

**Conceptual frameworks in the study of duty hour changes
in graduate medical education: An integrative review**

Prepared for

The Accreditation Council for Graduate Medical Education

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Executive Summary

Resident physicians bear an enormous burden of responsibility for the nature and quality of patient care in the hospitals in which they are employed and residency training has traditionally been a period of demanding and rigorous service. In 2003, the Accreditation Council for Graduate Medical Education (ACGME) instituted duty hour regulations in which residents of all specialties were limited to 80 hours per week. In 2009, the Institute of Medicine issued a report, *Resident Duty Hours: Enhancing Sleep, Supervision, and Safety*, in which, despite noting a lack of empirical evidence, they recommended additional changes to duty hour regulations, including protected sleep periods and additional time off.

In choosing which outcomes of duty hours to describe and how to study them, researchers and others advance arguments that employ conceptual frameworks, which represent simplified representations of the complex relationships between duty hours and outcomes to patients, residents, faculty, institutions, and other health professionals. These frameworks may be based on theories (evidence-based, explanatory, and predictive), best practices (evidence-based observations), or models (presumptive relationships). The goal of this study was to identify and specify the conceptual frameworks employed in the development, implementation, and study of duty hour regulations in the Institute of Medicine report and publications since the report.

Articles were searched across multiple bibliographic databases in July 2009, with additional articles through September 2009 located through automated alerts. Web sites and conference proceedings for organizations involved in GME in the primary care specialties were also searched. Articles were reviewed to identify outcomes of duty hour changes, and to describe and critique conceptual frameworks used explicitly or implicitly to argue for the relationship between duty hour changes and outcomes. Frameworks identified were reviewed by the seven-member project team to confirm their structure and disagreements were resolved by discussion and consensus.

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

Several gaps in the literature were identified as a result of the critique of conceptual frameworks. The concept of "duty hours" itself is contested, and long-standing questions about the balance of education and service for house staff have yet to be explicitly resolved. Too little attention has been paid to the nature and intensity of the activities that occupy those hours. Reflection on the European experience with 48-hour limits has rarely been given serious attention by U.S. authors despite considerable European work on the scientific study of fatigue and risk associated with particular shift configurations, schedules, and rota at the ward or service level.

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

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

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Introduction

Graduate medical education in the United States serves multiple purposes. First and foremost, residency seeks to develop medical practitioners who are capable of specialty practice or pursuit of further subspecialty training. Residents develop their knowledge and skills primarily through supervised clinical care of patients and must be exposed to a breadth and depth of patient experiences in order to master their specialty. At the same time, residents are inculcated with the cultural norms of the medical profession, which include dedication to individual patients, an obligation to maintain continuity of care throughout patients' clinical courses, and, often, a "hidden curriculum" in which residency is perceived to be a professional rite of passage during which the resident's stamina as well as his or her skills will be tested. Hospitals that employ residents receive education funds to offset the additional costs of supervision; all else being equal, resident time is considerably less expensive to hospitals than that of attending physicians.

As a result of all of these factors, residents bear an enormous burden of responsibility for the nature and quality of patient care in the hospitals in which they are employed, and residency training has traditionally been a period of demanding and rigorous service. The need to care for many patients and to provide continuity of care to patients admitted by a resident can encourage long work hours. Furthermore, residents, as house officers, have traditionally been responsible for staying at the hospital overnight to admit patients presenting in the evening and early morning hours.

Concern about resident duty hours in the United States was brought to the fore by the death of Libby Zion in a New York hospital. Zion's death has been attributed to the long duty hours and sleep deprivation of the residents caring for her, as well as inadequate supervision by her attending physicians

(Lerner, 2009). The resulting investigation, by a grand jury and a state commission, led to recommendations for an 80-hour work week and increased on-site supervision for residents (Bell, 2003).

In 2003, the Accreditation Council for Graduate Medical Education (ACGME) instituted duty hour regulations in which residents of all specialties were limited to 80 hours per week (averaged over 4 weeks), 30 continuous hours (of which 24 could be spent in admitting patients), and overnight call no more than every third night (on average) (Accreditation Council for Graduate Medical Education, 2003). In addition, ACGME mandated at least 10 hours off after each long shift and at least one day off per week (averaged over 4 weeks). Internal, but not external, moonlighting was also included as hours worked. Even as these regulations were being promulgated, ACGME investigators recognized that sleep deprivation during residency was prevalent and that limiting duty hours would not necessarily increase sleep (Baldwin & Daugherty, 2004).

In 2009, the Institute of Medicine (IOM) published a report, *Resident Duty Hours: Enhancing Sleep, Supervision, and Safety* (2009; hereafter, "the IOM report"), that contains a comprehensive review of the literature on the impact of duty hour changes and the relationship between sleep, fatigue, and effective functioning (in humans in general). The IOM report recommends changes to the 2003 duty hour regulations, including: 30-hour shifts with 16 hours of admissions and a 5-hour protected sleep period (or, alternatively, 16 hour-shifts), overnight call no more than every third night with no averaging, additional time off after night shifts, one day off per week with no averaging, at least one 48-hour period off per month, and inclusion of all internal and external moonlighting in the calculation of hours worked.

The IOM report reviewed the literature through 2008 and reported answers to five key questions about duty hours. First, it concluded that resident duty hours had in fact lessened since the implementation of the 2003 rules. Second, although few large-scale rigorous studies had been conducted, that there had been no detriment to patient outcomes attributable to the 2003 rules. Third, despite lit-

tle research on the relative contribution of resident fatigue to patient safety, that regulations designed to further reduce fatigue should be recommended. Fourth, that insufficient evidence exists to draw conclusions on the impact of the 2003 rules on the educational outcomes of residents. Fifth, that the 2003 rules improved resident quality of life (IOM Report, pp. 9-10).

The IOM report has been received with strong and varied opinions. The ACGME has solicited responses from organizations involved in graduate medical education, and commissioned a series of reviews of the literature on the observed impact of the resident duty hour regulations since 2003, and the predicted impact of the changes recommended in the IOM report. Investigators have performed thorough systematic reviews of the research literature to characterize the reported effects of duty hour limitations on particular outcomes, such as patient safety (J. W. Caruso, et al., 2009; Fletcher, et al., 2004) and resident quality of life (Fletcher, et al., 2005). Indeed, the IOM report itself is notable as an extensive review of research on duty hours for residents. These reviews identify key outcomes (e.g. medical errors by residents) and assess the quality and findings of studies that measured those outcomes. The result greatly enhances our understanding of the factors contributing to the key outcomes.

Evidence does not simply accumulate on its own. In choosing which outcomes of duty hours to describe and how to study them, researchers and others advance arguments that employ conceptual frameworks. The goal of this study is to identify and specify the conceptual frameworks employed in the development, implementation, and study of duty hour regulations since 2003.

Conceptual Frameworks

Conceptual frameworks "represent ways of thinking about a program or a study, or ways of representing how complex things work the way they do." (Bordage, 2009) A conceptual framework typically specifies a set of relevant entities of study or action (such as actors, organizations, and outcomes), processes acting on these entities, and the presumed, observed, or predicted relationships between entities and processes (Rocco & Plakhotnik, 2009).

Conceptual frameworks may be based on theories, best practices, or models. Theories and models are deductive in nature, while best practices are inductive. Theories are distinguished by being evidence-based, explanatory, and predictive in nature (Reyna, 2008). Best practices reflect observed relationships between entities. Models describe presumptive relationships between entities. These features are summarized in Table 1.

Table 1: Bases for conceptual frameworks

| | <u>Reasoning</u> | <u>Source</u> | <u>Function</u> |
|----------------|------------------|----------------|----------------------------|
| Theories | Deductive | Evidence-based | Explanatory and predictive |
| Best practices | Inductive | Evidence-based | Descriptive |
| Models | Deductive | Presumptive | Descriptive |

A key feature of conceptual frameworks is that they are simplified representations of reality. Each conceptual framework includes and focuses on certain entities, processes, and relationships, and excludes others. Bordage (2009) describes these functions as illumination (shedding light on particular aspects of reality to the exclusion of others) and magnification (permitting more fine-grained observation of the illuminated aspects).

Conceptual frameworks may be presented explicitly by researchers and policy makers in describing their work or may be implicit in the work. In the former case, the conceptual framework and its elements may be easily identified. In the latter case, conceptual frameworks may be idealized cognitive models of reality (Barsalou, 2008; Fauconnier, 1985; Fillmore, 1982; Lakoff, 1987), and may even be unconsciously held by their users (McGaghie, Bordage, & Shea, 2001). Implicit conceptual frameworks are more likely to be based on simple causal models and image schemas (Johnson, 1987).

Every argument advanced in favor of or against changes in duty hour regulations, as well as every research study that seeks to measure the impact of such changes, involves an explicit or implicit conceptual framework that underlies the reasoning. Arguments can be critiqued either by presenting evidence (or demonstrating a lack of evidence) for the relationships included in the underlying conceptual framework or by describing the limitations of the conceptual framework itself – for example, by noting evidence for relationships that are not included as part of the framework.

In this study, we describe and critique conceptual frameworks in which duty hour changes are cast as predictors of important outcomes. That is, rather than focus on an outcome, such as resident quality of life, and ask "what is the relative effect of duty hours on resident quality of life (among the many factors that affect resident quality of life is duty hours a strong or weak predictor?)", we focus on duty hours as predictors and ask "what outcomes (e.g. resident quality of life) are known, predicted, or presumed to be most strongly affected by changes in duty hours?" On the basis of our descriptions and critiques, we identify gaps in the literature within and across frameworks.

