Final Progress Report:

Implementing Reduced Work Hours for All House Staff to Improve Patient Safety

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Structured Abstract (200 words maximum)

Purpose: The purpose of this Partnerships in Implementing Patient Safety (PIPS) Project was to study the effectiveness of implementing evidence-based reductions in resident-physician work hours and to disseminate information on best practices in work hour redesign.

Scope: A pilot project was carried out at Brigham and Women's Hospital (BWH) to test the effects of reducing work hours, in a sustainable and culturally acceptable manner, on patient safety and resident care experience. Concurrently, a web-based toolkit was developed to aid in the dissemination of best practices in work-hour reduction.

Methods: We conducted a prospective intervention trial in the Surgical Intensive Care Unit at BWH. Work hours, sleep hours, and physician experiences pre- and post-intervention were collected using daily logs and surveys. Errors were collected using an established multifaceted surveillance methodology. A toolkit was developed to facilitate dissemination of best practices.

Results: Sixty-one residents and senior physicians consented to participate in the study pre-intervention (Apr-June 2006); 60 residents, physicians, and physician extenders participated post-intervention (Apr-June 2009). Data on medical errors were collected for 3 months pre-intervention and 3 months post-intervention; analyses are ongoing. The toolkit went live in December 2007.

Key Words: resident, intern, work hours, sleep, sleep deprivation

Purpose (Objectives of the study)

The overall purpose of this Partnerships in Implementing Patient Safety (PIPS) Project was to study the effectiveness of implementing evidence-based reductions in resident-physician work hours and to disseminate information on best practices in work-hour redesign. Physicians-in-training (residents; house staff) work some of the most demanding schedules known. Frequent work shifts of 30 consecutive hours lead to decrements in performance due to acute and chronic sleep deprivation, misalignment of circadian phase, and sleep inertia. Patients expect physicians to perform flawlessly, but sleep deprivation degrades residents' cognition, alertness, and reaction time, leading to attentional failures and serious medical errors. Medical errors are an important public health hazard, as they may cause up to 44,000-98,000 deaths and more than a million injuries each year. Despite the demonstrated benefits of eliminating extended duration shifts, however, residents continue to work 24 to 30 consecutive hours in most teaching hospitals in the United States, including our own. Such extremely extended shifts continue to be permitted by the Accreditation Council for Graduate Medical Education under the duty hour standards implemented in July 2003 for all residents nationwide (1), despite mounting evidence that they are unsafe. To evaluate the effectiveness of implementing reduced resident work-hour schedules that address these limitations, we carried out a study with the following **Specific Aims:**

1. To implement new house staff work schedules in three surgical ICUs, which will eliminate extended shifts for all interns, junior residents, and senior residents in these settings.

2. To test the hypothesis that, compared with a traditional schedule, mean house staff sleep duration as well as serious medical error rates will improve with implementation of the new schedule.

In addition, we developed a toolkit with the purpose of aiding program directors and others seeking guidance on how to implement evidence-based reductions in resident work hours.

Scope (Background, Context, Settings, Participants, Incidence, Prevalence)

In 1999, the Institute of Medicine reported that 44,000 to 98,000 patients are killed each year due to medical error. Subsequent studies have found reductions in serious medical errors following implementation of computerized order entry systems (2-5), employment of clinical pharmacists to monitor medication orders (6), and adoption of structured patient sign-out systems (7), to name but a few. Despite this accumulation of knowledge, however, patient safety in the United States remains largely unchanged. (8;9) In large measure, this stagnancy has been due to difficulties in overcoming financial and cultural barriers to adoption and implementing proven patient safety interventions. (10)

Over the past several years, several studies have demonstrated the effectiveness of interventions intended to reduce rates of errors. Both computerized physician order entry and ward-based clinical pharmacists have been shown to decrease serious medication errors. Bates and colleagues have demonstrated that computer order entry decreased rates of serious medication errors by 55% initially and 81% following full implementation of iterative improvements in decision support; rates of all medication errors fell 83%. (2;3) These findings have been substantiated elsewhere. (11-14) Leape et al. found that clinical pharmacists participating in ICU rounds decreased preventable ADE rates by 66%. (6)

The use of an enhanced, structured computer sign-out has been found to reduce the risk of adverse events attributable to cross-coverage of patients by house staff less familiar with them (OR, 1.5; 95% CI, 0.2-9.0).(7)

Until a few years ago, data directly linking sleep deprivation with medical errors was lacking, as documented in an AHRQ-sponsored review in 2002 (15) and subsequently replicated elsewhere. (16-19) Our prior work (20) has helped link data on sleep deprivation accumulated in nonmedical settings (described below) with data on patient safety.

