New Sleep Awareness Program Aimed at Residents and Shift Workers

3 Contact Hours
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New Sleep Awareness Program Aimed at Residents and Shift Workers

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Course # 291007                    3 CEUs

Learning Objectives
Upon successful completion of this course, you will be able to:

- Identify the AASM’s recommended hours of work for hospital residents (S.A.F.E.R).
- List the key points of the AASM’s program for improving sleep hygiene of medical interns.
- List the key aspects of the AASM’s report on the interns’ compliance with accreditation council for graduate medical education work-hour limits.

Shift Work Overview

Nowhere are the effects of lifestyle on sleep more evident than in shift work disorder, also called shift work change (SWC) and shift lag. As the global marketplace continues to turn the time-to-productivity ratio to its favor, more and more employees are needed to work unconventional shifts. Nearly 20% of employees in industrialized countries are employed in shift work, which requires them to drastically change their sleep habits weekly or even daily.

While there are few statistics for the prevalence of shift work disorder, approximately 20% of shift workers report falling asleep during work, which increases the risk of industrial accidents and decreases productivity. Ironically, shift work can diminish the economic gain it is designed to create.

Good news for (yawn) shift workers and residents

Long-term care professionals around the country cheered wildly last week when the Food and Drug Administration approved Belsomra, a new sleep drug. Shift workers applauded the addition to their medicine cabinets, already well-stocked with sleep aids. “I’ve tried melatonin and Ambien, but I didn't feel great on either one of those dr—” said certified nursing assistant Susie Sleepless, interrupted by a yawn.

Okay, I exaggerate. But the FDA did indeed approve Belsomra last week, and a research paper came out showing that many shift workers rely on medications to regulate their sleep cycles. Or that's what workers hope
for, but the jury’s still out on how well these medications actually perform.

“There isn't good evidence that these drugs can be considered for more than temporary use and some may have quite serious side effects," review author Juha Liira, of the Finnish Institute of Occupational Health in Helsinki, stated in a news release.

Liira and co-investigators with the Cochrane Occupational Safety and Health Group analyzed findings of 15 clinical trials of shift workers taking sleep or alertness drugs. Nine found that over-the-counter melatonin helped workers sleep longer, but did not help them fall asleep faster. Hypnotic drug zopiclone (Imovane) was no more effective than a placebo at helping workers sleep during the day, another trial found.

Belsomra is the first drug of its type, and it combats sleeplessness by altering the action of a brain chemical called orexin, according to the FDA. Perhaps future trials will show Belsomra is more effective than other sleep aids. If so, it might benefit nursing home residents as well as workers.

In yet other sleep-related news to come out last week, a JAMA Psychiatry article tied suicide risk to disturbed sleep in older adults. People 65 and older had a 1.4 times greater chance of death by suicide within the 10-year study period if they reported poor sleep, the study authors determined.

In fact, poor sleep was a better predictor of suicide than depressive symptoms, the investigators found. The strongest predictor was a mix of poor sleep and depression.

Granted, putting a nursing home resident on a pill likely is not the ideal choice for addressing restless sleep, given the chances that he or she already is on multiple medications. But statistics indicate that hypnotics and sedatives already are being administered at a fairly high rate in nursing homes. Even if this rate could come down, it appears that there's still a need for these pharmacological interventions in some cases.

It's likely that shift workers themselves know that behavioral and environmental modifications alone sometimes just don't do the trick. As Liira noted, "For lots of people who do shift work, it would be really useful if they could take a pill that would help them go to sleep or stay awake at the right time."

Belsomra doesn't appear to be a silver bullet by any stretch — the FDA warns that it has side-effects similar to other sleep drugs. But as a new
constant pattern, biological rhythms remain out of synch. Without a person’s previously adjusted circadian rhythm, and he or she must adapt to it. Resynchronization may take a while, but it is possible.

Circadian rhythms operate on a 24-hour cycle. In nonfluctuating shift daylight, his or her circadian rhythm can adjust to the body’s new sleep-wake pattern when they go back to work. For example, a person may work the night shift for five nights in a row, alternating external cues. The sleep-wake routine varies with continually changing time and shift start time. For SWC patients, predisposition to sleep and waking is governed by consistently mistimed circadian rhythm and external cues, known in the sleep medicine world as “zeitgebers.”

There are two types of shift work. Employees can either be required to work an unconventional nonfluctuating shift, like 11 p.m. to 7 a.m., or can work an unconventional nonfluctuating shift, like 11 p.m. to 7 a.m., and the night shift is usually from 11 p.m. to 7 a.m.; and the evening or second shift generally lasts from 3 p.m. to 11 p.m. The first shift usually runs from 7 a.m. to 3 p.m., or can be taken seven hours remaining before the planned time of waking. The total dose should not exceed 20 mg once daily.

The most commonly reported adverse reaction reported by clinical trial participants taking Belsomra was drowsiness. Medications that treat insomnia can cause next-day drowsiness and impair driving and other activities that require alertness. People can be impaired even when they feel fully awake.

### FDA News Release

**FDA approves new type of sleep drug, Belsomra**

August 13, 2014

The U.S. Food and Drug Administration today approved Belsomra (suvorexant) tablets for use as needed to treat difficulty in falling and staying asleep (insomnia).

Belsomra is an orexin receptor antagonist and is the first approved drug of this type. Orexins are chemicals that are involved in regulating the sleep-wake cycle and play a role in keeping people awake. Belsomra alters the signaling (action) of orexin in the brain.

Insomnia is a common condition in which a person has trouble falling or staying asleep. It can range from mild to severe, depending on how often it occurs and for how long. Insomnia can cause daytime sleepiness and lack of energy. It also can make a person feel anxious, depressed, or irritable. People with insomnia may have trouble with attentiveness, learning, and memory.

“To assist health care professionals and patients in finding the best dose to treat each individual patient’s sleeplessness, the FDA has approved Belsomra in four different strengths – 5, 10, 15, and 20 milligrams,” said Ellis Unger, M.D., director of the Office of Drug Evaluation I in the FDA’s Center for Drug Evaluation and Research. “Using the lowest effective dose can reduce the risk of side effects, such as next-morning drowsiness.”

Belsomra should be taken no more than once per night, within 30 minutes of going to bed, with at least seven hours remaining before the planned time of waking. The total dose should not exceed 20 mg once daily.

The most commonly reported adverse reaction reported by clinical trial participants taking Belsomra was drowsiness. Medications that treat insomnia can cause next-day drowsiness and impair driving and other activities that require alertness. People can be impaired even when they feel fully awake.
The FDA asked the drug manufacturer, Merck, Sharpe & Dohme Corp., to study next-day driving performance in people who had taken Belsomra. The testing showed impaired driving performance in both male and female participants when the 20 mg strength was taken. Patients using the 20 mg strength should be cautioned against next-day driving or activities requiring full mental alertness. Patients taking lower doses should also be made aware of the potential for next-day driving impairment, because there is individual variation in sensitivity to the drug.

The effectiveness of Belsomra was studied in three clinical trials involving more than 500 participants. In the studies, patients taking the drug fell asleep faster and spent less time awake during the remainder of the night compared to people taking an inactive pill (placebo). Belsomra was not compared to other drugs approved to treat insomnia, so it is not known if there are differences in safety or effectiveness between Belsomra and other insomnia medications.

Like other sleep medicines, there is a risk from Belsomra of sleep-driving and other complex behaviors while not being fully awake, such as preparing and eating food, making phone calls, or having sex. Chances of such activity increase if a person has consumed alcohol or taken other medicines that make them sleepy. Patients or their families should call the prescribing health care professional if this type of activity occurs.

Belsomra will be dispensed with an FDA-approved patient Medication Guide that provides instructions for its use and important safety information. Belsomra is a controlled substance (Schedule-IV) because it can be abused or lead to dependence.

Belsomra is made by Merck, Sharpe & Dohme Corp. of Whitehouse Station, N.J.

The FDA, an agency within the U.S. Department of Health and Human Services, protects the public health by assuring the safety, effectiveness, and security of human and veterinary drugs, vaccines and other biological products for human use, and medical devices. The agency also is responsible for the safety and security of our nation’s food supply, cosmetics, dietary supplements, products that give off electronic radiation, and for regulating tobacco products.

###
Causes for Shift Work Disorder

There are two types of shift work. Employees can either
1. work an unconventional nonfluctuating shift, like 11 p.m. to 7 a.m., or can
2. alternate between the three different shifts. Both versions of shift work produce a specific set of effects.

A person can usually adjust to working a new shift, if the change is permanent. Although the worker may have to get used to sleeping during daylight, his or her circadian rhythm can adjust to the body’s new sleep-wake routine. It is common for a person who sleeps from 8 a.m. to 4 p.m. consistently to function productively at work from 11 p.m. to 7 a.m. Circadian rhythms operate on a 24-hour cycle. In nonfluctuating shift work, the shift in circadian rhythm remains constant once the body adapts to it. Resynchronization may take a while, but it is possible.

Shift work change affects circadian rhythm, which, similar to delayed sleep phase syndrome and jet lag, desynchronizes the body’s sleep-wake schedule. This happens when shift workers toggle between the three common shifts, each one-third of the 24-hour day. The first shift usually runs from 7 a.m. to 3 p.m.; the evening or second shift generally lasts from 3 p.m. to 11 p.m.; and the night shift is usually from 11 p.m. to 7 a.m. Many shift workers frequently change shifts, thus intensifying the severity of circadian rhythm disturbance.