Methods

Sources of data

Articles were searched across multiple bibliographic databases, including BEME, CINAHL, EMBASE, PsycInfo, PubMed, and others. Searches used terms specific to the controlled vocabularies of each database (e.g. MESH) as well as variations on "resident" and "work hours" or "duty hours". Citations were combined into a RefWorks database and reviewed by hand to eliminate articles that did not focus on duty hours. The initial search was conducted in July 2009, and was supplemented through automated alerts to additional articles that appeared in July-September 2009. The data sources and literature search strategy to identify published articles relating to the impact of duty hours are described in detail in Appendix A.

Because conceptual frameworks are often presented in theoretical articles, letters to editors, and official publications of organizations involved in GME, we did not limit our search to the traditional peer-reviewed published literature. Web sites and conference proceedings for organizations involved in GME in the large primary care specialties were also searched for online publications related to "resident" and "duty hours"; the complete list of sites and search strategy is also described in Appendix A. In addition, the ACGME Annotated Bibliography of Resident Duty Hours (updated August 2008) and the ACGME Sleep Deprivation and Performance Relevant to Resident Education bibliography were reviewed.

Identification of Outcomes and Conceptual Frameworks

In order to be included in this review, articles must have explicitly described or argued for the effect of resident duty hours or work hours on another outcome. Articles that mentioned duty hours but did not posit relationships in which duty hours were antecedents to other outcomes (e.g., simple descriptions of ACGME educational projects) were not included. After eliminating articles that clearly did not address impacts of duty hours, each article and the IOM report were reviewed to identify outcomes following changes in resident duty hours. We broadly defined an "outcome" as any consequence of duty

hour changes that was studied, reported, predicted, presumed, or assumed in any of the texts reviewed. Outcomes were collated into a list and the list was reviewed repeatedly by the investigators in order to combine similar outcomes with different names and to organize the outcomes into a general taxonomy.

Following identification of outcomes, articles were reviewed again to identify, when present, conceptual frameworks used implicitly or explicitly to describe the relationship between duty hours (or duty hours regulations) and outcomes in the taxonomy. Identification of frameworks proceeded inductively to saturation. Frameworks identified were reviewed by multiple members of the project team to confirm their structure and disagreements were resolved by discussion and consensus.

Results

Our search identified 196 articles that were reviewed in full. The number of relevant articles retrieved by each search in July 2009 ("retrieved") and the number included in the review ("included") are shown in the last two columns of Appendix A. Seven articles identified subsequently through PubMed alerts and other surveillance systems between July 2009 and September 2009 were also reviewed in full and are not represented in the table. Appendix B contains the list of all 203 articles reviewed.

Outcomes of duty hours changes

The 83 outcomes identified in our review are summarized in Table 2. Each outcome was the subject of study or discussion as a potential outcome of changes to resident duty hours. Broadly speaking, the literature on duty hour regulations has considered outcomes to patients, residents, and, less frequently, faculty, institutions, and other health professionals.

A hierarchical taxonomy derived from these outcomes appears in Figure 1. The largest variety of outcomes measured relate to the impact of duty hour changes on residents themselves, both in terms of proximal outcomes like sleep and fatigue, and more distal outcomes like the acquisition of professional knowledge, skills, and attitudes, and personal quality of life.

The outcomes have most often been studied independently, in isolation from one another. Trade-offs about the relative value of outcomes (e.g. what reduction in continuity-of-care for patients is acceptable to maintain adequate quality of life for resident physicians?) are rarely measured, or indeed, explicitly acknowledged.

The IOM report provided a comprehensive review of studies reporting several kinds of outcomes through 2008. Below, we summarize knowledge developed about key outcomes since the publication of the IOM report through September 2009.

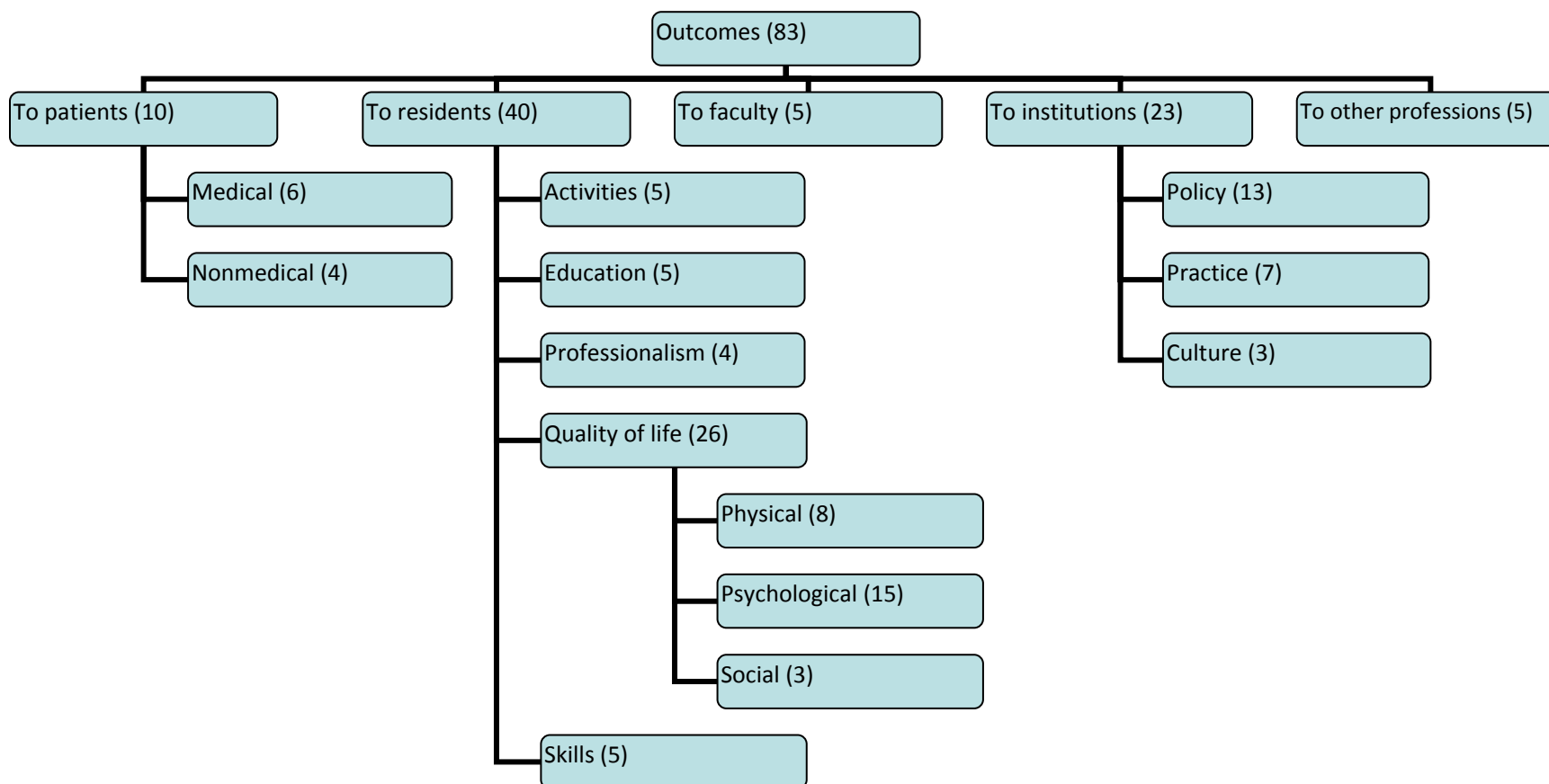
Table 2: Outcomes of duty hours changes reported or predicted

| <u>To Patients</u> | <u>To Residents</u> | | | |
|--|---|--|---|---|
| <u>Medical</u> | <u>Activities</u> | <u>Quality of Life (Physical)</u> | <u>Quality of Life (Psychological)</u> | <u>Skills</u> |
| Adverse event Length of stay Mortality Patient safety Readmission rates Patient education and adherence | Research Moonlighting Teaching Handoffs Home call assignments | Fatigue Pregnancy outcomes Safety Sleep deprivation Sleepiness Circadian performance variation Prolonged wakefulness Sleep efficiency and hygiene | Anxiety Burnout Depression Attrition/drop-out Suicide Mental fatigue Mental health Mood Well-being Attentional failure Concentration Effort reward imbalance Work compression Work stressors Workload | Cognitive/metacognitive Communication Procedural Compassion/empathy Psychomotor vigilance |
| <u>Non-medical</u> | <u>Professionalism</u> | <u>Quality of Life (Social)</u> | | <u>Education</u> |
| Disclosure Ethical treatment Perception of patients Continuity/fragmentation of care | Hostility toward other residents Professional behavior Ethical development Hostility toward other health professions | Marriage/childbirth Life change events Length of program | | Learning Case volume Inexperience Interdisciplinary training Inadequately supervised |