Resident work hours. Residents, or post-graduate medical trainees, work some of the longest hours in our society; 80-hour workweeks are typical, with 30-hour-long work shifts work occurring approximately twice per week in many settings. Though the links between sleep deprivation and medical error rates have only recently been definitively established in clinical settings, the adverse neurocognitive effects of sleep deprivation and its impact on performance has been thoroughly proven in many other industries. An abundance of data exist demonstrating the adverse effects of sleep deprivation on simulated medical tasks as well.

Sleep deprivation and performance. There are four principal physiological determinants of alertness and performance: 1) circadian phase; 2) number of consecutive hours awake (sleep homeostat); 3) nightly sleep duration (chronic partial sleep deprivation); and 4) sleep inertia. Each of these factors can be adversely affected by working night shifts, rotating shifts, or extended weekly hours, and each can be exacerbated more by sleep disorders. Their combined effect creates an imposing biological force that can overpower a resident's ability to remain alert and to maintain a high level of performance, leading to increased risk of accidents, errors, and injuries on the job and decreased job performance.

Impact of circadian misalignment on neurobehavioral performance and sleep. Laboratory (21-23) and field studies (24;25) have shown that, during extended wakefulness, alertness and performance show a daily variation as well as an overall decline.(26) Residents working overnight frequently perform critical tasks at adverse circadian phases, when the tendency to sleep is at a peak. Performance at an adverse circadian phase is particularly impaired among residents who are acutely or chronically sleep deprived, whose nadir of performance will be significantly worse than that of their more rested peers.(27;28)

Acute and chronic sleep deprivation. Acute sleep deprivation has been systematically documented to cause decrements in human alertness and performance, independent of the circadian system. (21;26;29-37) Each consecutive hour awake induces increasing decrements in performance. In addition, the history of nightly sleep duration affects performance. Sleep loss on a nightly basis, also known as chronic partial sleep deprivation, results in a sleep “debt.” The consequences of the sleep debt are cumulative and affect health and performance.(38-46)

Sleep inertia. In addition to these factors, alertness and performance are quite impaired immediately following awakening (47), even in subjects who are not sleep deprived and are waking at their normal circadian phase.(28;48;49) This impairment is called sleep inertia (50) and can profoundly impair performance.

Sleep deprivation and night work in other high-risk occupations: safety implications. Night work and sleep deprivation have been implicated as root causes of accidents and adverse events in nuclear power plants, transportation, and other industries.(51) Disastrous examples include the Three Mile Island nuclear power plant incident, the Chernobyl nuclear power plant explosions, and the grounding of the oil tanker Exxon Valdez. Studies have shown that gas meter readers (52) and train drivers (53) make more errors during the night shift, likely due to increased sleepiness.(51) Rosekind et al.

documented increased sleepiness, microsleeps, and performance lapses among commercial pilots working during the night.(54)

Shift workers, particularly night shift workers who invert their normal sleep/wake schedule, suffer for several reasons. First, their endogenous circadian rhythms and the imposed sleep/work schedule are typically out of phase. For the shift worker, the timing of meals, work, and sleep remain perpetually out of phase with the timing of environmental light, which is the most powerful synchronizer of the human circadian pacemaker.(55-75;75-81) This probably accounts for the observation that most permanent shift workers fail to adapt completely.(82-84) Second, this circadian misalignment leads to a substantial loss of sleep efficiency during the (daytime) sleep period (85), independent of, and in addition to, environmental obstacles to sleep (e.g., noise, light). Finally, night shift workers typically begin their work day 8-10 hours after awakening (86), leaving them with more accumulated homeostatic pressure to sleep at the beginning of their night work shift compared with day workers.

