different resident work schedules on adverse events, medical errors, and other patient outcomes at two academic medical-surgical intensive-care units in Toronto.<sup>51</sup> Blocks of residents were randomly assigned to schedules with 12-hour, 16-hour, or 24-hour maximum shift durations and included 807 patients and 971 admissions, totaling 5,894 patient-days. The study found no significant differences in the rates of adverse events, preventable adverse events, medical errors, mortality, or other patient outcomes among the three work schedules.

However, this study had three critical flaws. First, the authors did not monitor whether residents were compliant with the shift limits to which they had been assigned. Second, the study did not directly monitor individual residents to see whether they made serious medical errors, nor were adverse events attributed to individual residents. This likely diluted out any differences among the three groups in the rates of adverse events or medical errors directly resulting from the residents' different work schedules. Third, the authors identified only eight preventable adverse events during 971 patient admissions (1.4 per 1,000 patient-days), which is a small fraction of what would be expected, indicating that the study lacked adequate procedures for detecting such events. By way of comparison, the Intern Sleep and Patient Safety Study, which did use rigorous procedures for detecting preventable adverse events, found 39 such events per 1,000 patient-days.<sup>52</sup>

In contrast to the Parshuram et al. trial, the Intern Sleep and Patient Safety Study<sup>53</sup> monitored residents' compliance with the assigned shift limits through daily sleep logs, validated by third-party observers.<sup>54</sup> Furthermore, interns were directly observed by a physician "continuously, day and night" to detect serious medical errors that they made. This ensured that the study was measuring the direct effects of sleep deprivation in individual interns on patient care.

The FIRST trial, published in 2016, is the latest study to claim that a 16-hour limit on interns' work shifts has no impact on patient outcomes.<sup>55</sup> The trial found no significant difference in the rate of death or serious complications between patients cared for by residents randomized to the ACGME's 2011 duty-

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<sup>48</sup> Rajaram R, Chung JW, Jones AT, et al. Association of the 2011 ACGME resident duty hour reform with general surgery patient outcomes and with resident examination performance. *JAMA*. 2014; 312(22): 2374-2384.

<sup>49</sup> Antiel RM, Thompson SM, Hafferty FW, et al. Duty hour recommendations and implications for meeting the ACGME core competencies: Views of residency directors. *Mayo Clin Proc*. 2011;86(3):185-191.

<sup>50</sup> Rajaram R, Chung JW, Jones AT, et al. Association of the 2011 ACGME resident duty hour reform with general surgery patient outcomes and with resident examination performance. *JAMA* 2014; 312(22): 2374-2384.

<sup>51</sup> Parshuram CS, Amaral AC, Ferguson ND, et al. Patient safety, resident well-being and continuity of care with different resident duty schedules in the intensive care unit: A randomized trial. *CMAJ*. 2015;187(5):321-329.

<sup>52</sup> *Ibid*.

<sup>53</sup> Landrigan CP, Rothschild CM, Cronin JW, et al. Effect of reducing interns' work hours on serious medical errors in intensive care units. *N Engl J Med*. 2004;351(18): 1838-1848.

<sup>54</sup> Lockley SW, Cronin JW, Evans EE, et al. Effect of reducing interns' weekly work hours on sleep and attentional failures. *N Engl J Med*. 2004;351(18):1829-37.

<sup>55</sup> Bilimoria KY, Chung JW, Hedges LV, et al. National cluster-randomized trial of duty-hour flexibility in surgical training. *N Engl J Med*. 2016;374(8):713-727.

hour restrictions and residents assigned to a “flexible” duty-hour schedule that did away with caps on shift duration. We have previously detailed the serious flaws in the trial’s design that undermine its findings and conclusions,<sup>56</sup> but briefly summarize them here:

- The following factors resulted in a minimization of differences between the control and experimental arms of the FIRST trial, making it unlikely that any significant differences in the measured patient outcomes would be detected:
  - The trial assessed patient outcomes related to the care received by the entire patient care team, even though interns were the only members of the typically sizable team in whom there was any substantial difference in work schedules between the two groups;
  - General surgery interns are almost never the primary surgeons in the operating room, spend the least amount of time in the operating room compared to other residents, and never operate unsupervised; and
  - Experimental-arm programs were not required to implement all of the permitted changes from the 2011 program requirements.
- No intern-specific patient health care outcomes — most importantly, medical errors made by interns — were measured in the trial.