Table 2: Outcomes of duty hours changes reported or predicted, continued

| <u>To Institution (residency program and/or hospital)</u> | | | <u>To Faculty</u> | <u>To other health professions (substitutes for resident time)</u> |
|---|-----------------------------|----------------------------|---|--|
| <u>Policy</u> | <u>Practices</u> | <u>Culture</u> | Satisfaction | Advanced nursing practice |
| Day float, night float | Schedule instability | Work environment | Lower pay | Allied Health Professions |
| Night work | Scut work | Hospital culture of safety | Less research | Ancillary staff |
| On-call schedules | Entropy | Learning environment | Availability of specialists for co-management | Nurses |
| Protected time | Administrative load | | Supervision | Physician extenders |
| Cost | Hospitalists | | | |
| Funding | Malpractice claims | | | |
| Patient admissions/census | Violation types & frequency | | | |
| Uncompensated care | | | | |
| Accountability | | | | |
| Chief medical office compliance & quality | | | | |
| Moonlighting policy | | | | |
| Organizational and curricular structure | | | | |
| Teamwork | | | | |

Figure 1: A hierarchy of outcomes of duty hour changes



Outcomes to patients

Studies published since the IOM report, including several very large observational studies, have suggested that the 2003 ACGME regulations resulted in neither substantial detriment nor substantial medical benefit to patients (Rosen, et al., 2009; Shonka, Ghanem, Hubbard, Barker, & Kesser, 2009). Alshekhlee and colleagues (2009) in a review of 377,266 patients admitted in the years 2000-2005 in both teaching and non-teaching hospitals showed no difference in hospital stroke mortality across time or between teaching and non-teaching hospitals. Morrison, Wyatt, and Carrick (2009) compared mortality in trauma patients on a national level between 2001-2002 and 2004-2005 in teaching and non-teaching hospitals, and found a small but significant decrease in mortality at teaching hospitals and a small but significant increase in mortality in nonteaching hospitals. Rosen et al. (2009) reviewed 826,047 VA and 13,367,273 Medicare acute-care hospital admissions from 2000-2005 for 10 patient-safety indicators organized into continuity of care, technical care, and other indicators, and found only very small differences between more and less teaching-intensive hospitals before and after changes in duty hours. Prasad et al. (2009) analyzed 230,151 patients admitted to 40 hospital ICUs, controlling for severity of illness, and found an overall reduced mortality from 2001-2005, but no difference in the reduction between teaching and non-teaching hospitals.

Continuity of care has been an important outcome identified in both the IOM report and the literature since its publication. Patients prefer to have continuous contact with a single physician, and discontinuity creates opportunities for poor transfer of patient care information between physicians, at best leading to redundant examination and testing, and at worst to errors that threaten patient safety. Fletcher, Wiest, et al. (2008) found that inpatients were concerned with both physician and nurse fatigue and discontinuity of care.

Concerns about continuity of care arise because duty hour reductions can prevent residents from following a patient's case from admission to discharge, and in the case of some subspecialties,

even prevent a resident from completing a single procedure (Grady, Batjer, & Dacey, 2009). However, despite the existence of several relevant (and conceptually distinct) continuity-of-care measures developed in the context of outpatient treatment (Jee & Cabana, 2006), few studies of resident duty hours have quantified changes to patient continuity of care or explained exactly what concept of continuity of care is to be measured. On the other hand, increases in the number of handoffs have been documented, and this necessarily decreases continuity of care as measured by the number of different managing physicians during a given hospital visit.

Outcomes to residents

Research subsequent to the IOM report has been equivocal about the impact of the 2003 regulations on resident education. Many studies report retrospective surveys of faculty or resident perception of the impact of regulations on education and many of these are subject to a variety of well-known demand and recall biases. A small number of studies have attempted to use more objective measures. A study of the American Board of Neurological Surgery written examination scores between 2002 and 2006 found a significant decrease in scores of PGY2 and PGY3 residents taking the exam for self-assessment or credit despite significant increases in the USMLE Step 1 scores for students matching to neurosurgery residencies (Jagannathan, et al., 2009)

Research subsequent to the ACGME regulations suggests that the 80-hour rule has led to moderately increased well-being among residents in most cases. Two studies have appeared since the IOM report that add to this understanding. Lopez and Katz (2009) point out conflicts between loss of autonomy (associated with being unable to continue to care for a patient beyond work hour limits) and increased well-being (associated with greater rest); the former is associated with job dissatisfaction and the latter with job satisfaction. Stucky, et al. (2009) conducted naturalistic measurement of stress in interns, residents, and attending physicians in internal medicine or pediatrics at four hospitals in San Diego using ecological momentary assessment, in which physicians reported their stress levels in re-

sponse to prompts issued at randomly determined moments during their daily practice. They found no difference in sleep quality or quantity on average among the groups, but low sleep quality (but not quantity) was associated with significantly increased emotional stress.

Several recent papers have argued for consideration of duty hours within a broader moral framework. Concern is often expressed that duty hour regulations may lead residents to adopt a "shift" mentality in place of "patient ownership" – abandoning patients at the end of their shift in order to remain in compliance even if the resident would prefer to remain with the patient (West, Cook, Popkave, & Kolars, 2007). (Some specialties, such as emergency medicine, adopted a shift-oriented approach to care long before duty hour regulations, and do not appear to consider it a threat to their professional ethics, but these specialties may be particularly suited to such work by the nature of their patients.) In contrast, Higginson (2009) suggests that underlying concerns about costs and the impact of a larger workforce on physician pay and specialty mix conflict with the physician's moral imperatives and notes that the assumption that shift workers can not perform with dedication and commitment often goes unquestioned. Lopez and Katz (2009) suggest that the ethical identity of physicians must be shifted to team responsibility for patient care, and that systems for residency training should be designed to give residents options that are "ethical, safe, and easy." Dembe (2009) asserts the need to balance the rights of employers to set conditions of work against the interests of the employee, and notes that in nursing, "mandatory overtime" arrangements have been criticized. He also points out that long work hours may expose others beyond the work to risk. For example, New Jersey criminal law has codified the moral implications of endangering others since 2003 by presuming criminal recklessness when a driver awake for 24 or more hours causes a fatal accident ("AN ACT concerning vehicular homicide and amending N.J.S.2C:11-5," 2003).

Outcomes to faculty

Reduction in resident duty hours has often led to a concomitant increase in faculty work hours, as attending physicians may now be the only personnel who are permitted to attend a case from start to finish. As a result, faculty well-being and work-life balance has been reduced as faculty work hours have lengthened (Goitein, Shanafelt, Nathens, & Curtis, 2008; Klingensmith, Winslow, Hamilton, & Hall, 2006), although not all studies have shown that faculty work hours increase (Winslow, Berger, & Klingensmith, 2004). If faculty work longer hours, they will also be susceptible to increased fatigue and sleepiness. Discussion in the literature has recently begun to speculate on whether regulations on attending work hours, on the same basis as the recommendations in the IOM report, are likely to follow in coming years (Hyman, 2009).

Outcomes to institutions and other health professionals

A single major evidence-based analysis of labor costs associated with changes in duty hours proposed in the IOM report has been conducted (Nuckols, Bhattacharya, Wolman, Ulmer, & Escarce, 2009), following an approach used by the same team to examine costs associated with 2003 duty hour regulations (Nuckols & Escarce, 2005). The analysis considers the impact of shifting work to more residents or to substitute providers, as well as potential costs or savings from changes in preventable adverse events, and does so from the perspective of both teaching hospitals and society as a whole. The article employs a standard cost-benefit framework (cost per admission, cost per averted death) that explicitly considers (and models) tradeoffs between impacts on patient care, the labor force, and costs, as well as compares the costs of implementing the IOM recommendations to other patient safety interventions (such as computerized physician order entry systems or one-nurse-per-four-patient policies). The authors also identify long-range questions about the physician labor supply. The study concludes that the cost burden to society of implementation of the IOM recommendations is sensitive to the potential reduction in adverse events. Using substitute providers, an 11.3% reduction in preventable adverse events would

make implementation free to society; using a strategy of increasing the numbers of residents, a 3.6%-12.5% decrease in preventable adverse events would make implementation free to society. However, they also note that under any of these scenarios, implementation will still be costly for teaching hospitals, and additional subsidization of these hospitals or GME will likely be necessary to make implementation feasible without reducing physician salaries, increasing workload, increasing patient charges, or reducing services or quality of care. Their analysis does not include the cost of training physician substitutes.

Conceptual frameworks

For each framework identified, we describe the basis (theory, model, or best practices), main outcomes (to patients, residents, faculty, institutions, or other health professions), predictors that are framed (actors, organizations, processes, etc.), key relationships among predictors and outcomes, and limitations of the framework as an approach to evaluating the impact of duty hour regulations. The identified conceptual frameworks are summarized in Appendix C.

Frameworks based on theory

For conceptual frameworks based on theory, the relationships between the framework predictors and outcomes are those specified by the theory. These relationships have special status, as they have sufficient strength of evidence to be explanatory and generalizable. In addition, theories make testable predictions about their subjects that make it possible to challenge the theory on the basis of contradictory evidence (and thus discount frameworks that apply it).

Sleep deprivation

The IOM Report represents a major effort in the review of the relationships between resident duty hours, sleep, supervision, education, and patient safety. It incorporates multiple conceptual frameworks, both explicit and implicit. The preface of the report outlines its basic explicit conceptual framework:

Many factors affect safety; fatigue is one. Redesigning resident duty hours and other aspects of GME could contribute to improved safety. There is no question that the evidence base is still nascent and much more research must be done. The committee reviewed the scientific literature on sleep and human performance as well as evidence that continues to emerge concerning the benefits to patient safety, resident learning, and overall resident work life of well-structured limits to resident duty hours. The evidence was sufficient to recommend action now. Providing safe patient care during residency is a matter not just of hours at work, but also of the amount of effective supervision, sleep obtained, and a balanced workload. Recommended changes to these elements of GME are all interrelated and should be considered together.