The body simply cannot rest and rebuild when circadian rhythms are frequently disrupted. Sleep-wake routines vary with continually changing external cues, known in the sleep medicine world as “zeitgebers,” the German word for “timer.” In shift work disorder, zeitgebers such as daytime and nighttime are never permanently synchronized with shift end time and shift start time. For SWC patients, predisposition to sleep and wake is governed by consistently mistimed circadian rhythm and alternating external cues.

For example, a person may work the night shift for five nights in a row, followed by two days off. During the two days off, the person resumes a normal daytime (diurnal) activity with family or friends. This disrupts the person’s previously adjusted circadian rhythm, and he or she must readjust their sleep-wake pattern when they go back to work. Without a constant pattern, biological rhythms remain out of synch.

The ultimate type of shift worker is a resident working at a hospital. Here we present some studies that have been done to deal with the critical problems these employees face:
ABSTRACT

Background
Because of concerns regarding sleep deprivation, the Accreditation Council for Graduate Medical Education limits duty hours and endorses education regarding sleep loss for residents. We assessed the effectiveness of a 60- to 90-minute lecture, the Sleep, Alertness, and Fatigue Education in Residency (SAFER) program, on sleep loss and recovery sleep in residents adhering to Accreditation Council for Graduate Medical Education duty hours.

Methods
From July 1, 2003, through June 24, 2005, interns from the inpatient medicine service at the University of Chicago were asked to wear wristwatch activity monitors. In March 2005, interns received the SAFER program intervention. We used fixed-effects linear regression to estimate within-subject mean sleep per call day (on-call, precall, postcall, and second-day postcall sleep). These estimates were compared with recommended minimum levels of preventive (7 hours of precall) and recovery (16 hours during the 2 days after call) sleep in healthy populations using 2-tailed t tests. These analyses were repeated to test the effect of the SAFER program.

Results
Fifty-eight of 81 interns (72%) participated for 147 intern-months (63%). Interns on call slept an average of 2.84 hours (95% confidence interval, 2.75-2.93 hours). Interns obtained less than recommended amounts of recovery sleep (14.06 hours [95% confidence interval, 13.84-14.28 hours]; \( P < .001 \)). Intern preventive sleep was also less than recommended (6.47 hours [95% confidence interval, 6.39-6.56 hours]; \( P < .001 \)). Interns attempted to compensate for their acute sleep loss; for each hour of on-call sleep loss, they received 18 minutes (95% confidence interval, 7-30 minutes) more recovery sleep (\( P = .003 \)). The SAFER program had no significant beneficial effect on intern sleep.

Conclusions
Under the current duty-hour regulations of the Accreditation Council for Graduate Medical Education, residents continue to be sleep deprived. The SAFER program has no impact on resident precall or postcall sleep.

Vineet M. Arora, MD, MA; Emily Georgitis, BS; James N. Woodruff, MD; Holly J. Humphrey, MD; David Meltzer, MD, PhD
Introduction

Concerns regarding the adverse effects of sleep deprivation on resident health led to the implementation of resident duty-hour restrictions in July 2003 by the Accreditation Council for Graduate Medical Education (ACGME). These mandates restrict duty hours to a maximum of 80 per week, with 30-hour consecutive shifts, provision of 10 hours off between duty periods, and 1 day off per week. Because these restrictions still include extended shifts of up to 30 hours, and because compliance is poor, the effectiveness of these limits in achieving their primary aim of reducing sleep loss and fatigue remains questionable. To work effectively under these conditions, it is imperative that house staff come to work as rested as possible. Obtaining adequate levels of preventive and recovery sleep in the setting of acute sleep deprivation is important to reducing the effects of a cumulative sleep debt. According to the American Academy of Sleep Medicine, 7 to 9 hours of preventive sleep before anticipated sleep loss in a normal, healthy population helps to defend against sleep deprivation. Under the conditions of chronic sleep deprivation characteristic of residency training, obtaining 8 to 10 hours of sleep is more appropriate. Recovery from on-call sleep loss is also important to restore baseline alertness. Although recovery sleep is traditionally defined as 2 nights of extended sleep, more recent literature supports longer recovery periods after acute sleep deprivation.

Because of these findings, the Agency for Healthcare Research and Quality recommends that residents and other long-shift workers receive education regarding effective sleep hygiene. The ACGME similarly requires that all residents receive education on the effects of sleep deprivation on health and medical care. To respond to this need, the American Academy of Sleep Medicine developed the Sleep, Alertness, and Fatigue Education in Residency (SAFER) program, which is available for purchase and is currently used by several teaching hospitals. The SAFER program is a 60- to 90-minute lecture covering the neurobiological characteristics of sleep-wake activity, the effects of sleep loss on the personal and professional lives of residents, and effective countermeasures to reduce fatigue and improve performance. Although the effectiveness of this program has not been established, it is reasonable to be concerned that a 1-time, 1-hour lecture may not have lasting effects on behavior. There is good reason to question the effectiveness of an educational program designed to improve sleep hygiene. In the single study to date that assesses the effect of an educational program on sleep hygiene, the educational program effected no change on the sleep habits of law-enforcement officers. Furthermore, educational programs may not be effective in the presence of long-standing myths regarding the ability of individuals to overcome excessive sleepiness. Residents, in particular, have been reported to believe that they can perform well under sleep-
deprived conditions. This is also consistent with the observation that sleep-deprived individuals often do not recognize themselves as being tired or even asleep.

This study aims to assess whether medical interns obtain adequate levels of preventive and recovery sleep in the setting of acute sleep deprivation. In addition, this study will also assess whether implementation of the sleep education (SAFER) program among residents in internal medicine at the University of Chicago improved the sleep practices of the interns. It is hypothesized that:

1. medical interns do not obtain adequate levels of preventive or recovery sleep, and,
2. the SAFER program, designed by the Academy of Sleep Medicine to improve sleep hygiene in residents, does not affect the sleep hygiene (defined as preventive and recovery sleep) of medical interns.

Methods

Study Design

From July 1, 2003, through June 24, 2005, we conducted a prospective cohort study of the internal medicine first-year residents (interns) from rotations at the inpatient general medicine service at the University of Chicago Hospital. The institutional review board approved this study. Interns served on the 1-month general medicine inpatient rotation 3 or 4 times per year. During these rotations, interns were assigned to teams consisting of 1 attending physician, 1 resident, and 2 interns, who each took call every fourth night. On-call interns cared for patients assigned to their team and provided night coverage for patients treated by the interns who had left the hospital. Interns were encouraged to forward the care of their patients to a night-float resident from midnight to 7 AM so that they could finish their remaining work and obtain uninterrupted sleep for a few hours. All interns were required to comply with the ACGME duty-hour restrictions.

Data Collection

Sleep data were obtained using wristwatch activity monitors (Actiwatch; Mini Mitter, Bend, Oregon). Actigraphy is a valid and convenient alternative to polysomnography for detecting sleep, including in shift workers and especially when polysomnography is not tolerated. Subjects were instructed to wear these wristwatch monitors 24 h/d for the duration of their general medicine month. Actigraph data were downloaded weekly at an intern conference into an actigraphy-based sleep-scoring software program (Actiware Software; Mini Mitter), which enables calculations of total sleep time (Figure 1).
Intern call schedules were used to match sleep to the specific day in the call cycle (ie, precall, postcall, second-day postcall, or on-call day). Sleep obtained the night before call (precall sleep) was defined as preventative sleep. Recovery sleep was calculated from the addition of the sleep obtained in the 2 nights after call (postcall and second-day postcall sleep). From hospital paging logs, the time (in minutes) that interns forwarded their pager alerts to night-float physicians was abstracted to yield protected sleep time, which constituted an opportunity to obtain uninterrupted sleep. The total shift duration on call was also calculated. Because of the major adjustments interns must make as they begin a medical internship in July, only the data obtained from August to the following June were included in both years of this study.

**Intervention**

On March 3, 2005, the SAFER program was presented by a faculty member (V.M.A.) during a routine lunchtime conference for the residents. Attendance was documented for residents and interns (in study year 2). Per the SAFER program protocol, an Epworth Sleepiness Scale and an anonymous 14-item pretest were administered before the lecture. During the lecture, the meaning of the Epworth Sleepiness Scale and content corresponding to the test questions were discussed. At the end of the program, the answers to the test were reviewed and the answer key was given to the participants to ensure that the salient points were understood.
Figure 1. Two-day views of 1-week actigraphs (Actiware Software; Mini Mitter, Bend, Oregon) from a study intern (A) and a demonstration subject who obtained 7 to 9 hours of sleep nightly (B). Data from the wristwatch sleep monitors (Actiwatch; Mini Mitter) were downloaded every Monday. The intern’s actigraph demonstrates sleep loss on Wednesday and Sunday (arrows), which corresponds to the on-call schedule every fourth night. Nonshaded areas represent an 8-hour interval between 11 PM and 7 AM. Black represents movement, and the absence of black is scored as sleep.
Data Analysis

To assess whether medical interns obtain adequate levels of preventive and recovery sleep in the face of acute sleep deprivation, we used fixed-effects linear regression models, controlling for intern, to estimate the mean sleep time in minutes for each day in an intern’s call cycle. We compared these estimated means to the recommended means for the corresponding day of the call cycle using 2-tailed t tests. Recommended means were defined as a minimum of 7 hours (420-540 minutes) of precall sleep (preventive sleep) and 16 hours (960 minutes) for recovery sleep (8 hours of postcall and 8 hours of second-day postcall sleep) suggested by the American Academy of Sleep Medicine.\textsuperscript{10,26} Because of the potential effects of season and experience on intern sleep while on call and out of the hospital, estimates of how sleep varied by month were also calculated using regression models with indicator variables for each month.