Thus, there has yet to be a post-2011 study as rigorous as the 2004 Intern Sleep and Patient Safety Study that assessed the effect of the reduced, 16-hour shifts on *resident-specific* patient outcomes. In the absence of such new data, the pre-2011 evidence of the deleterious effects of sleep deprivation resulting from shifts of longer than 16 hours on serious medical errors still stands as dispositive.

### **Night Float and the Feasibility of a 16-Hour Shift Limit for All Residents**

Arguments against a 16-hour shift limit for residents on grounds of feasibility are belied by the reality that numerous residency programs across the country already have implemented night float systems, in which residents work day shifts and go home at night, to be replaced by other residents who work only at night, usually for a few weeks at a time. Under such a system, residents work shifts lasting 16 hours or less (often as short as 12 hours) for much of each training year. According to the American Medical Association, 391 (90.7%) of the 431 ACGME-accredited internal medicine residency programs and 219 (83.9%) of the 261 ACGME-accredited general surgery residency programs already have a night float system.<sup>57</sup> Furthermore, in some programs, such schedules have been instituted for upper-level residents.<sup>58</sup>

#### Lines 580-584

The removal of the “strongly suggested” strategic nap after 16 consecutive hours of duty is yet another example of the task force’s rollback of even the most basic resident and patient safety provisions in the 2011 program requirements. As demonstrated by the evidence presented above, effectively encouraging residents to stay awake for the duration of a 28-hour or longer shift ensures harm to both them and their patients during the latter, sleep-deprived half of the shifts.

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<sup>56</sup> Public Citizen and the American Medical Student Association. Letter to OHRP Regarding the FIRST Trial Comparing Standard and Long Work Schedules for General Surgery Residents. November 19, 2015. <http://www.citizen.org/documents/2284.pdf>. Accessed December 13, 2016.

<sup>57</sup> Personal communication with the American Medical Association (AMA) on September 8, 2016. Data are based on the AMA’s FREIDA residency database. Of the programs with a night float system, 349 of 391 (89.3%) internal medicine and 195 of 219 (89.0%) general surgery programs reported that first-year residents participate in the night float system.

<sup>58</sup> *Ibid.*

Lines 624-631

The removal of the requirement that residents document, and supervisors review and monitor, all instances in which the resident continues to work beyond the 28 consecutive-hour shift limit renders the shift limit essentially meaningless. Residents are now all but encouraged to work beyond the 28-hour limit, without needing to explain the reasons for doing so. The removal of the need for supervisors even to document the number of such instances of working beyond the 28-hour limit is particularly inexplicable, as it makes it impossible for the ACGME to determine the frequency with which such > 28-hour shifts occur.

Lines 637-638

Removing all restrictions mandating a minimum of eight hours off after shifts of less than 24 hours in duration is one of the most dangerous provisions of the proposed program requirements. Allowing residents to return to the hospital after less than eight hours essentially means that the residents are not permitted to get enough sleep before beginning another, potentially long shift. The eight hours of time off mandated in the 2011 program requirements were itself patently insufficient, given that these eight hours were expected to encompass the commute to and from the hospital, activities of daily living, rest and mental and physical recuperation, as well as sleep. Removing even this eight-hour minimum is inexplicable and guarantees that residents forced to return to the hospital in fewer than eight hours will be sleep-deprived and consequently a danger to themselves and their patients.