Motor Vehicle Accidents. Traffic accidents represent one of the leading causes of death among individuals aged 6-33 years (87), and, as described below, are a major hazard for physicians in training. Cognitive performance impairment after 19 hours of sustained wakefulness has been reported to be comparable to that observed at a blood alcohol concentration of 0.05%; after 24 hours of sleep deprivation, cognitive performance decrements were comparable those observed at a blood alcohol concentration of 0.10% (88), a level higher than that defined as legally drunk (0.08%) in the US. In a survey study, 21.7% of rotating shift workers reported at least one motor vehicle crash or near miss, whereas only 7.2% of nonrotating shift workers recalled such an event. (89) Nurses working rotating shift schedules had twice the odds of falling asleep while driving to and from work and 2.5 times the odds of a reporting a near-miss crash.(90) In our prior work studying medical residents, we found that residents driving home after an extended duration work shift had more than twice the risk of a car crash and six times the risk of a near-miss accident.(91)

Resident performance and sleep. Many studies have attempted to assess the performance of fatigued residents working extended shifts and long work weeks. Performance measures studied have included reaction time tests, memory tasks, and manual dexterity tasks. Though a few have failed to demonstrate a decrement in performance (132-134), most have found a significant deterioration in performance on one or more tasks.(135-141).

Fatigue intervention strategies. Although the effects of shift work on sleep, alertness, performance, and health have been well documented, there have been fewer systematic assessments of interventions implemented to reduce the adverse effects of sleep deprivation. In the earliest published shift work intervention study in 1982, Czeisler et al. were able to improve work schedule satisfaction, subjective health estimates, personnel turnover, and worker productivity in a group of mining and chemical workers by implementing a work schedule that adhered to circadian principles.(92) In a similar demonstration project of the Philadelphia Police Department in 1988, Czeisler implemented a schedule that resulted in a 40% decrease in patrol car crashes by police officers and 29% improvement in subjective alertness during the night shift.(93)

Preliminary Studies. We conducted a series of experiments that informed the current intervention project. In 2001, our team members founded the **Harvard Work Hours, Health, and Safety Group**, a multidisciplinary collaborative whose mission is to investigate sleep and work practices among physicians, police officers, and other occupational groups and to implement strategies to improve the safety of patients, workers, and the general public. This collaborative effort led to the Intern Sleep and Safety Study, funded by AHRQ (94;95), a national survey study of interns (96), as well as

ongoing investigations funded by the National Institute of Justice and the Centers for Disease Control into the causes and consequences of sleep deprivation among police officers.

Harvard Work Hours, Health, and Safety Study I: Intern Sleep and Patient Safety Study. In 2001, we conducted a randomized controlled trial to test the effect on intern sleep and patient safety of an intervention schedule that limited interns' work to ≤16 consecutive hours, and reduced weekly work hours.Sleep and work hours were rigorously documented using daily logs validated by use of electroencephalography (EEG) and third-party confirmation of work hours. Errors were detected using a four-pronged data collection methodology that included trained physician observers continuously monitoring the performance of the interns around the clock as well as daily medical record review. All suspected errors were rated by two independent reviewers blinded as to study condition. The intervention schedule was found to reduce weekly work hours from 85 to 65 per week, increase sleep duration by approximately 1 hour per night, and significantly reduce (by more than half) the occurrence of objectively documented attentional failures during night work hours. With respect to patient safety, interns made 35.9% more serious medical errors and 5.6 times as many serious diagnostic errors on the traditional schedule compared with the intervention schedule. (97;98)

Harvard Work Hours, Health, and Safety Study II: A Nationwide Study of Interns' Sleep and Safety. Concurrently, we conducted a prospective, nationwide, web-based survey of 2,737 medical residents in their first postgraduate (intern) year after medical school. The survey collected detailed information on work hours, extended duration work shifts, motor vehicle crashes, near-miss accidents, medical errors, percutaneous injuries (i.e., injuries from needle sticks and scalpel laceration), and 'fall-asleep' incidents. Motor vehicle crash risk during the commute from work was more than doubled, and near-miss motor vehicle accident risk increased nearly six-fold, following extended-duration shifts compared to non-extended-duration shifts. (99) In addition, the odds of a needlestick injury, of making a reported medical error, and of having an on-the-job fall-asleep incident also significantly increased in months with extended duration work shifts. (100) By their own reports, the odds of interns making a fatigue-related error that injured or killed a patient also increased with multiple 24-hour or longer shifts in a month. (101)