The committee well understands that implementing more circumscribed limits on resident duty hours carries real costs and significant challenges. Resident work restrictions can create new costs in terms of personnel and systems required to compensate for fewer hours worked per resident. There can also be added risks to patient safety from related issues, including increased “handoffs” among providers and breaks in continuity of care. New administrative costs can be incurred from changes to scheduling, management, and reporting requirements. Society should weigh the real and hoped-for benefits of further reform against these costs. (p. xii)

In short, the key outcome is patient safety. Fatigue reduces safety. Sleep reduces fatigue. Changes to duty hours can provide increased sleep. Workload balance will be improved through more time spent on sleep and off-duty relative to time spent at work. The limitations on resident hours can also be used as a lever to improve supervision (see the discussion of the “compensatory improvement” framework below). Greater restriction on work hours will also increase handoffs, and that may reduce safety. Implementation will involve substantial costs to replace lost person-hours and to put scheduling, supervision, and compliance systems into place.

The emphasis on sleep as the key modifiable determinant in resident fatigue is significantly different from most other conceptual frameworks that have been applied to duty hours. The IOM report framework emphasizes that it is increasing time for sleep, not merely reduced working hours, that is predicted to result in reduced fatigue, and the report's recommendations thus focus on protected sleep periods and reducing outside activities that could detract from sleep, such as moonlighting.

Some links in this model are based on strong empirical evidence. Lack of sleep reliably produces fatigue, and the availability of fewer resident-hours will require patients to be seen by more residents,

and hence necessitate more handoffs, all other things being equal. Other relationships are less clear. For example, the relative contribution of fatigue and other factors (including handoffs) to patient safety is unknown, making it unclear whether a larger number of less tired residents per patient will be an improvement in patient safety compared with a smaller number of more tired residents. As the IOM report notes, it is also unclear whether and how society will consider the trade-offs between benefits and costs of changes.

Swiss cheese and human error

In addition to cross-industry reviews, many studies have been published reviewing the impact of changes in work hours in specific industries with a focus on accident outcomes. The conceptual framework for much of this research has been the human factors analysis and classification system (HFACS) based on the work of Reason (1990). Reason's conceptual framework, often denoted the "Swiss cheese" framework, posits that organizations erect multiple systems to serve as barriers to error. Each of these systems, like slices of Swiss cheese, contain "holes" – opportunities for active failure of the system or latent conditions that permit or encourage failure. When the holes of all the systems are aligned, error can occur. The framework directs attention to the function of multiple systems, predicts condition under which errors will or will not occur, and explains why stress on a single system (such as sleep deprivation in residents) may not directly result in a large increase in patient care errors – for example, because of oversight by attending physicians (Lewis, 2009). Perneger (2005) has noted, however, that users of the framework vary in their understanding and use of its entities and relationships.

The framework has been widely applied. Most recently, Baysari et al. (2009) reviewed 19 rail safety investigation reports using the HFACS and the Technique for retrospective and predictive analysis of cognitive errors (TRACEr), a system originally used for air traffic control error investigation. Both frameworks led to the conclusion that decreased alertness was one of the main factors contributing to driver error. Similarly, sleepiness has been found to be a cause of accidents in ground transportation

(Philip & Åkerstedt, 2006) and a cause of error in aviation (Jackson & Earl, 2006; Wiegmann & Shappell, 2001). With respect to resident duty hours, residents have been conceptualized as one of the error-prevention systems employed by hospitals, and fatigue as a potential latent condition that contributes to failure of the resident system (Fletcher, Parekh, et al., 2008). Most of these studies, however, have focused on determining relative or root causes of accidents or errors (one of which may be work hours or schedules), rather than on work hours themselves.

Resident-reported contributions to patient care mistakes

Research on duty hours in 2008-2009 has resulted in several conceptual frameworks that have become the basis for discussion and research in the area. Fletcher, Parekh, et al. (2008) present qualitative evidence for a framework in which work hour changes lead to a set of intended consequences (less resident time in hospital, improved resident well-being) and a set of unintended consequences (greater discontinuity of care, more entropy in the institution, the adoption of work hours themselves as a goal). Improved resident well-being can mitigate factors leading to patient care mistakes, but the other consequences serve to aggravate the effects of these factors.

Deliberate practice

The impact of reduced duty hours on resident learning has been an important focus of discussion in the literature. Most of the discussion has simply assumed that fewer hours of clinical service will result in reduced opportunities for education and skill practice; few authors have presented conceptual frameworks based in educational theory. Omahen (2009) applied Ericsson's (Ericsson, 2004; Ericsson & Charness, 1994; Ericsson, Krampe, & Tesch-Römer, 1993) theory of deliberate practice with feedback to highlight the importance of both sufficient hours available for learning and sufficient quality of training during those hours. Deliberate practice requires "individualized training on tasks selected by a qualified teacher...closely related to the level of acquired performance," and is a key factor in the transition from competent to expert performance (Ericsson & Charness, 1994) A limitation of this conceptual framework

is the *de facto* difficulty of distinguishing between deliberate and non-deliberate practice in resident training as it current exists, in order to preserve deliberate practice in the face of reduced duty hours.

Shift worker fatigue and risk

Although there is an extensive literature within medicine that addresses the impact of duty hours, there is also a considerable body of research dealing with the effects of various configurations of work hours in other fields. For example, night work has been shown to reduce quality of sleep, overall health, and work-family balance in nurses, and these observations have been theorized to apply to physicians as well (Bamford & Bamford, 2008), particularly when night-float or shift work systems are implemented in response to changes in duty hour requirements. However, it is important to note that research on work hours in many industries outside of health care is often strongly impacted by selection biases; workers are rarely assigned to, for example, night shifts, at random. Instead, the youngest workers, unmarried workers, or the healthiest workers may self-select into night shifts or overtime, particularly when compensation for working unpleasant shifts is higher (Folkard & Lombardi, 2006).

Several significant reviews have considered the impact of work hours on worker safety across industries. In 2006, the National Occupation Research Agenda (NORA) Long Work Hours Team proposed a framework for the study of the impact of long working hours on a series of outcomes (C. C. Caruso, et al., 2006). The framework incorporates both antecedents and consequences of work schedules (including both working hours and other characteristics). Key intermediate outcomes to workers under long work hours include “reduced availability of time or ability to use time effectively for sleep, recovery from work, family, or other non-work activities,” and “longer exposure or increased vulnerability to job demands and workplace hazards.” These outcomes, in turn, lead to fatigue, stress, etc., resulting in negative impact on individual workers and their families, on employers, and on the community at large—the latter impact characterized by accidents and errors. Other individual and job characteristics may moderate the impact of long work hours.

The National Institute for Occupational Safety and Health (NIOSH) reviewed 52 published research studies conducted in the U.S., Asia, and Europe that focused on the associations between long work hours and illnesses, injuries, health behaviors, and performance in industries including manufacturing, white collar work, transportation, public administration, construction, mining, and utilities (C. C. Caruso, Hitchcock, Dick, Russo, & Schmit, 2004). Performance measures identified in the review included cognitive and executive functioning, alertness, automobile crashes, and muscle and cardiovascular fatigue. Most studies reported increases in relative risk for accidents, higher fatigue levels, and poorer performance on cognitive function tests among the workers with longer shifts and more overtime. This was exacerbated when extended work shifts were combined with more than 40 hours of work per week. Studies conducted since that review found similar results, including severe sleepiness after 12-hour shifts among auto industry workers in Korea (Son, Kong, Koh, Kim, & Harma, 2008) and oil refinery operators in Finland (Sallinen, et al., 2004).

Folkard and Lombardi (2006) developed a risk index based on review of studies of predictors of acute accidents and injuries across industries. The index is an additive model of the relative risk of various work schedules based on the baseline risk of the first shift of a particular type, the change in risk for number of successive shifts of the same type, the change in risk for the length of shifts, and the change in risk for the interval between breaks. The most important conclusion of their review is that reducing total work hours decreases risk only when all else is equal; other features of the work schedule, such as shift length, number of successive shifts, and rest periods, have larger effects. In this, their review reflects the IOM report's recommendation that while overall work hours need not be reduced, the organization of work should be reconfigured. Folkard and Lombardi, however, suggest that limitations should be placed on acceptable levels of fatigue or risk, rather than on specific features of the work schedule. Determining "acceptable" fatigue requires making tradeoffs at the employer or societal level; measuring

actual fatigue in order to assess fitness for duty is not straightforward, given interindividual variation in susceptibility to functional impairment from sleep loss.

Frameworks based on best practices

In conceptual frameworks based on best practices, the relationships between the framework predictors and outcomes have been observed in practice, but these observations have not developed into the level of coherent explanation, prediction, and falsifiability to receive acknowledgment as a theory. In many cases, practices are observed in a limited number of settings, or in the presence of other potentially confounding relationships. Nevertheless, conceptual frameworks based on best practices have some weight of empirical evidence behind them.