To assess whether the SAFER program had an effect on the sleep hygiene of interns, we performed precall-postcall within-subject analyses on our outcomes of interest. Because the SAFER program encourages preservation of sleep before and after a period of acute sleep deprivation, the specific outcomes examined included precall and postcall sleep times. The SAFER program also encourages taking maintenance naps, or naps on the job during long shifts, such as the protected sleep time provided to on-call interns by night-float coverage. As a result, we also examined whether the use of maintenance naps, as defined by the use of night-float coverage by on-call interns, increased after the SAFER program was administered. We conducted fixed-effects multivariate linear regression, controlling for intern, month, night-float coverage, and the number of calls taken in that month, to assess the effect of the SAFER presentation on sleep time under each call condition. All statistical tests were performed using Intercooled Stata software (version 7.0; StataCorp, College Station, Texas), with statistical significance defined as $P<.05$.

From July 1, 2003, through June 30, 2005, 81 interns (40 in the first year and 41 in the second) rotated in the inpatient general medicine service. Fifty-eight interns (72%) (35 in the first academic year and 23 in the second) participated in the study, wearing a wristwatch sleep monitor for at least 1 month for a total of 147 intern-months (62.8% of 234 possible intern-months). The wristwatch data were obtained on 2638 of 4340 nights sampled (60.8%). Intern compliance with wearing the wristwatch varied by call day, with interns most likely to wear the watch when they were on call (795/1085 call days [73.3%]) and least likely to wear the watch on their postcall day (599/1085 call days [55.2%]). Average shift duration on call was 29.7 hours (95% confidence interval, 29.57-29.85 hours).
Data confirmed that on-call interns experienced acute sleep deprivation (mean of 2.84 hours obtained while on call). However, interns obtained less-than-adequate amounts of preventive and recovery sleep. Intern preventive sleep, defined as precall sleep, was a mean of 6.47 hours. Although only half an hour short of the recommended minimum of 7 hours for a normal, healthy population, this level is likely clinically significant in a chronically sleep-deprived population. Recovery sleep was estimated at a mean of 14 hours (roughly 7 hours each on the postcall night and the second postcall day), which is well below the recommended minimum recommended recovery sleep time of 16 hours. This difference was also statistically significant (Table 1).

### Table 1. Intern Sleep by Call Day: Comparison with Recommended Levels

<table>
<thead>
<tr>
<th>Sleep type</th>
<th>No. Of interns</th>
<th>Nights observed, No. (%)</th>
<th>Mean no. Of observations per intern</th>
<th>Average sleep time (85% CI, h)</th>
</tr>
</thead>
<tbody>
<tr>
<td>On-call</td>
<td>58</td>
<td>795 (73)</td>
<td>13.7</td>
<td>2.84 (2.75-2.93)</td>
</tr>
<tr>
<td>Precall preventive</td>
<td>58</td>
<td>623 (57)</td>
<td>10.7</td>
<td>6.47 (6.39-6.56)</td>
</tr>
<tr>
<td>Postcall</td>
<td>57</td>
<td>599 (55)</td>
<td>10.5</td>
<td>7.16 (7.00-7.39)</td>
</tr>
<tr>
<td>Second day post call</td>
<td>58</td>
<td>621 (57)</td>
<td>10.7</td>
<td>6.97 (6.84-7.10)</td>
</tr>
<tr>
<td>Recovery³</td>
<td>56</td>
<td>507 (47)</td>
<td>9.1</td>
<td>14.06 (13.84-14.28)</td>
</tr>
</tbody>
</table>

Abbreviation: CI, confidence interval

³The following recommended sleep levels are derived from the American Academy of Sleep Medicine for a normal, healthy population: 7 to 9 precall hours; 8 postcall hours; 8 second-day postcall hours; and an average of 16 hours of total recovery. Longer periods of sleep are likely needed for a chronically sleep-deprived population.

Indicates the number (percentage) of night when sleep data were obtained from the wristwatches (variations due to intern noncompliance or technical failure).

³P<.001 when comparing hours slept with recommended levels.

Intern sleep varied significantly by month. On-call sleep ranged from a mean of 2.16 hours in August to 3.56 hours in June \( (P<.001) \) (Figure 2). Although interns failed to meet the recommended sleep levels on average, interns’ recovery sleep varied with the degree of on-call sleep loss. For every hour of acute on-call sleep loss, interns slept an additional 13 minutes on their postcall night \( (P=.005) \) (Table 2). Recovery sleep also increased a mean of 18 minutes \( (P=.003) \) for every hour of acute sleep.
loss on call (Table 2). For every hour of acute sleep loss on call, intern preventive sleep increased by 5 minutes ($P=.03$).

**Figure 2.** On-call sleep by month. Estimates are based on a multivariate, fixed-effects linear regression to predict on-call sleep, controlling for intern and month (as an indicator variable, with August as the reference month). The model included sleep data from 795 of 1085 call days (73.3%) obtained from 58 of 81 interns (71.6%). On-call sleep averages for October, November, December, January, February, March, April, May, and June were significantly higher than those for August ($P < .05$). Limit lines indicate 95% confidence interval.
Table 2. Preventive and Recovery Sleep: Response to 1 Hour of On-Call Sleep Loss

<table>
<thead>
<tr>
<th>Sleep Type</th>
<th>No. of interns</th>
<th>No. of Observations</th>
<th>Change in Sleep Time (95% CI), min b</th>
</tr>
</thead>
<tbody>
<tr>
<td>Precall preventive</td>
<td>58</td>
<td>569</td>
<td>5 (1 to 10)</td>
</tr>
<tr>
<td>Postcall</td>
<td>56</td>
<td>567</td>
<td>13 (4 to 21)</td>
</tr>
<tr>
<td>Second day postcall</td>
<td>58</td>
<td>556</td>
<td>2 (%) (-5 to 9)</td>
</tr>
<tr>
<td>Recovery c</td>
<td>55</td>
<td>479</td>
<td>18 (7 to 30)</td>
</tr>
</tbody>
</table>

Abbreviation: CI, confidence interval

a Number of observations used in regression models (on-call sleep and day of interest were obtained).
b Based on multivariate, fixed-effects linear regression controlling for intern, night-float coverage, number of call days that month, and month of the year.
c Defined as the sum of postcall sleep and second-day postcall sleep.

Using a multivariate, fixed-effect, linear regression controlling for intern, month of the year, and the number of calls taken that month, the data showed that the SAFER program did not significantly increase the amount of sleep interns received during any of the call conditions (Table 3). The estimated mean precall sleep with the SAFER program was 6.63 hours compared with 6.47 hours without the program. A nonsignificant trend was observed for increased on-call sleep with the SAFER program (3.27 vs 2.85 hours; P = .10), with a corresponding reduction of nearly 90 minutes in recovery sleep (12.56 vs 14.08 hours; P = .08).
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Table 3. Effect of the SAFER Program on Intern Sleep by Call Day

<table>
<thead>
<tr>
<th>Call day</th>
<th>No. of interns</th>
<th>No. of observations</th>
<th>SAFER Estimated average sleep time, h&lt;sup&gt;a&lt;/sup&gt;</th>
<th>Control Estimated average sleep time, h&lt;sup&gt;a&lt;/sup&gt;</th>
<th>SAFER-Control sleep time difference (95% CI), min</th>
</tr>
</thead>
<tbody>
<tr>
<td>Precall</td>
<td>58</td>
<td>623</td>
<td>6.63</td>
<td>6.47</td>
<td>9 (-29 to 48)</td>
</tr>
<tr>
<td>On-call</td>
<td>58</td>
<td>795</td>
<td>3.27</td>
<td>2.85</td>
<td>25 (-5 to 56)</td>
</tr>
<tr>
<td>Postcall</td>
<td>57</td>
<td>599</td>
<td>6.51</td>
<td>7.13</td>
<td>-37 (-108 to 35)</td>
</tr>
<tr>
<td>Second-day postcall</td>
<td>58</td>
<td>621</td>
<td>6.72</td>
<td>7.05</td>
<td>-20 (-70 to 31)</td>
</tr>
<tr>
<td>Recovery&lt;sup&gt;b&lt;/sup&gt;</td>
<td>56</td>
<td>507</td>
<td>12.56</td>
<td>14.08</td>
<td>-91 (-195 to 13)</td>
</tr>
</tbody>
</table>

Abbreviation: CI, confidence interval. SAFER: Sleep, Alertness and Fatigue Education in Residency.
<sup>a</sup>Derived from multivariate, fixed-effect linear regression models using the number of observations and controlling for intern, night-float coverage, number of call days that month, and month of the year.
<sup>b</sup>Defined as the sum of postcall sleep and second-day postcall sleep.

Paging data showed that interns rarely used night-float coverage to obtain maintenance naps (21.5% in the first year vs 0% in the second year). More often, interns chose to sign over only their cross-coverage patients, continuing to be interrupted for the care of their own patients throughout the night. After the SAFER presentation, no intern chose to use night-float coverage to obtain uninterrupted sleep.