Effects of the ACGME Duty-Hour Standards. In addition, we conducted studies evaluating the effect of the Accreditation Council for Graduate Medical Standards on actual work and sleep hours as well as interns' compliance with the standards. Compliance was poor, with 84% of interns reporting work hours in violation of one of the three major work-hour standards following their implementation. (102) Actual work hours decreased only modestly in our nationwide survey study (102) and not at all according to a more intensive study conducted in three academic medical centers. (103)

In light of these prior studies, as well as the broader literature on the effects of circadian misalignment and sleep deprivation on performance, we sought to develop and study a sustainable intervention that would reduce resident work hours as a means of improving patient safety.

Methods (Study Design, Data Sources/Collection, Interventions, Measures, Limitations)

With a multidisciplinary team composed of experts in patient safety, sleep and circadian biology, intensive care medicine, anesthesiology, and surgery, we designed and implemented schedules that eliminated all 30-hour-long extended shifts for all staff in three surgical ICUs at Brigham and Women's Hospital. Prior to the implementation of this intervention, data on baseline patient safety in the three units were collected from April to June 2006. Development of the intervention itself,

which involved designing and refining the planned schedule several times, the hiring of two nurse practitioners, and two physicians' assistants, and the mobilization of an additional resident from another rotation (the costs of which were all borne by the involved departments at BWH), was implemented over the subsequent 2.5 years. Post-intervention data were collected from April to June 2009, intentionally matched by season with the pre-intervention data to control both for learning effects over the course of the year and seasonal variation in illness. A detailed description of the methods used in recruiting participants and collecting data for the study follow.

Subjects. We sought to recruit all residents, fellows, nurse practitioners (NPs), physicians' assistants (PAs), and attending physicians working in the SICUs during our data collection months to provide us detailed information on their work hours and sleep and to allow us to observe them each day on rounds. We collected data from all consenting physicians and "physician extenders" (PEs). "PEs" refers both to NPs and PAs. Attendings and fellows were recruited as subjects so that we could measure their work hours and sleep, to measure whether development of our resident/PA/NP focused intervention had an effect on their work and sleep patterns.

Recruitment. To recruit volunteers, we relied on established methods, which we have successfully used during our prior studies of BWH interns. (103) Working with the unit directors, we made presentations each month of the data collection period to the physicians and PEs working in our study units. All applicants were considered regardless of race, ethnicity, national origin, or gender.

Medical Condition. Staff must have a medical exam before beginning work at BWH; suitability for hospital employment was used to determine medical eligibility for study participation. Information regarding current medication/drug usage was recorded. Nicotine, alcohol, or other compounds (including herbal medications/remedies) were not restricted during the study.

Compensation. Monetary compensation for participation in the intervention study was provided ($200 per subject).

Preparation of subjects. Before the start of each study, volunteers received a detailed explanation of the special procedures involved in the study. They were shown the logs and performance tests before making a commitment to participate. Every attempt was made to acquaint each prospective subject with all of the procedures involved in this study in order to minimize the possible effect of uncertainty about the experimental procedures on the results. They were informed that they were free to discontinue participation in the experiment at any time should they wish to do so and that the investigators reserved the right to discontinue their participation in the research protocol at any time. Written informed consent was obtained from each subject before his/her study began.

Protocol. Patient safety data collected during the baseline period were compared with data collected using identical methodology during the post-intervention period in each of the three units where a schedule intervention was made.

Intervention study environment and conditions. The interventions and study took place in three surgical ICUs (7c, 7d, and 11c) at Brigham and Women's Hospital. In general, subjects continued with their normal activities and carried out their normal responsibilities.