Presenteeism

Presenteeism refers to the propensity of workers to come to work when they are sick. Although presenteeism in business is often attributed to heavy workload and job insecurity, presenteeism has also been noted in residents, particularly among those who are concerned that their absence would put a strain on their colleagues (Nielsen & Allen, 2009). The implicit conceptual framework underlying this research is that residents are inculcated with a strong work ethic and sense of responsibility for their patients, as well as a sensitivity to the workload of their fellow residents. In order to protect their colleagues from overwork, residents subordinate their health to their work. As duty hour restrictions increase and scheduling becomes less flexible, residents may feel more pressured to work even when they are ill, and this may lead to reductions in patient safety. However, although there is evidence for the phenomenon of presenteeism in residents, there are as yet no studies linking presenteeism to adverse patient or resident outcomes.

Hourly Productivity

Jeanmonod, Jeanmonod, and Ngiam (2008) note that resident (or clinical service) productivity can be modeled as the product of hours worked and patients seen per hour. This conceptual framework

led them to investigate the possibility that the multiplicative relationship between these two variables could lead to overall greater productivity despite fewer duty hours, if more patients can be seen per hour by residents on shorter shifts. Their study found that residents working 9-hour shifts were able to care for more patients per hour, and, as a result, more total patients than residents working 12-hour shifts.

Preceptor Relationships

Balmer, et al. (2007) reported that duty hour restrictions have made scheduling resident time more difficult. As a result, they have led to an increase in the number of preceptors with which a resident must work and, because the number of available preceptors has not expanded substantially, a concomitant increase in the number of residents working with each preceptor. They found that preceptors reported feeling less attachment with individual residents and less satisfaction with their relationships with residents.

Frameworks based on models

In conceptual frameworks based on models, the relationships between the framework predictors and outcomes are primarily presumptive. Models, as we use the term here, lay out a set of relationships that are supposed to exist, and then use these relationships to derive implications about the impact of changes in duty hours; as such, they are useful guides in the development of future observation and research. When models are well-specified, they may be subject to empirical test, but the model-based frameworks that have been proposed for the impact of duty hours generally do not have substantial empirical evidence behind them. Most of the conceptual frameworks applied by training organizations in response to the IOM report have been based on models of this sort.

Specialty and training year differences

Many organizational responses point out differences among specialties and among residents at different points in their training (Borman & Fuhrman, 2009; Britt, Sachdeva, Healy, Whalen, & Blair,

2009; Lewis, 2009). For example, the American Board of Surgery response suggests that specialties engaged in emergency care require different working hours than those engaged in primarily elective care, and that as residents advance in training and autonomy, restrictions on their working hours should be relaxed to more closely approach what they will experience in practice (Lewis, 2009).

The American Association of Directors of Psychiatric Residency Training (AADPRT) noted that the proposed recommendations will have variable effects on programs depending on their size and nature of financial support, and considers cost to programs an important factor that needs additional attention (Greenberg, Faulkner, Kaye, & Roberts, 2009). AADPRT recommends flexibility, experimentation, and careful study of the impact of changes before mandating them and cautions that "one size does not fit all," a sentiment also expressed at the time of the 2003 ACGME regulations (Baldwin, Daugherty, Tsai, & Scotti, 2003).

The American Gastroenterological Association (AGA) notes that GME duty hour regulations will have a different impact on subspecialty fellowship services where there is often only a single fellow covering an entire hospital, attending physicians are already busy in patient care, and potential backup fellows may be engaged in research or other activities (Katzka & Proctor, 2009). They argue that while most of the IOM's recommendations present little problem for gastroenterologists, questions remain about whether home call (i.e., taking calls from home) on a lower-demand subspecialty should be counted toward hours in the same way as in-house call by residents, and whether physician extenders are capable of substantial involvement in the complex cases they see. They propose a conceptual framework in which the intensity and nature of work, rather than hours of work, should determine duty hour limitations. This response also argues that patients are an important stakeholder group in duty hour changes and should be surveyed to determine whether they favor these changes, particularly with respect to advanced subspecialty fellows. (This question has received some attention; Fletcher, Wiest, et

al.(2008) found that inpatients were concerned with both physician and nurse fatigue and discontinuity of care).

Concerns about the rigidity of regulations reflect a general conceptual framework, “regulation is constraint,” that reflects an idealized cognitive model of organizational action as motion, and innovation as motion in a new direction. Organizational responses that apply this framework argue that if regulations do not contain sufficient flexibility or are too rigidly enforced, the ability of residency programs to innovate and improve clinical care and resident education will be restricted (Grady, et al., 2009; Greenberg, et al., 2009).

Of course, regulations may also limit the ability of residency programs to overwork residents or to institute changes that will be detrimental to patient care. The fact that several organizational responses (Greenberg, et al., 2009; Lewis, 2009) simultaneously argue against any additional universal changes in work hour regulations and yet favor the existing overarching general limit (e.g., the current 80-hour framework), although strong evidence exists for neither regime, suggests that specialty difference frameworks may also be employed in an effort to preserve the status quo (Higginson, 2009).

Benefits of sleep deprivation

Several publications implicitly suggest beneficial results of sleep deprivation by proposing conceptual frameworks in which sleep deprivation is either manageable, necessary, or serves a symbolic or signaling function. For example, the American College of Surgeons response to the IOM report includes the following argument:

Residents must learn to prevent and mitigate fatigue by carefully regulating their personal and professional activities. This is especially important before of vast individual variations in the need for sleep. Implementation of artificial time controls for residents will fall short of the goals; instead, residents must be provided the support to learn and apply self regulation principles for preventing, mitigating and managing fatigue that will place them in much better stead for the realities of surgical practice beyond residency (Britt, et al., 2009).

This conceptual framework assumes that residents are responsible for their level of sleep, capable of managing fatigue, and experience fatigue because they fail to regulate their personal as well as professional activities. It also assumes that residents will continue to practice as attending physicians under conditions of extended duty hours and fatigue. However, research suggests that it is not clear that attending physicians actually have such practice patterns or model them when practicing with residents (Anim, Markert, Wood, & Schuster, 2009; Cyr-Taro, Kotwall, Menon, Hamann, & Nakayama, 2008), and some authors predict that work hour restrictions for attending physicians in the United States may also be instituted in the future (Hyman, 2009; Sataloff, 2009).

A second variant of the argument is that sleep deprivation represents a demonstration of professional role and dedication to patient needs over physician needs. (Bamford & Bamford, 2008; Britt, et al., 2009; Cass, Smith, Unthank, Starling, & Collins, 2003; Charap, 2004). Proponents of this argument suggest that limits on duty hours will lead residents to see themselves as “shift workers” rather than responsible for a patient’s complete course of care (Anglen, et al., 2009). The assumption that a shift worker can not be a dedicated and high-performing professional is common in organizational responses to the IOM report, but has also been questioned (Dembe, 2009). It has also been noted that attending physicians seem to practice within an 80-hour week with little concern for “shift mentality”, perhaps because their practice is by choice rather than by mandate (Anim, et al., 2009; Cyr-Taro, et al., 2008).

A third variant introduces the idea that sleep deprivation is a rite of passage in the development of a physician. Work under extended duty hours is seen as increasing professional identity and bonds with other practitioners (Charap, 2004; Lopez & Katz, 2009). Lopez and Katz (2009) criticize this model, noting that research suggests that habituation to stress may lead to ethical erosion rather than to increased professional identity.

Worker rights

Duty hours for postgraduate trainees has also been a focus of study and regulation outside of the United States. Under the UK National Health Service's "New Deal" requirements, junior doctors were limited to 56 hours per week on average beginning in 1991, with longer duty periods when suitable rest is included (National Workforce Projects, 2008). The New Deal regulations, though arguably stricter in the number of hours permitted on average, emerged from a wholly different conceptual framework than the ACGME regulations. Just as the case of Libby Zion served as the exemplar for concerns about the relationship between working hours and patient safety in the U.S., cases such as those of Drs. Robin Senior and Alan Massie, whose deaths were blamed on overwork, were catalysts for change in the U.K. (Skentelbery, 1994; Wilkinson, 2008) Thus, unlike the ACGME experience, the New Deal was initially based on a conceptual framework emphasizing the relationship between long work hours and physician stress and satisfaction, rather than primarily a concern for patient safety, although patient safety frameworks were also applied.

Under the European Union's (EU) European Working Time Directive (EWTd), residents in EU countries were limited to a 58-hour work week in 2004, a 56-hour work week in 2007, and a 48-hour average work week beginning in August 2009. EWTd also requires 11 hours continuous rest in every 24 hours (thus limiting shift lengths to 13 hours maximum), a 20 minute break every 6 hours, and 24 hours off every 7 days or 48 hours off every 14 days. As a result of these regulations, traditional resident "on-call" shifts are no longer feasible, and there are a limited number of possible rota (typically employing two 13-hour or three 9-hour shift periods) for providing 24-hour coverage for a service (Horrocks & Pounder, 2006). The motivating framework for the EWTd is worker health and safety, rather than patient safety. Physicians are permitted to "opt out" of the EWTd; in the UK, they remain subject to the New Deal 56 hour week.