Lines 671-677

The removal of the limit of six consecutive night shifts is dangerously misguided. Allowing residents to work more than six consecutive nights in a row exposes them to the risk of burnout. Night shifts are relatively unsupervised compared to day shifts, with skeleton staffing and with attendings and fellows often not in the hospital providing direct supervision of residents' work. The combination of burnout and lack of supervision increases the risk for medical errors and consequent patient harm.

Lines 688-690

We agree with the proposal to count clinical responsibilities performed at home toward the 80-hour average weekly limit.

General Comments:**The Handoff and Workload Questions***Handoffs*

One of the primary arguments against reducing the length of residents' work shifts is that this would increase the number of handoffs necessary to transition patient care from one resident to another and thus interfere with the continuity of care. This concern is, of course, valid, but the notion that shorter shifts must come at the expense of patient safety due to the increased number of handoffs represents a zero-sum mentality that fails to account for the fact that it is not primarily the number but the quality of handoffs that is crucial in ensuring the safe transfer of patients between physicians. Handoffs still occur at the end of a long resident shift, but residents handing off patients at the end of a 28-hour or longer shift are exhausted and more prone to omitting or erring on critical information than residents who are more alert after a 16-hour or shorter shift.

A 2009 systematic review of studies on physician handoffs found that "very little research ha[d] been done to identify best practices" and that there existed "a great need for high-quality handoff outcomes

studies focused on systems factors, human performance, and the effectiveness of structured protocols and interventions.”<sup>59</sup> Since then, an updated 2015 systematic review (Mardis et al.) identified a number of higher-quality studies in medical residents that attempted to address these shortcomings and arrive at effective means of handing off patients at shift transitions.<sup>60</sup>

One of these was a very large prospective cohort study published in 2014 in *The New England Journal of Medicine*.<sup>61</sup> This study was conducted to assess the effectiveness of a standardized handoff system in pediatric residents across nine different residency programs. The intervention involved a bundle of interventions that included extensive resident training in how to conduct handoffs, changes to the verbal handoff process, changes to the written handoff process, and a faculty development and sustainment campaign, all organized around the handoff procedure using a mnemonic known as I-PASS (illness severity, patient summary, action list, situation awareness and contingency plans, and synthesis by receiver). The primary outcome was the rate of medical errors and preventable adverse events before and after implementation of the new system.

In 10,740 patient admissions, the rate of medical errors decreased by 23% (24.5 vs. 18.8 per 100 admissions;  $p < 0.001$ ), the rate of preventable adverse events decreased by 30% (4.7 vs. 3.3 events per 100 admissions;  $p < 0.001$ ), and the rate of near misses and non-harmful medical errors decreased by 21% (19.7 vs. 15.5 per 100 admissions;  $p < 0.001$ ) from the pre-intervention to the post-intervention period, respectively. There was no significant change in the rate of *non-preventable* adverse events. The inclusion of key information in written and oral handoffs significantly increased after the intervention, even though residents spent the same amount of time preparing for, and conducting, the handoffs as before.

Three handoff studies published since the 2015 Mardis et al. systematic review are summarized below. All were prospective cohort studies that compared outcomes before and after the implementation of a standardized handoff system:

- A 2016 study evaluating outcomes in 5,407 patients on general medicine and general surgery wards demonstrated that training on and use of a web-based standardized handoff procedure, incorporating a checklist for the most important points to be relayed, significantly reduced overall medical errors by 51%, medical errors resulting from a failure in communication by 60%, and medical errors due to mistakes in the handoff by 62% in the year after the procedure was implemented ( $p < 0.001$  for all comparisons).<sup>62</sup>
- A 2016 study in psychiatric residents involved the implementation of a handoff system known by the mnemonic PSYCH (patient information/background, situation leading to the hospital visit, your assessment, critical information, and hindrance to discharge).<sup>63</sup> The standardized handoff system significantly reduced the mean number of omissions from handoffs, while increasing residents’ rating of the clarity of expectations and confidence in the handoffs.