Comment

Our results provide objective quantitative measures of intern sleep and fatigue through a prospective cohort study on a general medicine service at an academic hospital after the implementation of duty-hour restrictions. Using actigraphic measurement of sleep, we are able to provide a quantitative assessment of interns’ sleep hygiene, including specific estimates of preventive and recovery sleep. Our findings confirm that, in the setting of restricted duty hours, medical interns still experience acute sleep deprivation and do not receive recommended amounts of preventive or recovery sleep. In addition to mandating duty-hour limits, the ACGME requires that residency programs offer their residents an educational presentation on sleep deprivation. Our analysis found no strong statistically significant evidence of an effect of the SAFER program on sleep. Although the limited size of our study prevents us from ruling out the presence of a small positive or negative effect of the SAFER program on sleep, we can reject the presence of a large beneficial effect. The nonsignificant trends observed suggest that,
New Sleep Awareness Program Aimed at Residents and Shift Workers

although the SAFER program may encourage interns to preserve their sleep while on call, recovery sleep could be compromised.

These findings raise important questions about how to alleviate resident sleep deprivation effectively, which is important to ensure the health of medical trainees and safe patient care. The negative health consequences of sleep deprivation on residents, such as motor vehicle accidents and obstetric complications, is well documented. More recent studies focus on the detrimental effects of extended duty shifts on residents’ health and patient care. Together, these studies suggest that further restrictions may be warranted to alleviate sleep deprivation in house staff.

The findings from this study suggest that duty-hour restrictions alone may not be effective in achieving this goal. Although an inverse relationship between total hours worked and sleep has been documented, there may be a variety of reasons that residents are not able to use off-duty time to obtain the necessary levels of preventive and recovery sleep. First, residents may have a high level of personal obligations, including relationship and family pressures. Sleep is unlikely to be the highest priority, even in the setting of acute and chronic sleep deprivation in residency. For example, many interns may choose to tend to other personal activities in lieu of obtaining additional sleep. Residents may also use extra time for education outside of their on-duty time spent in the hospital. In the currently mandated 80-hour work week, the remaining 88 hours per week (roughly 12.5 hours per day) may not be enough to obtain adequate sleep and maintain a healthy lifestyle. For instance, a resident who obtains the recommended levels of sleep (average of 7-9 h/d) would have only 3 to 5 h/d for eating, personal hygiene, other personal errands (eg, paying bills and shopping), commuting to and from work, and any other social or family obligations. Also, residents may have difficulty sleeping even if they wish to. For example, the intensity and constant sleep disruption of residency may contribute to an insomnia-type picture secondary to hyperarousal.

Given these realities, improving resident sleep deprivation in the current system will likely require more intensive workplace interventions coupled with a shift in culture to emphasize the importance of proper sleep hygiene for house staff. Such workplace interventions might include the adoption of alternate scheduling practices or countermeasures that have been effective in alleviating sleep deprivation and fatigue in long-shift workers in other occupations. Such changes may include the use of shift-work systems (as in nursing), or the use of a maintenance or an on-call nap (as in aviation). These interventions may also be targeted during the months at highest risk of sleep loss (eg, winter). Achieving a change in culture may be accomplished using methods to promote long-term
behavioral change, such as audit, feedback, reminder, and reinforcement systems coupled with strong endorsements from faculty and program leaders.

This study has several limitations. Perhaps the most important is that it was conducted in a single residency program in 1 institution, which limits the ability to generalize the results. However, given the paucity of studies exploring resident off-duty sleep habits and the interest in protecting residents from the effects of sleep deprivation, these findings suggest that better evidence about the effectiveness of interventions such as the SAFER program is badly needed. As we await additional data, these findings may be useful to help inform program changes and policies designed to target resident sleep deprivation. Another limitation is the presence of missing data, predominantly due to noncompliance and, to a lesser degree, technical difficulties. Interns were also less likely to wear the watch when not on call. There are several reasons that could explain this pattern. Interns may be less likely to wear the watch when out of the hospital owing to self-conscious feelings. In addition, on their call day, they may anticipate sleep loss, which serves as a reminder to wear the watch. They may also be conscious that peers or administrators will be observing their compliance. Although the data are not missing completely at random (ie, more noncall days missing), there was no relationship between sleep and the rate of compliance (or the degree of missing observations) observed in our data. In the event of a technical failure, we sent the watch to the manufacturer to retrieve source data and gave the intern a functioning watch.

Interns did not participate for every month they were on the general medicine rotation, which may have introduced an important source of selection bias. Interns may have chosen not to participate during the months they were most fatigued, and interns were less likely to participate in the second year of the study. Another limitation of this study was the difficulty in coordinating data collection with interns on a regular basis. Because of their heavy workloads and restricted duty schedules, we chose to integrate data collection into their routine work schedule by downloading data at a weekly intern conference whenever possible (Figure 1). Finally, although a 1-time educational lecture alone did not have a substantial effect on intern sleep, it is possible that subtle long-term effects on perceptions about appropriate sleep habits were present. Although we did not explore these effects, the provision of education remains important to increase awareness and educate residents about the detrimental effects of sleep deprivation.
New Sleep Awareness Program Aimed at Residents and Shift Workers

Conclusions
The ACGME duty-hour restrictions aimed to reduce sleep deprivation in medical trainees. However, the current ACGME duty-hour limits, particularly in the absence of effective interventions to improve the sleep hygiene of medical trainees, may be inadequate to achieve this goal. Educational programs, although recommended, may not be effective in changing the sleep hygiene of medical trainees. To prevent the negative consequences of sleep deprivation in residents, adoption of proven countermeasures to fatigue and promotion of a culture that facilitates healthy sleep habits are warranted.

References
New Sleep Awareness Program Aimed at Residents and Shift Workers


**S.A.F.E.R.**

The American Academy of Sleep Medicine (AASM) offers an extensively updated and revised version of S.A.F.E.R. (Sleep, Alertness and Fatigues Education in Residency), a tool for educating residents about the effects of sleep deprivation on performance.

The new version includes an expanded PowerPoint presentation with core sections on recognizing sleepiness, the effects of fatigue on medical education and strategies for managing drowsiness.

The updated program came about after researchers at Brown University determined that drowsy residents performed as poorly or worse as someone who had consumed three to four alcoholic beverages. The study is published in a September 2007 issue of *JAMA.*

“We have to continue to educate doctors-in-training,” said Judith Owens, director of the Pediatric Sleep Disorders Clinic at Hasbro Children’s Hospital, associate professor of pediatrics at Brown Medical School, and co-author of the study. “This is particularly important since our study shows that many sleep-starved residents don’t recognize that they’re impaired.”

Owens helped create the S.A.F.E.R. Program after she was involved in a serious car accident as a resident. The program is now used in residency programs across the nation.

She added that the results applied not only to med school residents but anyone employed in a field requiring long stretches of work without rest including nurses, truck drivers, and police officers.
For your information, here are the hours normally recommended for Residents:

**Duty Hours Language**

Resident Duty Hours in the Learning and Working Environment

A. Principles
1. The program must be committed to and be responsible for promoting patient safety and resident well-being and to providing a supportive educational environment.
2. The learning objectives of the program must not be compromised by excessive reliance on residents to fulfill service obligations.
3. Didactic and clinical education must have priority in the allotment of residents’ time and energy.
4. Duty hour assignments must recognize that faculty and residents collectively have responsibility for the safety and welfare of patients.

B. Supervision of Residents
The program must ensure that qualified faculty provide appropriate supervision of residents in patient care activities.

C. Fatigue
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 its potential negative effects on patient care and learning.

D. Duty Hours (the terms in this section are defined in the ACGME Glossary and apply to all programs)

Duty hours are defined as all clinical and academic activities related to the program; i.e., patient care (both inpatient and outpatient), administrative duties relative to patient care, the provision for transfer of patient care, time spent in-house during call activities, and scheduled activities, such as conferences. Duty hours do not include reading and preparation time spent away from the duty site.

1. Duty hours must be limited to 80 hours per week, averaged over a four-week period, inclusive of all in-house call activities.
2. Residents must be provided with one day in seven free from all educational and clinical responsibilities, averaged over a four-week period, inclusive of call.
3. 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.
E. On-call Activities
1. In-house call must occur no more frequently than every third night, averaged over a four-week period.
2. Continuous on-site duty, including in-house call, must not exceed 24 consecutive hours. Residents may remain on duty for up to six additional hours to participate in didactic activities, transfer care of patients, conduct outpatient clinics, and maintain continuity of medical and surgical care.
3. No new patients may be accepted after 24 hours of continuous duty.
4. At-home call (or pager call)
   a. 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.
   b. Residents taking at-home call must be provided with one day in seven completely free from all educational and clinical responsibilities, averaged over a four-week period.
   c. When residents are called into the hospital from home, the hours residents spend in-house are counted toward the 80-hour limit.

F. Moonlighting
1. Moonlighting must not interfere with the ability of the resident to achieve the goals and objectives of the educational program.
2. Internal moonlighting must be considered part of the 80-hour weekly limit on duty hours.

G. Duty Hours 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.
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.
2. Prior to submitting the request to the Review Committee, the program director must obtain approval of the institution’s GMEC and DIO.
Interns’ Compliance with Accreditation Council for Graduate Medical Education Work-Hour Limits

ABSTRACT

Context
Sleep deprivation is associated with increased risk of serious medical errors and motor vehicle crashes among interns. The Accreditation Council for Graduate Medical Education (ACGME) introduced duty-hour standards in 2003 to reduce work hours.