In the U.S., the Committee of Interns and Residents of the Service Employees International Union has expressed unreserved support for the immediate implementation of the IOM report recommendations, with the necessary funding to achieve them (presumably from government or other payers) (Committee of Interns and Residents/SEIU Healthcare, 2009). This response focuses largely on the working conditions of residents and their presumed impact on patient safety. Similar concerns for working conditions led residents in Québec, Canada to file a grievance against 24-hour on-call schedules allowed by the province's contract. Residents, supported by their union (Fédération des Médecins Résidents du Québec) have argued that extended duty hours violate the Canadian Charter of Rights and Freedoms (Eggertson, 2009).

Because the EWTD 48-hour week has only recently come into effect, there has been little research on objectively measured outcomes of the change in duty hours. Although the U.S. literature often claims that EWTD has had averse effects, these claims are generally supported by citations to essays, position papers, and surveys of physicians and other health care professionals (Bamford & Bamford, 2008; Mann, 2005; Wade & Henderson, 2009; Wilkinson, 2008). However, evidence from a pilot study of the implementation of 48-hour vs. 56-hour schedules at one UK hospital found that although sleep did not differ significantly among the two groups of junior doctors, and doctors reported worse educational opportunities on the 48-hour schedule, there were significantly fewer medical errors and adverse events (both intercepted and non-intercepted) in the group working shorter hours (Cappuccio, et al., 2009). In addition, a study recently undertaken in Finland found that patients in wards where physicians and nurses worked, on average, longer than 8.75 hours per day, were at over 3 times greater odds of a hospital-acquired infection (Virtanen, et al., 2009), controlling for a wide variety of patient and organizational factors. The Association of Surgeons in Training at the Royal College of Surgeons of England notes an observed reduction in operative cases performed by trainees, and recommends a proposal advanced by the European Union of Medical Specialties (Benes, 2006) to extend working hours to 48 hours of

combined service and training and 12 hours of dedicated training time (potentially through the use of the opt-out provision of the EWTD) (Marron, Shah, Mole, & Slade, 2006).

Fixed pie / zero sum

A common conceptual framework that we term the "fixed-pie / zero-sum" framework posits a system of fixed resources (resident hours, residency program length, educational dollars, faculty hours, patients) with a simple interdependent equilibrium model in which the reduction of one resource (resident hours) must be accompanied by an concomitant increase in another resource. For example, the Orthopedic Trauma Association (Anglen, et al., 2009) expressed concerns about increased handoffs, greater faculty workload, and the potential for cross-coverage to reduce resident education and patient safety. They also note that the recommendations may lead to lengthening training programs and significant economic burden to institutions not only for personnel for direct health care coverage but also for monitoring infrastructure needed to ensure compliance with the recommended protected sleep period. These concerns can also be seen in editorials by a residency program director and a resident in the *Journal of Clinical Sleep Medicine* (Blatman, 2009; Meinke, 2009).

Another suggested response to reduction in resident duty hours is to increase the time and level of care provided by other health professionals serving as physician extenders. Responses to the IOM report have suggested that non-educational patient care work should not be performed by residents (Blatman, 2009; Britt, et al., 2009). The increased responsibility laid on physician extenders may promote their recognition as important patient care professionals, but may also subject them to increased workloads. In Europe, the introduction of the 48-hour work week has led to increased emphasis on physician extenders, including substitution of advanced practice nurses and nurse practitioners for physicians in some roles (including procedures such as cannulation and intubation, and in some cases prescribing). The increased demand for nurses has further led to the substitution of health care support workers for nurses in patient comfort and support roles. An unanticipated consequence of duty hour

regulations in Europe, and potentially in the United States as well, may thus be increasing medicalization of the nursing profession (Wilkinson, 2008).

The fixed-pie conceptual framework stands or falls on the reality of the zero-sum assumption. If society is prepared to provide additional resources, or if innovation in education or health care delivery produce organizational slack (Bourgeois, 1981), the pie may be expandable, rather than fixed.

Degradation of skill

Of primary concern to many training organizations is the possibility that reduced duty hours will translated into less skilled residents (Britt, et al., 2009). Unlike the deliberate practice framework discussed earlier, this concern is not necessarily motivated by the potential of reduction in deliberate practice *per se*, but the potential of reduction in overall job experience; in addition, while deliberate practice focuses on the development of experts, the conceptual framework we denote "degradation of skill" is concerned with regression from competence. The degradation of skill conceptual framework appears in three variations in the literature.

In the most basic variation, resident duty hours are assumed to be spent primarily in educational patient care and other educational activities. A reduction in duty hours thus amounts to a reduction in educational time. Assuming that residencies are no longer than necessary to inculcate the required specialty education, reduced educational time will result in less skilled residents (Borman & Fuhrman, 2009). Those who apply this framework suggest that duty hour regulations have been in force for just barely long enough to see their impact on trainees in examinations that are normed to measure competence, and there is some limited evidence of worse performance on a board examination among residents trained since the 2003 regulations (Jagannathan, et al., 2009).

A more nuanced variation, covert degradation of skill, suggests that the impact of duty hour restrictions has been masked by the assumption of additional clinical workload by more senior residents, fellows, and attending physicians, for whom the work is primarily service rather than educational (Lewis,

2009). In this variation, duty hour regulations will have not been in force for long enough to see their impact on trainees until the trainees are themselves attending physicians, and the average skill of attending physicians decreases.

A final variation suggests that residents themselves will perceive their lesser skill and need for further training. As a result, residents will increasingly seek subspecialty fellowships, effectively lengthening their training and increasing their debt (Moalem, Brewster, & James, 2009). Over time, this will result in fewer primary care attending physicians, who will be potentially least skilled.

The degradation of skill frameworks evoke significant concern. Although there is as yet little evidence to support a general lessening of resident skill, these frameworks suggest that such evidence may emerge in the next five years, and argue for research that will determine the validity of the frameworks' assumptions.

Compensatory improvement

Several IOM report recommendations appear to be based on an implicit conceptual framework that we term the "compensatory improvement" framework. According to this framework, mission-based institutions (such as hospitals) strive to maintain an equilibrium position from which they can achieve their mission. When a change is imposed on such an institution and may lead to potentially threatening consequences (such as increasing handoffs leading to worse patient outcomes), the institution responds by applying resources and know-how in order to restore equilibrium. For example, the institution may develop and implement new systems for handoffs that increase continuity of care and patient safety. In this framework, new regulation promotes positive system change by requiring institutions to improve in order to compensate for their new restrictions:

..increasing [handoff] frequency requires that hospitals improve the process in order to maintain or improve the quality of care...Instead of merely viewing more frequent handovers as an increased opportunity for error, they can be viewed as another opportunity for resident learning. (IOM Report, p.269).

The compensatory improvement framework requires the assumption that organizations can and will proactively improve in response to regulatory changes rather than simply meet requirements; evidence for this assumption is not widespread. In addition, it is difficult to know the limits of the conditions under which a regulation will lead to positive system change. For example, it could be equally argued under this framework that massively increasing duty hours for residents will lead to better systems of fatigue management and monitoring in order to ensure that patient care is not impacted adversely.

Professional ethics

Several conceptual frameworks have been proposed with roots in models of professional ethics for physicians or societal concerns for equity. Professional ethics is an essentially contested concept (Gallie, 1955); although everyone may agree on the basic structure of an ethic, differing assumptions may lead to wholly different entailments of the ethic. For example, it is generally agreed that the professional ethics of medicine require physicians to place the needs of their patients ahead of their own. Those who oppose additional duty hour restrictions consider time for rest and sleep (derisively, “nap time”) to be a physician need that should be subordinated to continuity of care, a patient need (Borman & Fuhrman, 2009). Lewis (2009) goes further and argues that “the experience of 80-hour workweeks [sic] in residency will make lifestyle an important consideration for these individuals in practice, and one may assume that they will be less inclined to make themselves available for emergency call in hospitals and less likely to choose rural or solo practice.” In contrast, those who do not oppose additional restrictions on this basis consider a well-rested physician to be a patient need, and argue that the service needs of hospitals should be subject to this need (Katzka & Proctor, 2009).

Dembe (2009) proposed that the Oath of Hippocrates (or other variations undertaken by graduating medical students) establishes an ethic that prohibits physicians from working in ways that would cause harm to patients. Again, “ways that could cause harm” is contested; Dembe suggests that physicians working without adequate sleep are violating this ethic, while others would undoubtedly argue

that physicians handing off patients at the end of a shift would be doing so. Dembe also expresses concerns that fewer workers with longer duty hours will be preferred by employers, and that this preference may result in inequities in hiring among, e.g., women and men, if women have a preference for shorter duty hours in order to accommodate child-bearing and rearing, or younger and older residents. He points out that even if residents may *wish* to work "excessively long hours," there may be a societal interest in prohibiting the option.

Higginson (2009) uniquely discusses empathy and skill as the defining ethics of a physician. He proposes a conceptual framework in which rest and work-life balance lead to an enhanced appreciation of life, and this appreciation leads the physician to have increased empathy for the suffering of others, which contributes to his or her effectiveness in care. Although Higginson suggests that the potential positive impact of duty hours on increasing empathy outweighs the potential negative impact of duty hours in decreasing skill, no studies have yet attempted to quantify this trade-off.

Discussion

Summary of results

The directions of the key outcomes predicted by the conceptual frameworks reviewed, organized by the basis for the framework (theory, practice, or model), and the entities experiencing the outcome (patient, resident, faculty, institution, or other health professions), are summarized in Table 3. Conceptual frameworks focusing on patient outcomes either emphasize the reduction in errors that will result from better-rested residents or the increase in errors that is expected from decreased continuity and increased handoffs. These outcomes were weighed explicitly by the IOM report, and recent large-scale studies comparing patient outcomes before and after the 2003 ACGME regulations find small positive effects of those regulations.