11c Schedule. The new 11c schedule eliminated 24-hour shifts for all residents by adding an extra resident to the rotation, which allowed for equivalent staff coverage as the traditional system, with each resident working shorter shifts. This was done as a modified version of our prior intervention in the ICU and CCU at BWH several years ago by dividing the traditional 30-hour call roughly in half; a "night call" resident who was part of the regularly weekly day team came on duty to relieve the "day call" team at 5:00 pm (see **Figure 1** below, showing the schedule for 1 month in the unit). As in our prior rotation, this resulted in the same number of house staff on duty at any given time, but shorter work hours for all. There was an enhanced sign-out process in the evening in this study,

supervised by attendings/fellows.

To minimize the sign-out problems that accompanied our prior intervention, we put a formal, enhanced sign-out system into place. Residents signed out using both a written and verbal sign-out of all patients, supervised by an attending physician and/or fellow. We trained all house staff in the employment of the best practices as described in the background section, including use of a structured sign-out template.

	SUN	MON	TUE	WED	THUR	FRI	SAT
	1-Feb	2-Feb	3-Feb	4-Feb	5-Feb	6-Feb	7-Feb
11C Day 7a-7p		R2	R4	R3	R1	R2	R4
11C Night 5p-10a	R4	R3	R1	R2	R4	R3	R1
11C Swing 7a-3p				R4	R3	R1	
	8-Feb	9-Feb	10-Feb	11-Feb	12-Feb	13-Feb	14-Feb
11C Day 7a-7p	R3	R1	R2	R4	R3	R1	R2
11C Night 5p-10a	R2	R4	R3	R1	R2	R4	R3
11C Swing 7a-3p				R2	R4	R3	
	15-Feb	16-Feb	17-Feb	18-Feb	19-Feb	20-Feb	21-Feb
11C Day 7a-7p	R4	R3	R1	R2	R4	R3	R1
11C Night 5p-10a	R1	R2	R4	R3	R1	R2	R4
11C Swing 7a-3p				R1	R2	R4	
	22-Feb	23-Feb	24-Feb	25-Feb	26-Feb	27-Feb	28-Feb
11C Day 7a-7p	R2	R4	R3	R1	R2	R4	R3
11C Night 5p-10a	R3	R1	R2	R4	R3	R1	R2
11C Swing 7a-3p				R3	R1	R2	

Figure 1. *11c Schedule. Four residents (R1, R2, R3, R4) share coverage over the course of the month, working a series of 12-hour day shifts (Day), 17-hour night shifts (Night), and 8-hour day shifts (Swing).*

7c and 7d Schedule. The new 7c and 7d schedule likewise eliminated extended shifts but with more substantially altered staffing. Two NPs and two PAs were hired to rotate between the two units and share direct care responsibilities with the residents, allowing residents to work fewer hours per week and eliminating 24-hour shifts. As in 11c, residents in the new 7c/7d system were scheduled to work no more than 17 consecutive hours and rotated through day and night shifts, as in the CCU. NPs and PAs covered the majority of daytime work hours, as depicted in **Figure 2** below. NPs and PAs rotated back and forth from 7c to 7d every couple of weeks, with time off occurring between unit switches; residents were assigned to either 7c or 7d for a 1-month period. As in 11c, rounds occurred twice per day, and residents were trained in the principles of best sign-out practices.

7C

	SUN	MON	TUE	WED	THUR	FRI	SAT
	1-Feb	2-Feb	3-Feb	4-Feb	5-Feb	6-Feb	7-Feb
7C Day 7a-7p		R3	R2				R1
7C Night 5p-10a		R1	R3	R2	R1	R3	R2
PE 7a-5:30p		PE 1	PE 2	PE2	PE2	PE2	
PE 8:30a-7p				PE1	PE1	PE1	
	8-Feb	9-Feb	10-Feb	11-Feb	12-Feb	13-Feb	14-Feb
7C Day 7a-7p	R3	R2	R1				R3
7C Night 5p-10a	R1	R3	R2	R1	R3	R2	R1
PE 7a-5:30p		PE 2	PE 1	PE1	PE1	PE1	
PE 8:30a-7p				PE2	PE2	PE2	
	15-Feb	16-Feb	17-Feb	18-Feb	19-Feb	20-Feb	21-Feb
7C Day 7a-7p	R2	R1	R3				R2
7C Night 5p-10a	R3	R2	R1	R3	R2	R1	R3
PE 7a-5:30p		PE 2	PE 4	PE4	PE4	PE4	
PE 8:30a to 7p				PE2	PE2	PE2	
	22-Feb	23-Feb	24-Feb	25-Feb	26-Feb	27-Feb	28-Feb
7C Day 7a-7p	R1	R3	R2				R1
7D Night 5p-10a	R2	R1	R3	R2	R1	R3	R2
PE 7a-5:30p		PE 4	PE 2	PE2	PE2	PE2	
PE 8:30a-7p				PE4	PE4	PE4	