Objective
To estimate compliance with the ACGME duty-hour standards among interns.

Design, Setting, and Participants
National prospective cohort study with monthly Web-based survey assessment of intern work and sleep hours using a validated instrument, conducted preimplementation (July 2002 through May 2003) and postimplementation (July 2003 through May 2004) of ACGME standards. Participants were 4015 of the approximately 37,253 interns in US residency programs in all specialties during this time; they completed 29,477 reports of their work and sleep hours.

Main Outcome Measure
Overall and monthly rates of compliance with the ACGME standards.

Results
Postimplementation, 1068 (83.6%; 95% confidence interval [CI], 81.4%-85.5%) of 1278 of interns reported work hours in violation of the standards during 1 or more months. Working shifts greater than 30 consecutive hours was reported by 67.4% (95% CI, 64.8%-70.0%). Averaged over 4 weeks, 43.0% (95% CI, 40.3%-45.7%) reported working more than 80 hours weekly, and 43.7% (95% CI, 41.0%-46.5%) reported not having 1 day in 7 off work duties. Violations were reported during 3765 (44.0%; 95% CI, 43.0%-45.1%) of the 8553 intern-months assessed postimplementation (including vacation and ambulatory rotations), and during 2660 (61.5%; 95% CI, 60.0%-62.9%) of 4327 intern-months during which interns worked exclusively in inpatient settings.

Postimplementation, 29.0% (95% CI, 28.7%-29.7%) of reported work weeks were more than 80 hours per week, 12.1% (95% CI, 11.8%-12.6%) were 90 or more hours per week, and 3.9% (95% CI, 3.7%-4.2%) were 100 or more hours per week. Comparing preimplementation to postimplementation responses, reported mean work duration decreased 5.8% from 70.7 (95% CI, 70.5-70.9) hours to 66.6 (95% CI, 66.3-66.9)...
New Sleep Awareness Program Aimed at Residents and Shift Workers

hours per week ($P<.001$), and reported mean sleep duration increased 6.1% (22 minutes) from 5.91 (95% CI, 5.88-5.94) hours to 6.27 (95% CI, 6.23-6.31) hours per night ($P<.001$). However, reported mean sleep during extended shifts decreased 4.5%, from 2.69 (95% CI, 2.66-2.73) hours to 2.57 (95% CI, 2.52-2.62) hours ($P<.001$).

Christopher P. Landrigan, MD, MPH; Laura K. Barger, PhD; Brian E. Cade, MS; Najib T. Ayas, MD, MPH; Charles A. Czeisler, PhD, MD

Conclusion
In the first year following implementation of the ACGME duty-hour standards, interns commonly reported noncompliance with these requirements.

Introduction
In 2003, the Accreditation Council for Graduate Medical Education (ACGME) implemented work-hour limits for all physicians-in-training (residents) in the United States. Each trainee is limited to a maximum of 30 consecutive work hours, including the time used for sign-out, didactic teaching, and continuity of patient care (30-hour rule), and a maximum of 80 weekly work hours, averaged over 4 weeks (80-hour rule). In addition, 1 day in 7 (averaged over 4 weeks) must be free of all duties (7-day rule).

These limits were developed in response to national concern with the long work hours of residents, manifest by initiatives to limit the work hours of medical trainees through both federal regulation and legislation. In deferring federal action, both the executive and legislative branches chose to rely instead on the internal professional regulation being developed and implemented as the new ACGME work-hour limits.

Data reported by the ACGME suggest that these limits succeeded in eliminating nearly all work weeks greater than 80 hours and shifts greater than 30 consecutive hours. Based largely on mandatory reports submitted to the ACGME by residency programs, the ACGME reported that only 5.0% of residency training programs were noncompliant with the standards in the year after their release, and that only 3.3% of surveyed residents reported violations of the 80-hour rule. The reliability of these data is unclear, however, because the resident survey instrument used by the ACGME has not been validated and the manner in which residency programs collect work hours data is not standardized. Moreover, the ACGME has the authority to withdraw the accreditation of noncompliant programs, which could lead to inaccurate reporting by institutions. Preliminary cross-sectional surveys have suggested that house officers’ work hours may be higher than those reported to the
ACGME, but prospective, longitudinal studies using validated measures of work hours have not been conducted.

Since July 2002, we have been prospectively collecting independent data on the work and sleep of medical trainees through the Harvard Work Hours, Health and Safety (HWHHS) program. The primary purpose of this study was to estimate the frequency with which interns (first-year residents) were compliant with the ACGME duty-hour standards; as a secondary aim, we evaluated the degree to which reported work hours and sleep changed after implementation of the standards.

Methods
In April of 2002 and 2003, the Association of American Medical Colleges attempted on our behalf to email advertisements about the HWHHS study to a cohort of 18,447 medical students in 2002 and 18,806 in 2003. The students had been matched by the National Residency Matching Program to approximately 3200 programs for trainees in their first postgraduate year in 1100 teaching hospitals nationwide. In addition, in the spring of 2002, we sent email advertisements to all known email addresses of 4th year medical students graduating from US programs. It is not known how many reached the intended recipients. The mailing informed students of our intent to conduct a longitudinal study of work hours, health, and safety. Potential participants were directed to a secure Web site that gave detailed information about the study and enabled them to provide electronically written informed consent. Participants were entered into a cash lottery.

Those who consented to participate were asked to provide data on a monthly basis from July through May of their intern year, such that monthly data were collected from a national sample of interns in 2002-2003 and 2003-2004. In June of each year, interns who consented to participate used a password-protected secure Web site to enter baseline demographic, health, and safety information; data on work hours were not collected in the baseline survey. Interns who completed the baseline survey comprised the study cohort.

From July through May, on the 28th of each month, emails were sent to all participants in the study cohort, requesting detailed data on their work hours and sleep during the first, second, third, and fourth week of that month. These questions were administered alongside many others regarding monthly activities and work experiences that served as distractors, including use of caffeinated beverages and alcohol, motor vehicle crashes, needlestick injuries, and job performance. Key items analyzed for this study were “Hours spent physically awake in the hospital, classes, or workplace”; “Hours spent working or studying
outside of the hospital, classroom, or workplace (eg, at home or at the library) related to your program”; “Hours of sleep at school, the workplace, or hospital”; “Hours of sleep outside of school, the workplace, or hospital”; “Number of days off (ie, a full 24-hour period)”; “Average length of extended shift”; “Average hours of sleep during these extended shifts”; “In the month of [insert month], what was the longest number of continuous hours you were actually physically at work? Include protected time for sleep provided during an extended shift”; and “In the month of [insert month], what was the longest number of continuous hours you went without sleep?” No mention was made in the survey of the ACGME duty-hour standards or compliance with work-hour rules. Participants had the opportunity to provide monthly data from the time of the initial email through the 27th of the following month.

Participants completed data forms on Web sites hosted and maintained by Pearson NCS, Inc (Eagen, Minn). Pearson NCS securely transmitted all data on a weekly basis to Brigham and Women’s Hospital; data were coded and participants were assigned a study identification number. Potentially identifiable data were stored in a secure location separate from the main database. The Centers for Disease Control and Prevention issued a certificate of confidentiality for this study. In addition, because the Agency for Healthcare Research and Quality supported this research, the data confidentiality is protected by federal statute (Public Health Service Act 42 USC). The HWHHS study was approved by the Brigham and Women’s Hospital Human Research Committee. Further details regarding HWHHS recruitment and study methods have been published previously.17

Validation
As previously described,17 to validate hours reported using our monthly instrument, we had a 7% random sample of participants in 2002-2003 (year 1) complete daily work diaries. Total work hours and number of extended work shifts reported via the surveys and diaries were well correlated (Pearson coefficients, 0.76 and 0.94, respectively; P<.001 for both). We further validated daily diary data against directly observed work hours (r=0.98; P<.001) and polysomnographically recorded sleep (r=0.94; P<.001) in 20 interns in another study.18

Statistical Analyses
Descriptive statistics were used to estimate compliance with each of the ACGME duty-hour standards in the year after their implementation, as well as interns’ work and sleep hours before and after implementation of the standards. The HWHHS compliance data were compared with the ACGME’s published compliance data8 using Fisher exact tests. Mean work and sleep hours in the year before and after implementation of the
standards were compared using nonparametric Wilcoxon rank sum tests. Trends over time in rates of compliance were analyzed using the Cochran-Armitage test for trend. SAS version 9.1 (SAS Institute Inc, Cary, NC) was used for statistical comparisons. Significance level was set at .05; all reported P values are 2-sided.