Table 3: Direction of key outcomes predicted by the conceptual frameworks

| | <i>Patient</i> | <i>Resident</i> | <i>Faculty</i> | <i>Institution</i> | <i>Other Health Professions</i> |
|----------------------|---|--|---|---|---------------------------------|
| Theory | ↓Error from fatigue | ↓Accidents ↓Sleepiness ↓Practice ↓Skills | | ↑Costs | |
| Best practice | | ↑Productivity ↑Quality of life (rest) ↓Quality of life (night shifts) ↑Presenteeism | ↓Preceptor relationships ↓Quality of life (Workload) | ↑Productivity | ↑Workload |
| Model | ↑Quality of handoffs (compensatory improvement) ↓Continuity ↑Handoffs | ↑Empathy ↑Rights ↓Commitment ↓Ownership ↓Post-residency practice | ↓Future skill ↓Skilled primary care physicians | ↓Resources for education ↓Sustainability of small programs | ↑Autonomy ↑Medicalization |

Conceptual frameworks focusing on resident outcomes are most frequently proposed and tend to either emphasize improvements in health, safety, and quality of life for residents that will result from

increased sleep, or concerns about reduced educational opportunities and skill degradation, particularly in surgical specialties. There is evidence for each of these relationships. Other frameworks suggesting both positive impacts of duty hour regulations (on empathy, worker rights) and negative impacts (on professional identity, patient ownership, post-residency practice) are supported by little substantive evidence.

Conceptual frameworks focusing on faculty outcomes uniformly predict a negative impact on faculty from duty hour changes. There is evidence for increased faculty workload as a result of duty hour restrictions, and decreased quality of life for faculty. At the same time, there are concerns that can not yet be evaluated about how the skill of current residents will manifest in the future when they are faculty practitioners.

Conceptual frameworks focusing on institutions or residency programs are strongly driven by the high expected costs of implementing the IOM Report recommendations. These costs, acknowledged in the IOM report, may be recouped in part by society through increased patient safety, but are still likely to be substantial and to fall largely on the training programs. Without additional resources to support programs, the educational mission may be jeopardized, and smaller programs may face a crisis of viability.

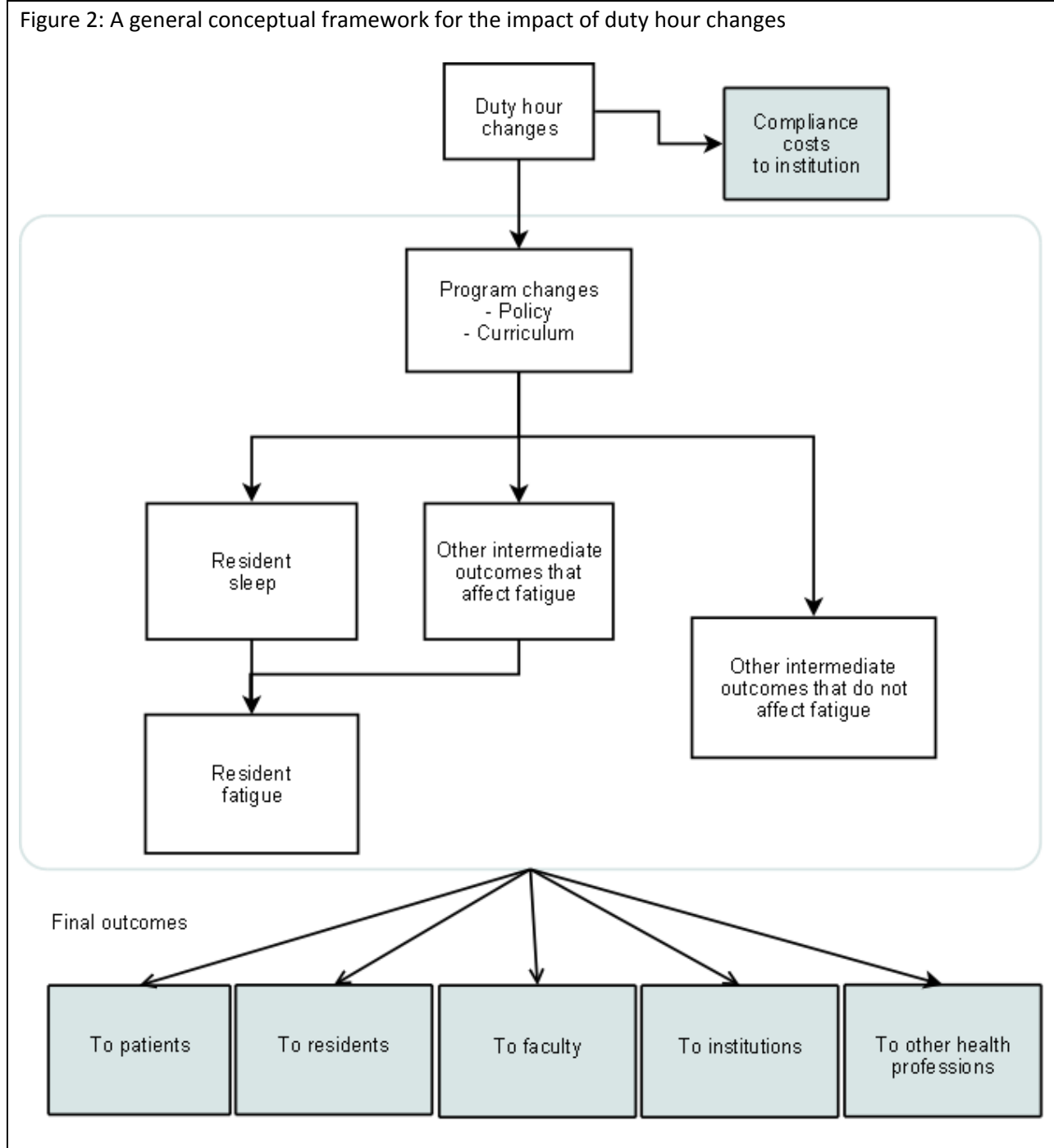
Conceptual frameworks focusing on the activities of other health professionals note the increased workload likely to fall on physician extenders in order to implement the IOM Report recommendations. It has also been suggested, however, that as a result of new and more medically-oriented patient care responsibilities, the professions of nursing and physician assistantship will become significantly more medicalized and characterized by greater autonomy, which some in these professions may find desirable.

The discourse of duty hours

This review identified and classified 83 relevant outcomes of duty hour changes and some 23 conceptual frameworks that have been applied in the study of the impact of resident duty hour changes. The frameworks vary both in their theoretical basis and the amount of empirical evidence supporting the hypothesized relationships. Many of the frameworks are in opposition, some even making directly opposite predictions about the impact of a change in duty hours on such important outcomes as patient welfare and resident quality of life. For example, the "sleep deprivation" framework employed throughout the IOM report posits a beneficial impact on patient welfare from reduction in fatigue, while the "degradation of skill" framework posits a detrimental impact on patient welfare from reduction in physician skill.

Many frameworks identified, particularly those explicitly adopted in the IOM report, are captured in the general conceptual framework shown in Figure 2. This framework posits that changes in duty hour regulations result in changes in residency programs to achieve compliance with new regulations as well as monitoring and compliance costs to the institution. Program changes have multiple levels of intermediate outcomes, some of which (such as shift length and sleep periods) contribute to, for example, resident fatigue, while others (e.g. increased numbers of handoffs) are simply other consequences – often unintended but predictable – of program changes. As a result of these intermediate outcomes, a set of final outcomes (to patients, residents, faculty, institutions, and other health professions) occur. Several of the conceptual frameworks outlined in Appendix C posit this set of simple causal relationships and differ primarily in which elements of program changes and which outcomes they choose to include or exclude.