7D

	SUN	MON	TUE	WED	THUR	FRI	SAT
	1-Feb	2-Feb	3-Feb	4-Feb	5-Feb	6-Feb	7-Feb
7D Day 7a-7p		R6	R5				R4
7D Night 5p-10a		R4	R6	R5	R4	R6	R5
PE 7a-3:30p		PE 3	PE4	PE4	PE4	PE4	PE4
PE 10:30a-7p				PE3			
PE 7a-7:30p					PE3	PE3	
	8-Feb	9-Feb	10-Feb	11-Feb	12-Feb	13-Feb	14-Feb
7D Day 7a-7p	R6	R5	R4				R6
7D Night 5p-10a	R4	R6	R5	R4	R6	R5	R4
PE 7a-3:30p		PE 4	PE 3	PE3	PE3	PE3	PE3
PE 10:30a-7p				PE4			
PE 7a-7:30p					PE4	PE4	

	15-Feb	16-Feb	17-Feb	18-Feb	19-Feb	20-Feb	21-Feb
7D Day 7a-7p	R5	R4	R6				R5
7D Night 5p-10a	R6	R5	R4	R6	R5	R4	R6
PE 7a-3:30p		PE 3	PE 1	PE1	PE1	PE1	PE 1
PE 10:30a-7p				PE3			
PE 7a-7:30p					PE3	PE3	
	22-Feb	**23-Feb**	**24-Feb**	**25-Feb**	**26-Feb**	**27-Feb**	**28-Feb**
7D Day 7a-7p	R4	R6	R5				R4
7D Night 5p-10a	R5	R4	R6	R5	R4	R6	R5
PE 7a-3:30p		PE 1	PE3	PE3	PE3	PE3	PE3
PE 10:30a-7p				PE1			
PE 7a-7:30p					PE1	PE1	

Figure 3. *7c and 7d Schedule. Three residents in each unit (R1, R2, R3 in 7c; R4, R5, R6 in 7d) share coverage over the course of the month with four NPs and PAs (PE1, PE2, PE3, PE4) who rotate between the two units. Residents work a series of 12-hour day shifts (Day) and 17-hour night shifts (Night); PEs work daytime shifts of 8.5 and 12.5 hours*.

Measuring errors and adverse events. We adapted methodologies we have previously used in the study of medication errors and adverse drug events to study rates of serious medical errors and adverse events. We will determine the effectiveness of our interventions in improving patient safety by comparing error rates before and after their implementation.

Development of staff support. Medical error and adverse drug events are uncomfortable topics for many clinicians. In studying medical errors and adverse events, it is essential to take every precaution to ensure confidentiality of data collection and to establish trusting, nonpunitive relationships with staff. As we have done before embarking on our prior studies of medication errors, we first gained the support of the nursing, pharmacy, medical, and administrative leadership. In addition, we spent many hours educating staff and enlisting the support of nurses, pharmacists, physician staff, and house staff in particular. Our efforts benefited from a very high level of institutional support at BWH, which we will continued to foster as we pursued this study.

Data collector selection. Chart reviewers were nurses with research and clinical experience as well as excellent data extraction skills. Our nurses and a physician also served as observers (on morning rounds). All new members of the research team were trained intensively in detection of medical errors and adverse events, as in our prior studies.