Results
The Association of American Medical Colleges attempted to send advertisements to 18,447 medical students in 2002 and 18,806 medical students in 2003. Of these, 2737 (14.8%) in 2002 (preimplementation) and 1278 (6.8%) in 2003 (postimplementation) volunteered to participate and completed baseline surveys, for a total cohort of 4015 participants. As interns, they completed a total of 29,477 baseline plus monthly reports of their work and sleep hours (mean [SD] 7.3 [4.0] out of 12 possible). Of the participants, 60.1% (17.1%) responded to each wave of the survey in year 1, and 63.5% (17.5%) responded to each wave of the survey in year 2. Compared with all applicants in the Electronic Residency Application Service database, there was a greater percentage of female residents in our study cohort (53% vs 41%) in 2002, and the mean age of our interns was lower (28.0 years vs 30.2 years) (data from the Electronic Residency Application Service; personal communication, Paul Jolly, PhD, Senior Associate Vice President, AAMC, July 19, 2006). The study cohort consisted of 79% medical specialties, 11% surgical specialties, and 10% other/not specified, compared with 88% medical specialties and 12% surgical specialties in the National Residency Matching Program cohort.19 Most hospitals in the study sample were represented by several interns, well-distributed geographically and across program types. There was a mean of 3.7 interns and 23.1 intern-months per represented hospital; 420 hospitals were represented in year 1 and 346 in year 2 of the approximately 1100 teaching hospitals nationwide.

Compliance With ACGME Duty Hour Standards
In the year following implementation, 1068 (83.6%; 95% confidence interval [CI], 81.4%-85.5%) of 1278 participating interns reported work hours that were noncompliant with the ACGME standards during at least 1 month (Table 1). Hours in violation of the duty-hour standards were reported during 3765 (44.0%; 95% CI, 43.0%-45.1%) of the 8553 monthly reports received postimplementation; 2660 (61.5%; 95% CI, 60.0%-62.9%) of the 4327 months during which interns worked exclusively in hospital settings contained reported hours in violation of the standards. Over the year, monthly rates of noncompliance decreased from 48.8% (95% CI, 46.0%-51.6%) in July 2003 to 38.0% (95% CI, 34.4%-41.2%) in May 2004 (P<.001).
Table 1. Proportion of Hospitals, Residency Programs, Interns, Intern-Months, and Inpatient Intern-Months with Reported Hours in Violation of the ACGME Work Hour Rules, 2003-2004

<table>
<thead>
<tr>
<th></th>
<th>No. of hospitals</th>
<th>Percent With Reported Violations (95% CI)</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>No.</td>
<td></td>
</tr>
<tr>
<td>Any rule violation</td>
<td>314</td>
<td>90.8 (87.2-93.3)</td>
</tr>
<tr>
<td>30-h Rule violation</td>
<td>276</td>
<td>79.8 (75.2-83.7)</td>
</tr>
<tr>
<td>80-h Rule violation</td>
<td>283</td>
<td>81.8 (77.4-85.5)</td>
</tr>
<tr>
<td>7-d Rule violation</td>
<td>220</td>
<td>63.6 (58.4-68.5)</td>
</tr>
<tr>
<td>No. of residency programs</td>
<td>707</td>
<td></td>
</tr>
<tr>
<td>Any rule violation</td>
<td>604</td>
<td>85.4 (82.6-87.8)</td>
</tr>
<tr>
<td>30-h Rule violation</td>
<td>496</td>
<td>70.2 (66.7-73.4)</td>
</tr>
<tr>
<td>80-h Rule violation</td>
<td>493</td>
<td>69.7 (66.2-73.0)</td>
</tr>
<tr>
<td>7-d Rule violation</td>
<td>360</td>
<td>50.9 (47.2-54.6)</td>
</tr>
<tr>
<td>No. of interns</td>
<td>1276</td>
<td></td>
</tr>
<tr>
<td>Any rule violation</td>
<td>1066</td>
<td>83.8 (81.4-86.5)</td>
</tr>
<tr>
<td>30-h Rule violation</td>
<td>862</td>
<td>67.4 (64.8-70.0)</td>
</tr>
<tr>
<td>80-h Rule violation</td>
<td>549</td>
<td>43.0 (40.3-45.7)</td>
</tr>
<tr>
<td>7-d Rule violation</td>
<td>559</td>
<td>43.7 (41.0-46.5)</td>
</tr>
<tr>
<td>No. of intern-months</td>
<td>8553</td>
<td></td>
</tr>
<tr>
<td>Any rule violation</td>
<td>3765</td>
<td>44.0 (43.0-45.1)</td>
</tr>
<tr>
<td>30-h Rule violation</td>
<td>2719</td>
<td>31.8 (30.9-32.8)</td>
</tr>
<tr>
<td>80-h Rule violation</td>
<td>1865</td>
<td>21.8 (20.9-22.7)</td>
</tr>
<tr>
<td>7-d Rule violation</td>
<td>850</td>
<td>9.9 (9.3-10.5)</td>
</tr>
<tr>
<td>No. of inpatient intern-months*</td>
<td>4327</td>
<td></td>
</tr>
<tr>
<td>Any rule violation</td>
<td>2960</td>
<td>61.5 (60.0-62.9)</td>
</tr>
<tr>
<td>30-h Rule violation</td>
<td>1925</td>
<td>44.5 (43.0-46.0)</td>
</tr>
<tr>
<td>80-h Rule violation</td>
<td>1874</td>
<td>38.7 (37.2-40.1)</td>
</tr>
<tr>
<td>7-d Rule violation</td>
<td>561</td>
<td>13.0 (12.0-14.0)</td>
</tr>
</tbody>
</table>

Abbreviations: ACGME, Accreditation Council for Graduate Medical Education; CI, confidence interval.

*Inpatient intern-months is defined as months during which interns’ primary activity for the entire month was working in hospital settings, including hospital wards, hospital consult services, or intensive care units; excludes months that contained vacation, electives, ambulatory rotations, and other nonhospital rotations.
Error bars indicate 95% confidence intervals. A mean (SD) of 778 (199) reports of work hours were submitted each month (range, 491-1212). There is a significant decrease in the percentage of months with any violation ($P < .001$, Cochran-Armitage test for trend). ACGME indicates Accreditation Council for Graduate Medical Education.

Violations were reported from 604 (85.4%; 95% CI, 82.6%-87.8%) of the 707 represented residency programs (Table 2) and from interns in 314 (90.8%; 95% CI, 87.2%-93.3%) of the 346 represented hospitals (Table 3). Fewer reports were submitted from hospitals without any reported violations than from hospitals with violations (mean 6.0 [95% CI, 4.4-7.6] vs 24.8 [95% CI, 22.2-27.4]; $P < .001$). Violations were reported from a smaller proportion of hospitals in New York and Puerto Rico (the only 2 states or commonwealths with governments that currently have laws enforcing resident work limits$^{20}$) than from hospitals in all other states, where no such laws are in effect (78.1% [95% CI, 61.1%-88.9%] vs 92.0% [95% CI, 88.5%-94.5%]; $P = .02$); 30-hour violations were reported in less than half as many New York and Puerto Rican hospitals (37.5% [95% CI, 22.9%-54.9%] vs 84.1% [95% CI, 79.6-87.7%]; $P < .001$).
New Sleep Awareness Program Aimed at Residents and Shift Workers

Table 2. Proportion of Residency Programs With Interns Reporting Violations of the ACGME Work Hour Rules by Program Type, 2003-2004

<table>
<thead>
<tr>
<th>Program Type</th>
<th>No. of Programs</th>
<th>No. (%; 95% CI) of Programs With Any ACGME Violations</th>
<th>No. (%; 95% CI) of Programs With 30-Hour Violations</th>
<th>No. (%; 95% CI) of Programs With 80-Hour Violations</th>
<th>No. (%; 95% CI) of Programs With 7-Day Violations</th>
</tr>
</thead>
<tbody>
<tr>
<td>Family medicine</td>
<td>76</td>
<td>66 (86.8; 77.4-92.6)</td>
<td>58 (76.3; 65.6-84.4)</td>
<td>53 (69.7; 58.8-78.9)</td>
<td>41 (63.9; 42.8-64.7)</td>
</tr>
<tr>
<td>Internal medicine</td>
<td>105</td>
<td>99 (94.3; 88.1-97.3)</td>
<td>89 (84.8; 76.6-90.4)</td>
<td>90 (85.7; 77.7-91.1)</td>
<td>53 (50.5; 41.0-69.9)</td>
</tr>
<tr>
<td>Preliminary medicine year</td>
<td>64</td>
<td>54 (84.4; 73.5-91.2)</td>
<td>45 (70.3; 58.2-80.1)</td>
<td>46 (71.9; 59.8-81.4)</td>
<td>29 (45.3; 33.7-57.5)</td>
</tr>
<tr>
<td>Medicine-pediatrics</td>
<td>19</td>
<td>18 (94.7; 75.1-98.8)</td>
<td>17 (89.5; 68.3-96.6)</td>
<td>14 (73.7; 50.9-88.1)</td>
<td>12 (63.2; 40.8-80.9)</td>
</tr>
<tr>
<td>Pediatrics</td>
<td>81</td>
<td>74 (91.4; 83.2-95.7)</td>
<td>62 (76.5; 66.2-84.4)</td>
<td>64 (79.0; 68.9-86.4)</td>
<td>44 (54.3; 43.5-64.7)</td>
</tr>
<tr>
<td>Emergency medicine</td>
<td>44</td>
<td>40 (90.9; 78.8-96.2)</td>
<td>35 (79.5; 65.4-88.6)</td>
<td>32 (72.7; 58.1-83.6)</td>
<td>23 (52.3; 37.9-66.3)</td>
</tr>
<tr>
<td>Transitional year</td>
<td>54</td>
<td>48 (88.9; 77.8-94.7)</td>
<td>42 (77.8; 65.0-86.8)</td>
<td>36 (66.7; 53.3-77.8)</td>
<td>20 (37.0; 25.4-50.4)</td>
</tr>
<tr>
<td>Obstetrics/gynecology</td>
<td>47</td>
<td>33 (70.2; 55.9-81.3)</td>
<td>22 (46.8; 33.3-60.6)</td>
<td>27 (57.4; 43.2-70.5)</td>
<td>22 (46.8; 33.3-60.6)</td>
</tr>
<tr>
<td>Pathology</td>
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<td>3 (15.0; 5.4-36.3)</td>
<td>8 (40.0; 21.8-61.6)</td>
</tr>
<tr>
<td>Psychiatry</td>
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<td>31 (86.1; 71.2-93.8)</td>
<td>25 (69.4; 53.0-82.0)</td>
<td>18 (50.0; 34.4-65.6)</td>
<td>21 (58.3; 42.1-72.9)</td>
</tr>
<tr>
<td>General surgery</td>
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<td>51 (79.7; 68.2-88.0)</td>
<td>39 (60.9; 48.6-72.0)</td>
<td>43 (67.2; 54.9-77.4)</td>
<td>40 (62.5; 50.2-73.3)</td>
</tr>
<tr>
<td>Preliminary surgery year</td>
<td>35</td>
<td>32 (91.4; 77.5-96.5)</td>
<td>22 (62.9; 46.2-76.9)</td>
<td>27 (71.1; 60.8-87.9)</td>
<td>23 (65.7; 49.0-79.2)</td>
</tr>
<tr>
<td>Other residency</td>
<td>62</td>
<td>48 (77.4; 65.5-86.0)</td>
<td>39 (62.9; 50.4-73.9)</td>
<td>40 (64.5; 52.0-75.3)</td>
<td>24 (38.7; 27.6-51.2)</td>
</tr>
<tr>
<td>Total</td>
<td>707</td>
<td>604 (85.4; 82.6-87.8)</td>
<td>496 (70.2; 66.7-73.4)</td>
<td>483 (69.7; 66.2-73.0)</td>
<td>360 (50.8; 47.2-54.6)</td>
</tr>
</tbody>
</table>