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<sup>59</sup> Riesenber LA, Leitzsch J, Massucci JL, et al. Residents’ and attending physicians’ handoffs: A systematic review of the literature. *Acad Med*. 2009;84(12):1775-1787.

<sup>60</sup> Mardis M, Davis J, Benningfield B, et al. Shift-to-shift handoff effects on patient safety and outcomes: A systematic review. *Am J Med Qual*. 2015 Oct 30. pii: 1062860615612923. [Epub ahead of print]

<sup>61</sup> Starmer AJ, Spector ND, Srivastava R, et al. Changes in medical errors after implementation of a handoff program. *N Engl J Med*. 2014;371(19):1803-1812.

<sup>62</sup> Mueller SK, Yoon C, Schnipper JL. Association of a web-based handoff tool with rates of medical errors. *JAMA Intern Med*. 2016 Aug 1. doi: 10.1001/jamainternmed.2016.4258. [Epub ahead of print]

<sup>63</sup> Mariano MT, Brooks V, DiGiacomo M. PSYCH: A mnemonic to help psychiatric residents decrease patient handoff communication errors. *Jt Comm J Qual Patient Saf*. 2016;42(7):316-320.

- A 2016 study in pediatric residents found that implementation of the I-PASS system, including the integration of I-PASS into the electronic medical record system, resulted in significantly fewer omissions of important information, as well as improvements in identification of disease severity and other measures of handoff efficiency.<sup>64</sup>

Thus, the implementation of best practices and standardized, validated handoff protocols has the potential to decrease medical errors resulting from poorly conducted handoffs.

Supervision of interns' handoffs by senior residents or attending physicians is another element that might ensure that the necessary information is conveyed. As the ACGME noted in its report related to the 2011 revisions to the duty-hour rules, "transitions of care and handoffs are complex clinical acts, which benefit from supervision and coaching, particularly for junior learners."<sup>65</sup> Studies, including one randomized trial, have found significant improvements in various aspects of handoff efficiency after the implementation of retrospective feedback from faculty to residents regarding their handoff procedures.<sup>66,67</sup>

"Intrateam" handoffs offer further potential for reducing critical omissions, as explained in a 2012 letter to the editor in *JAMA Internal Medicine*:<sup>68</sup>

Finally, one must consider that it is not only the number but the quality of handoffs. More importantly, not all handoffs are created equal. Systems can be designed to maximize continuity despite handoffs through the use of intrateam handoffs by having team members work serially so that someone from the team is always present and has both knowledge of and professional responsibility to the patient. This is in contrast to interteam handoffs, when all members on a team work in tandem; when they leave and handoff, no one who has primary knowledge of the patient is left.

Ultimately, handoffs must occur no matter the length of a shift. But, all else being equal, a resident handing off a patient after a 16-hour shift will undoubtedly be more alert than will a sleep-deprived resident at the end of a 28-hour or longer shift. The best way to minimize critical omissions or errors during transitions of care is to ensure that handoffs are (a) conducted by alert, well-trained residents using standardized, validated procedures; (b) supervised by senior residents or attending physicians; and (c) intrateam.

### *Resident Workloads*

The debate over resident duty hours has largely sidestepped the question as to whether hospitals have adjusted interns' workloads sufficiently in order to accommodate the interns' shortened 16-hour duty shifts. Failing to do so not only would require interns to rush through much of their work during the shortened shift, thus attenuating the intended benefits of reduced work hours, but would force senior residents within the care team who are allowed to work shifts of up to 28 hours to complete any

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<sup>64</sup> Walia J, Qayumi Z, Khawar N, et al. Physician transition of care: Benefits of I-PASS and an electronic handoff system in a community pediatric residency program. *Acad Pediatr*. 2016;16(6):519-523.