Detection of Errors and Adverse Events. We used an intensive, four-pronged data collection approach to comprehensively measure rates of errors and adverse events:

1) Direct Observation: Direct observation on morning rounds was the first method for detecting incidents. A trained observer followed residents during morning rounds, listening in particular to concerns raised on rounds that problems occurred overnight. Data collected for incidents included description of the event, classification of the event, where the event occurred, services and personnel involved, and additional work resulting from the event. Follow-up of all adverse events and errors detected by the observers was performed by the chart reviewers to collect additional information.

2) Voluntary and solicited reports: Forms were made available and prominently posted in the units to facilitate voluntary reporting of possible errors and events by staff. Chart reviewers also requested reports from staff of errors and adverse events 5 days per week. Any reported error or event was pursued by the chart reviewers, who collected additional information.

3) Hospital incident reports: BWH currently has a computerized incident reporting system in place. Data on computer detected ADEs were collected by the chart reviewers. Additional information was collected on each confirmed event.

4) Chart review: Chart reviewers served as the focal point for data collection and organization, and they followed up and reviewed all data collected by observers, reported by staff, or identified through the incident reporting system. In addition to coordinating collection from other sources, reviewers examined all orders and charts 5 days per week for evidence of adverse events and medical errors. Reviews on Monday included a review of the entire weekend. Data collected for each incident included a description of the event and patient, classification of the event, where the event occurred, services and personnel involved, and additional work resulting from the event. Medication incidents also included name, dose, route and category of the drug involved, type of error, and services and level of personnel involved.

Classification by severity, attribution, and preventability. The methods for evaluating medical errors and adverse events will be modeled on the methods employed in our previous studies. Data collectors and observers identified events. Two independent physician reviewers are subsequently classifying events as errors, potential adverse events, or adverse events; this step is ongoing. Potential adverse events and adverse events are being rated on severity using a four-point Likert scale and preventability using a five-point Likert scale. Disagreements will be resolved by discussion. Any event for which consensus cannot be reached will be re-rated by a third reviewer. Pre-discussion and consensus inter-rater reliability will be evaluated using the Kappa statistic.

Identification of patient risk factors. Clinical and demographic data for all patients were collected from patient records and institutional administrative databases. Severity will be assessed using the DRG weight and Charlson index. Morbidity and disability data were collected until discharge for all patients with an adverse event, as were data about the complexity of conditions, interventions, and drug regimens.

Measuring Sleep and Fatigue. *Post-sleep Questionnaire.* A diary of sleep and wake times was maintained by the research volunteers throughout the SICU rotations. A post-sleep questionnaire was completed immediately following wake time from all sleep episodes and will provide information on sleep onset, duration, consolidation, quality, wakefulness during sleep, etc. This questionnaire was previously validated in the AHRQ-funded Intern Sleep and Safety Study; resident reports of sleep and work hours were shown to correlate very highly with polysomnographically recorded sleep (r=0.94) and third-party confirmed work hours (r=0.98).

Measuring Resident and Staff Experience. An end-of-rotation questionnaire was also administered to all subjects to gather data on their experiences with the rotation; analyses of these data are currently underway.

Confidentiality. The nature of data acquired by this study is considered Protected Health Information under the Health Insurance Portability and Accountability Act of 1996 (HIPAA). Moreover, this information is highly sensitive. We therefore took every precaution to protect privacy, ensure confidentiality, and establish a trusting, nonpunitive environment. Confidentiality is critical to obtaining participation and endorsement by both the hospital and the resident subjects. The data were thus strongly protected.

Some data were collected electronically; most were collected on paper forms initially and subsequently stored electronically (password protected) in a secure location. Through our prior research, we have developed extensive experience with maintaining data security. Only study investigators have access to these data. Data from individual participants were assigned numerical identification numbers, which were used to link data records for each individual, and then the remainder of the analysis record was de-identified. All identifiers are maintained in a locked filing storage facility at the Brigham and Women's Hospital.