Abbreviations: ACGME, Accreditation Council for Graduate Medical Education; CI, confidence interval.
Table 3. Number of Hospitals with Interns Reporting Violations of the ACGME Work Hour Rules by State/Commonwealth, 2003-2004

<table>
<thead>
<tr>
<th>State/Commonwealth</th>
<th>No. of Represented Hospitals</th>
<th>Hospitals With Any ACGME Violations</th>
<th>Hospitals With 30-Hour Violations</th>
<th>Hospitals With 80-Hour Violations</th>
<th>Hospitals With 7-Day Violations</th>
</tr>
</thead>
<tbody>
<tr>
<td>Alabama</td>
<td>5</td>
<td>4 (80.0)</td>
<td>4 (80.0)</td>
<td>4 (80.0)</td>
<td>2 (40.0)</td>
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<tr>
<td>Arizona</td>
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<td>7 (100.0)</td>
<td>7 (100.0)</td>
<td>7 (100.0)</td>
<td>5 (71.4)</td>
</tr>
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<td>3 (100.0)</td>
<td>2 (66.7)</td>
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</tr>
<tr>
<td>California (Northern)</td>
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<td>18 (90.0)</td>
<td>18 (90.0)</td>
<td>17 (85.0)</td>
<td>12 (60.0)</td>
</tr>
<tr>
<td>California (Southern)</td>
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<td>24 (100.0)</td>
<td>24 (100.0)</td>
<td>22 (91.7)</td>
<td>14 (58.3)</td>
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<td>5 (100.0)</td>
<td>4 (80.0)</td>
<td>5 (100.0)</td>
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<td>5 (83.3)</td>
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<td>3 (50.0)</td>
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<td>2 (100.0)</td>
<td>2 (100.0)</td>
<td>2 (100.0)</td>
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<tr>
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<td>3 (100.0)</td>
<td>3 (100.0)</td>
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<td>6 (100.0)</td>
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<td>4 (66.7)</td>
</tr>
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<td>1 (33.3)</td>
<td>1 (33.3)</td>
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<td>1 (100.0)</td>
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<tr>
<td>Illinois</td>
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<td>9 (56.3)</td>
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<td>2 (66.7)</td>
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<td>2 (66.7)</td>
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<tr>
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<td>6 (60.0)</td>
<td>5 (50.0)</td>
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<tr>
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<td>17 (81.0)</td>
<td>17 (81.0)</td>
<td>13 (61.9)</td>
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<tr>
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<td>Wisconsin</td>
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<td>6 (85.7)</td>
<td>7 (100.0)</td>
<td>5 (71.4)</td>
</tr>
<tr>
<td><strong>Subtotal (percent with violations; 95% CI)</strong></td>
<td><strong>314</strong></td>
<td><strong>289 (82.0; 58.5-94.5)</strong></td>
<td><strong>264 (84.1; 79.6-87.7)</strong></td>
<td><strong>250 (82.8; 78.2-86.5)</strong></td>
<td><strong>201 (64.0; 58.6-69.1)</strong></td>
</tr>
<tr>
<td>New York*</td>
<td>29</td>
<td>23 (82.1)</td>
<td>12 (41.4)</td>
<td>22 (75.9)</td>
<td>17 (58.6)</td>
</tr>
<tr>
<td>Puerto Rico*</td>
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<td>2 (66.7)</td>
<td>0 (0.0)</td>
<td>1 (33.3)</td>
<td>2 (66.7)</td>
</tr>
<tr>
<td><em><em>New York and Puerto Rico</em> (percent with violations; 95% CI)</em>*</td>
<td><strong>32</strong></td>
<td><strong>25 (78.1; 51.1-85.9)†</strong></td>
<td><strong>12 (37.5; 22.9-54.9)‡</strong></td>
<td><strong>23 (71.9; 54.4-84.4)¶</strong></td>
<td><strong>19 (59.4; 42.1-74.5)</strong></td>
</tr>
<tr>
<td><strong>Total (percent with violations; 95% CI)</strong></td>
<td><strong>346</strong></td>
<td><strong>314 (90.8; 87.2-93.3)</strong></td>
<td><strong>276 (79.5; 75.2-83.7)</strong></td>
<td><strong>283 (81.8; 77.4-85.5)</strong></td>
<td><strong>220 (63.6; 58.4-68.5)</strong></td>
</tr>
</tbody>
</table>
New Sleep Awareness Program Aimed at Residents and Shift Workers

Abbreviations: ACGME, Accreditation Council for Graduate Medical Education; CI, confidence interval.
*New York and Puerto Rico are the only two state/commonwealth governments in the U.S. that currently have laws enforcing work hour limits (80 hour maximum per week, average over 4 weeks, and no more than 24 consecutive hours). Violating hospitals in New York are subject to civil penalties; violating hospitals and residents in Puerto Rico are subject to civil penalties.

Interns’ Sleep and Work, Pre- vs Post-ACGME Duty-Hour Standards

Interns’ reported mean weekly work hours (excluding vacation time and extended leave) decreased 5.8% following implementation of the ACGME standards from 70.7 hours (95% CI, 70.5-70.9) to 66.6 hours (95% CI, 66.3-66.9) ($P<.001$) (Table 4). Of the 63,455 reported work weeks of interns in the preimplementation group, 25,313 (40.0%; 95% CI, 39.5%-40.3%) were more than 80 hours per week; 15,509 (24.4%; 95% CI, 24.1%-24.8%) were 90 or more hours per week, and 7,098 (11.2%; 95% CI, 10.9%-11.4%) were 100 or more hours per week. In comparison, of the 31,256 reported work weeks of interns in the postimplementation group, 9,141 (29.0%; 95% CI, 28.7%-29.7%) were more than 80 hours per week, 3,815 (12.1%; 95% CI, 11.8%-12.6%) were 90 or more hours per week, and 1,235 (3.9%; 95% CI, 3.7%-4.2%) were 100 or more hours per week ($P<.001$ for each category).

Table 4. Duration of Interns’ Reported Work and Sleep, Preimplementation vs. Postimplementation of the ACGME Duty Hour Standards

<table>
<thead>
<tr>
<th></th>
<th>Preimplementation (95% CI)</th>
<th>Postimplementation (95% CI)</th>
<th>Change, %</th>
<th>$P$ Value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Mean No. of weekly work hours*</td>
<td>70.7 (70.5-70.9)</td>
<td>66.6 (66.3-66.9)</td>
<td>-5.8</td>
<td>&lt;.001</td>
</tr>
<tr>
<td>Mean duration of extended work shifts, h</td>
<td>32.1 (32.0-32.2)</td>
<td>29.9 (29.8-30.0)</td>
<td>-6.9</td>
<td>&lt;.001</td>
</tr>
<tr>
<td>Mean longest period with no sleep, h</td>
<td>25.3 (25.1-25.4)</td>
<td>24.9 (24.7-25.0)</td>
<td>-1.6</td>
<td>.25</td>
</tr>
<tr>
<td>Mean nightly sleep duration, h</td>
<td>5.91 (5.88-5.94)</td>
<td>6.27 (6.23-6.31)</td>
<td>+6.1</td>
<td>&lt;.001</td>
</tr>
<tr>
<td>Mean nightly sleep during extended shifts, h</td>
<td>2.69 (2.66-2.73)</td>
<td>2.57 (2.52-2.62)</td>
<td>-4.5</td>
<td>&lt;.001</td>
</tr>
</tbody>
</table>

Abbreviations: ACGME, Accreditation Council for Graduate Medical Education; CI, confidence interval.
*Excludes vacation weeks and leaves of absence.
Following implementation, the mean reported duration of extended work shifts decreased 6.9% from 32.1 (95% CI, 32.0-32.2) hours to 29.9 (95% CI, 29.8-30.0) hours (P<.001) (Table 4). In weeks with extended duration work shifts, the weekly mean length of extended duration work shifts was reported to exceed 30 hours on 56.1% of weeks before and 22.5% of weeks after implementation of the 30-hour rule (P<.001). The longest number of hours in a month that interns reported remaining continuously awake was not significantly changed (25.3 [95% CI, 25.1-25.4] vs 24.9 [95% CI, 24.7-25.0] hours; P = .25). Postimplementation, reported mean nightly sleep increased 6.1% (22 minutes) from 5.91 (95% CI, 5.88-5.94) hours to 6.27 (95% CI, 6.23-6.31) hours per night (P<.001); reported sleep during extended shifts, however, decreased 4.5%, from 2.69 (95% CI, 2.66-2.73) hours to 2.57 (95% CI, 2.52-2.62) hours (P<.001).