<sup>65</sup> Accreditation Council for Graduate Medical Education. *The ACGME 2011 Duty Hour Standards: Enhancing Quality of Care, Supervision, and Resident Professional Development*. 2011. <https://www.acgme.org/acgme/web/Portals/0/PDFs/jgme-monograph%5B1%5D.pdf>. Accessed December 13, 2016.

<sup>66</sup> Martin SK, Farnan JM, McConville JF, Arora VM. Piloting a structured practice audit to assess ACGME milestones in written handoff communication in internal medicine. *J Grad Med Educ*. 2015;7(2):238-241.

<sup>67</sup> Bump GM, Bost JE, Buranosky R, Elnicki M. Faculty member review and feedback using a sign-out checklist: Improving intern written sign-out. *Acad Med*. 2012;87(8):1125-1131.

<sup>68</sup> Farnan JM, Arora VM. The "new normal". *JAMA Intern Med*. 2013;173(19):1845.

unfinished work after the intern leaves; this latter phenomenon was reported as having occurred by 66% of residents in a 2012 national survey.<sup>69</sup>

It would also increase the chance that interns would work beyond the 16-hour maximum in order to complete their work and then falsify their self-reported hours to their residency program. In a national survey published in 2013, nearly half (43%) of 6,202 residents stated that they had falsely reported their duty hours at some point, including 19% who did so at least once or twice a month.<sup>70</sup> It is perhaps not surprising that more than twice as many residents disapproved (48%) than approved (23%) of the 2011 ACGME rules in a 2012 national survey.<sup>71</sup>

Sen et al., in reporting the results of their survey study of three large cohorts of interns in 2009, 2010, and 2011, pointed out that work compression may have been at play in the first year of implementation of the 16-hour shift limit for interns:<sup>72</sup>

In addition, for many hospitals, the new duty hour restrictions were not accompanied by funding to hire additional clinical staff. As a result, the duty hour restrictions may have exacerbated the problem of work compression, with residents expected to complete the same amount of work as previous cohorts but in less total time. Increased work compression has been associated with poorer clinical performance and decreased satisfaction among residents.

It has now been more than five years since the 16-hour shift limit was first implemented. We are not aware of any comprehensive study assessing to what extent academic hospitals have adjusted to the 2011 duty-hour rules by making appropriate reductions to intern workloads and hiring the additional health care practitioners necessary to compensate for the reduction in intern labor. But it is clear that there is an ample and rapidly growing supply of physician assistants and nurse practitioners who could considerably reduce interns' (and other residents') workloads.<sup>73</sup> Academic hospitals genuinely interested in reducing residents' burdens while minimizing medical errors committed by overstretched residents would be wise to invest in these and other health care workers.

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<sup>69</sup> Drolet BC, Christopher DA, Fischer SA. Residents' response to duty-hour regulations — a follow-up national survey. *N Engl J Med*. 2012;366(24):e35.

<sup>70</sup> Drolet BC, Schwede M, Bishop KD, Fischer SA. Compliance and falsification of duty hours: Reports from residents and program directors. *J Grad Med Educ*. 2013;5(3):368-373. Survey response rate: 23% of interns.

<sup>71</sup> Drolet BC, Christopher DA, Fischer SA. Residents' response to duty-hour regulations — a follow-up national survey. *N Engl J Med*. 2012;366(24):e35.

<sup>72</sup> Sen S, Kranzler HR, Didwania AK, et al. Effects of the 2011 duty hour reforms on interns and their patients: A prospective longitudinal cohort study. *JAMA Intern Med*. 2013;173(8):657-662.

<sup>73</sup> Salsberg E. The Nurse Practitioner, Physician Assistant, and Pharmacist Pipelines: Continued Growth. Health Affairs Blog. May 26, 2015. <http://healthaffairs.org/blog/2015/05/26/the-nurse-practitioner-physician-assistant-and-pharmacist-pipelines-continued-growth/>. Accessed December 13, 2016.