Statistical analysis. We will measure the difference between the incidence of resident-related and total serious medical errors in the pre- and post-intervention phases of the study per 1,000 patient days. Rates will be compared using the exact test for comparison of incidence rates, assuming a binomial distribution. We will report the relative risk for serious medical errors occurring at pre- versus post timepoints. We will also perform exploratory analysis of differences in the impact of the 7c/7d and 11c interventions; in our prior study, we found that the incidence of serious medical errors in the MICU and CCU were similar and that the intervention schedule reduced errors in both settings. We anticipate similar improvements in both units here, but differences in the nature of the implementation plan in the two units make exploratory comparisons imperative so that future improvements can continue to be made.

Results (Principal Findings, Outcomes, Discussion, Conclusions, Significance, Implications)

Sixty-one residents and senior physicians consented to participate in the study pre-intervention (Apr-June 2006); 60 residents, physicians, and physician extenders participated post-intervention (Apr-June 2009). The demographic distribution of participants was as follows:

Pre-intervention:

30 White/Caucasian (18 male, 12 female)
14 Asian (8 male, 6 female)
3 Hispanic (3 male, 0 female)
3 Black/African American (1 male, 2 female)
11 Other (7 male, 4 female)

Post-intervention:

40 White/Caucasian (23 male, 17 female)
10 Asian (5 male, 5 female)
4 Black/African American (1 male, 3 female)
3 Hispanic (2 male, 1 female)
2 Other (1 male, 1 gender not reported)
1 Unknown (gender not reported)

Data on sleep, work hours, resident and staff experience, and medical errors were collected for 3 months pre-intervention and 3 months post-intervention; physician classification of these data and analyses are ongoing.

List of Publications and Products (Bibliography of Outputs) from the study.

In developing this intervention and seeking to disseminate efforts to implement evidence-based work hours, we have published several papers to date and created a web-based toolkit for hospitals, program directors, and others seeking to improve care. We anticipate publication of the results from our SICU intervention studies as well.

Publications

1. Lockley SW, Landrigan CP, Barger LK, Czeisler CA. When Policy Meets Physiology: The Challenge of Reducing Resident Work Hours. *Clinical Orthopaedics & Related Research* 2006; 449:116-27.

2. Lockley SW, Barger LK, Ayas NT, Rothschild JM, Czeisler CA, Landrigan CP. Effects of Health Care Provider Work Hours and Sleep Deprivation on Safety and Performance. *Joint Comm J Qual Patient Saf* 2007; 33 (suppl 1): 7-18.

3. Landrigan CP, Czeisler CA, Barger LK, Ayas NT, Rothschild JM, Lockley SW. Reducing Fatigue-Related Errors and Injuries in Health Care: Effective Implementation of Work-Hour Limits and Systemic Improvements. *Joint Comm J Qual Patient Saf* 2007; 33 (suppl 1): 19-29.

4. Volpp KG, Landrigan CP. Building physician work hour regulations from first principles and best evidence. *JAMA* 2008; 300: 1197-1199.

Toolkit.

The toolkit we developed through the PIPS grant is available at http://www.workhoursandsafety.org/2007-12-01_HWHHSG_MedHome_Page_Template.html **:**

Figure 3. Screenshot of HWHHS toolkit for reducing resident work hours. The site can be accessed at http://www.workhoursandsafety.org

In the toolkit, we detail the physiologic determinants of alertness and performance and the practical issues necessary to consider when designing a new schedule intended to reduce provider sleep deprivation. We provide some example schedules from our current and past work, as well as other settings, and provide a series of tips on how to effectively implement these schedules while addressing concerns about continuity of care, education, and other potential issues. The site also provides links to a number of helpful websites, references to the past work of our group and others on this topic, and contact information for those wishing to learn more.

Future Work

Through publication of the results of our intervention study, as well as the development and dissemination of our toolkit, we hope to foster ongoing efforts to implement safer work hours for residents. Our prior AHRQ-funded research was cited extensively by the Institute of Medicine in their recent report, *Resident Duty Hours: Enhancing Sleep, Supervision, and Safety,*(104) which called for the elimination of 24-hour shifts without sleep. We are now engaged in ongoing efforts to further implement evidence-based schedules and study their effects on safety and residency experience, so that program directors and hospitals will have the necessary tools to translate these findings into daily practice.

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