Comment

In this cohort study, 83.6% of participating interns reported working hours that were noncompliant with the ACGME duty-hour standards during at least 1 month in the year following their introduction. Violations were reported during 44.0% of intern-months, including inpatient months as well as months with vacations, electives, and ambulatory rotations; violations were reported during 61.5% of all intern-months worked exclusively in inpatient settings.

Violations of the 30-hour rule remained common following implementation of the standards, despite the mean decrease of 6.9% in the length of extended duration work shifts. The weekly mean length of reported extended duration shifts postimplementation exceeded 30 hours during 22.5% of all intern-weeks. Reports of working patterns that violated the 80-hour rule likewise remained common, even though having up to 3 weeks in a row that each exceed 80 hours is permissible under current ACGME standards and was not counted as a violation. Because interns are considered to be in violation of the 80-hour and 7-day rules only if work hours exceed these limits averaged over 4 weeks, there was by definition only 1 opportunity per 4 weeks per intern for such violations to occur. Therefore, the reported rates of 80-hour and 7-day violations per intern-month (21.8% and 9.9%, respectively) and per inpatient intern-month (38.7% and 13.0%, respectively) represent not only the total percentage of months during which interns were in violation of these rules but also the absolute rate of violations per opportunity.

There are limitations that need to be considered in interpreting this study. First, although the number of interns (4015) who enrolled was large, they represented only a small percentage (10.8%) of all potential interns. Our method of recruitment is similar to that of large epidemiological studies,
such as the Nurses Health Study II, in which advertisements were sent to a large number of potential participants nationwide, in the expectation that only a small percentage would enroll. Although selection bias may have occurred, we believe that the study design reduced that possibility and that these data are likely to be informative regarding compliance with ACGME standards. Interns were recruited prospectively before commencing their internships and therefore as a group should not have been biased by dissatisfaction with their residency program. During recruitment and after entering the study cohort, they were not made aware of our study aim to measure compliance, and they were administered many distractor questions alongside key questions. Although not all questions regarding work and sleep patterns were validated, the measures of total work hours and number of extended work shifts underwent a 2-step validation process that provides supporting evidence for the accuracy of the reported work hours.

Second, because not all monthly surveys were completed, reporting bias may have occurred. Several participants reported that they could not complete work-hour reports during their busiest months, indicating that our data may underestimate the actual rate of violations. Furthermore, although we were able to provide assurances of data confidentiality, some interns may have been reluctant to report violations since data collection was not anonymous.

Third, we did not have access to the identities of the few programs granted exceptions to the 80-hour rule by the ACGME, which allows residents to work up to 88 hours. Because only 75 (0.9%) of 7973 of accredited programs were granted exceptions in 2003-2004, this information would be unlikely to alter our calculated rates of violations substantially. Fourth, while the diversity and large total number of interns in the study allow us to present state and specialty-specific data, our program-level and hospital-level analyses were not adequately powered to provide reliable data on individual programs.

Finally, our data reflect the effects of the ACGME duty-hour standards in their first year only. Compliance may increase over time as programs learn to adapt to these regulations; indeed, we found a trend toward decreasing noncompliance, although the monthly rates of noncompliance at the end of the academic year remained high. Further studies of the longer-term effects of the ACGME duty-hour standards using a validated instrument are warranted.

Our results are notably different from those of the ACGME, which found in its national survey of residents that only 3.3% were noncompliant with the 80-hour rule. Similarly, in full reviews of 2027
residency programs nationwide, the ACGME cited only 2.6% of residency programs for noncompliance with the 80-hour rule, 1.3% of programs for noncompliance with the 30-hour rule, and 1.4% of programs for noncompliance with the 7-day rule.8

Much of the difference in our results is likely explained by differences in survey method. We estimated violations using open-ended questions principally directed toward accurately measuring work and sleep hours. The questions in the ACGME survey directly assessed noncompliance: “[During the previous 4 week rotation], on average, excluding call from home, how many hours were you on duty per week?”; “How many times did you work more than 30 continuous hours?”; and “How many days (24-hour periods) did you have completely free from all educational and clinical responsibilities?”22 Such closed-ended inquiries may have limited the accuracy of responses, and framing the questions about noncompliance may have altered reporting. In addition, our study investigated interns only, whereas the ACGME evaluated the work hours of residents at all postgraduate levels.

Although by mandating participation, the ACGME achieved a very high response rate (89%),23 residency programs and residents themselves face a direct conflict of interest in acknowledging violations to the ACGME,14 because the identities of those reporting violations have not been adequately protected in the past.24 Because disclosure of violations to the ACGME could lead to loss of program accreditation, disclosure could threaten residents' own careers.

The ACGME asked residents to report violations during the prior 4 weeks, whereas we captured work hours longitudinally over a year. Consequently, we had many more opportunities to capture reports of violations. However, this cannot explain all of the discrepancy in rates, because even on a per 4-week basis, we found more than 10 times as many interns to be in violation than did the ACGME. Finally, vacation is not included by the ACGME in its counting of duty-hour compliance. Although inclusion of vacation has the effect of lowering rates of noncompliance, this difference in methods would tend to narrow differences in results. Moreover, we found markedly higher rates even when excluding vacation months.

Several studies have reported work hours and noncompliance rates exceeding those reported by the ACGME, but most have been limited to single medical centers or specialties and have not used validated instruments. Studies of pediatric, neurology, and otolaryngology residents have found 10% to 39.5% reported noncompliance with the 80-hour rule, and 22% to 50% noncompliance with the 30-hour rule.11-13 In a cross-
sectional study, the American Medical Association found that 11% of 1010 residents reported working more than 80 hours per week during their most recent rotation.14 Our study adds to this literature by providing prospective, longitudinal data on the work hours and compliance rates of a national multispecialty cohort of interns, both before and after the implementation of the ACGME duty-hour standards, using self-reports that have had objective validation.

The ACGME developed the duty hour standards out of concern for the effects of excessive resident work hours on patient and resident safety.25 Staying awake for 24 consecutive hours induces decrements in human performance similar to a blood alcohol level of 0.10%;26 despite often obtaining some sleep while on call, residents working 24-hour overnight shifts in the hospital every 4th to 5th night perform similarly to those with a blood alcohol level of 0.04% to 0.05%.27 Interns working traditional 24-hour to 30-hour shifts make significantly more serious medical errors than those whose consecutive work is limited to 16 scheduled hours,28 and they have more than twice the odds of having a motor vehicle crash on the drive home from work.17 A recent meta-analysis of studies investigating the effects of sleep loss on performance found that 24 hours of consecutive sleep loss reduced physicians’ clinical performance to the 7th percentile of their performance when rested.29 In light of these studies, further reductions in current limits on consecutive duty hours appear to be needed.

There are several reasons why rates of noncompliance may be high. First, the ACGME duty-hour standards were unaccompanied by financial and technical support. Programs may not have the resources or expertise to redesign their schedules to the extent required. In addition, house officers are typically unwilling to depart precipitously at the scheduled change of shift when an emergent patient care situation demands their continued presence.18 Such situations are common in high intensity settings, yet most scheduling systems do not account for these commonplace emergencies. Rather, house officers are routinely scheduled to be working up until the minute of their sign out, a situation that could predictably lead to overstaying work limits. Multicenter studies of the changes implemented at various medical centers are needed to better understand program-level successes and reasons for noncompliance.

Noncompliance also might be due to attitudes within an institution’s medical culture. Some senior physicians have expressed disapproval of work-hour limits,30,31 and there exists a widespread perception among many physicians that fatigue is not a problem14,25 despite the accumulation of considerable evidence to the contrary. Concerns about continuity of care and sign out32 may slow adoption of reduced-hour
work schedules, particularly in settings in which robust sign-out tools have not been implemented, and in which teamwork training and functioning is limited.

In the United Kingdom, physicians’ work was limited recently to 13 consecutive hours and 58 hours per week by law. By contrast, the ACGME duty-hour standards continue to permit 30 consecutive hours of work and 80 hours per week, yet even these relatively mild limits have not been consistently achieved. Even though the downward trend in noncompliance during the first year following implementation of the standards is encouraging, the decrease has been modest, and noncompliance remains common. To achieve further reductions in work hours consistent with current best evidence, additional efforts to implement safe schedules are needed, as is research into reasons for noncompliance.

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