Figure 2: A general conceptual framework for the impact of duty hour changes



Although the general conceptual framework and those with similar structure are intuitively appealing and undoubtedly capture several important impacts of duty hour regulations, they also demon-

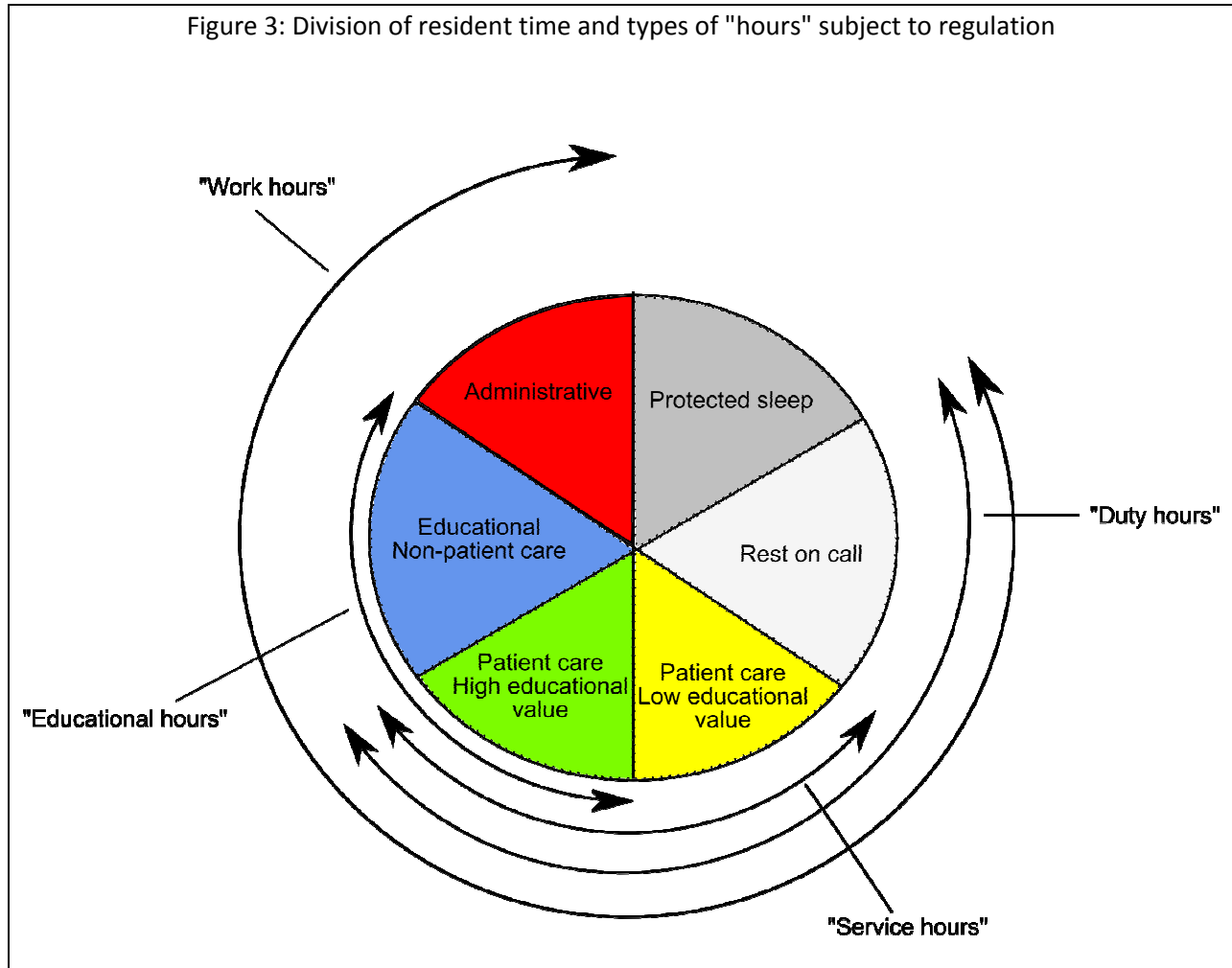
strate important limitations in how the effect of duty hour regulations are currently conceptualized. These simple causal frameworks often neglect to consider moderating variables, most obviously those related to differences by specialty and training program. In addition, these frameworks do not incorporate feedback or consider endogenous changes in the behavior of residents, faculty, institutions, or even patients in response to regulatory changes.

Gaps in the discourse

Reflection on the EU experience with the EWTD is valuable at a time when U.S. organizations are considering further restrictions on duty hours; unfortunately, the EU experience has rarely been given serious attention by U.S. authors. Two key aspects of the EWTD bear immediate attention. First, because of the stricter EWTD rules, considerably more focus has been placed on the scientific study of fatigue and risk associated with particular shift configurations, schedules, and rota at the ward or service level. This work should be helpful and informative in the design and evaluation of new duty systems in the U.S. as well.

Second, and perhaps more crucially, the EU experience has led programs in Europe to more careful consideration of the different kinds of activities in which residents engage. This consideration reveals that the concept of "duty hours" itself is contested. As shown in Figure 3, residents engage in a variety of activities (inner circle), including uninterrupted protected sleep, interruptible (e.g. home call or call room) rest, patient care tasks with low educational value (e.g. "scut"), patient care tasks with high educational value, educational activities that do not include patient care (e.g. didactic conferences or practice with simulators), and administrative activities apart from the hospital. Whether or not non-patient educational activities and on-call rest should be included in "duty hours" is of sufficient controversy as to have led to legal cases in the European Court (Mommaerts, 2009) and proposals for distinguishing "purely training" hours from "combined service and training hours" (Benes, 2006). Concerns

about the balance of education and service for house staff have a long history in medicine, and remain an important unresolved issue in medical education (Cooke, Irby, & O'Brien, 2010; Ludmerer, 1999).



Although a great deal of attention has been paid to duty hours, too little attention has been paid to the nature and intensity of the activities that occupy those hours. Theories of fatigue, as well as descriptions of the activities of residents, suggest that fatigue and risk depend on the relationship between hours worked and the content of the work, and the nature of this relationship, as well as the development of measurements of work intensity and consequent fatigue, needs further study.

Most of the literature to date focuses on isolated outcomes of changes in duty hours. Few conceptual frameworks have explicitly posited mediational relationships or led to path-analytic tests of mediation. For example, reconfiguring duty hours is expected to reduce fatigue, and reduced fatigue is expected to enhance resident learning (IOM report). However, reconfiguring duty hours is also expected to reduce opportunities to practice and reduced practice is expected to degrade resident learning (Anglen, et al., 2009). We could identify no studies in which the conceptual framework includes both of these relationships and thus motivates tests of the respective power of fatigue and practice as mediators between duty hour regulations and learning. In addition, few frameworks explicitly propose moderator variables that might palliate or aggravate the relationships between predictors and outcomes; the NORA Long Work Hours Team framework (C. C. Caruso, et al., 2006) and the Fletcher, Parekh, et al. (2008) model of resident-reported contributes to patient care mistakes are notable exceptions.

Another, and related, critical gap in the literature is the dearth of studies that investigate the net tradeoffs between such key outcomes as patient safety, resident safety, resident education, resource costs (to society and programs), and quality of life for resident and attending physicians. We do not yet know, for example, to what degree a particular scheduling system increases patient safety by sacrificing what degree of resident education. Filling this gap in the literature requires not only a concerted and coordinated set of investigations, but investigations designed to guide the development and refinement of a theory of the relationships between these outcomes, which are not likely to be simply additive.

Although understanding the tradeoffs between duty hours and key outcomes would itself represent a major contribution to both our understanding of residency training and to the implementation of improved duty hour systems at a given program, the development of overall duty hour regulations requires a further step. We must understand not only the tradeoffs inherent in changes to duty hour configurations, but also the *value* society places on such tradeoffs, and its concomitant willingness to pay to maximize value (or, alternatively, the resource constraints under which value is to be maximized). As an

extreme example, a society that values safety much more than other outcomes might institute overlapping short shifts, extend residency by several years to compensate for less educational time, and invest heavily in information and simulation technology as well as subsidizing residents and programs.

At the same time, in addition to research that will develop improved theory of the impact of duty hours, we recognize such scholarship is time-consuming and that practice-based research on the implementation of changes to duty hours may be necessary in the short-term. We support calls for rigorous study of innovative approaches to realigning duty hours that have been made by other investigators (Volpp & Landrigan, 2008).

Limitations

Extracting from the reported research the underlying conceptual frameworks is a qualitative analysis problem that does not lend itself to quantification of the assumptions and principles. Rather it requires identifying the assumptions and principles implicit and explicitly stated, clarifying the connections between them while maintaining a "neutral" position about their value. As such, and as with other qualitative research projects, researcher bias is a potential limitation. We attempted to reduce the impact of researcher bias through the use of a team approach in which articles and conceptual frameworks were reviewed by multiple investigators and discrepancies were resolved by discussion and consensus.

This review focuses primarily on literature evaluating the 2003 ACGME regulations or the 2004 amended European Working Time Directive (and, to a lesser extent, the 1991 U.K. New Deal provisions related to duty hours). The ACGME regulations have only been in place for six years, and large-scale studies of their impact (particularly on patient care) are only just emerging; the most important of these studies have been published after the IOM Report. Further, as the IOM Report recommendations are not yet implemented anywhere, there are only responses to the recommendations, and no studies of the recommendations as such. The extant literature necessarily limits this review.

The recommendations in the IOM Report go beyond changes in the configuration of resident duty hours. Important recommendations relating to handoff practices, supervision, and monitoring of regulations also appear in the IOM Report, but were not reviewed or considered in this review.

Conceptual frameworks are important. They not only underlie arguments about the impact of duty hour changes but also frame assumptions about research hypotheses and necessary research designs to provide evidence about the impact of changes. Despite this important role, however, conceptual frameworks are often implicit, serving as a backdrop to argument and research rather than receiving attention themselves. A key recommendation in the advancement of our knowledge about the design of working conditions for residents is to encourage researchers and advocates to make their conceptual frameworks explicit and to detail their bases, workings, and implications. Such practices will not only make researchers explicitly aware of the conceptual frameworks they are using and the position of their work in a broader picture of duty hours research, but will help them better select key variables for their studies and foster knowledge building.

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Appendix A: Data sources, literature review strategy, and results

For searching published literature (searches conducted in July 2009)

| <i>Data source</i> | <i>Search strategy</i> | <i>Retrieved</i> | <i>Included</i> |
|---|--|------------------|-----------------|
| BEME | "Find on page" search for the term "80" | 0 | 0 |
| CINAHL | keyword search of resident AND 80 hours | 1 | 1 |
| COCHRANE database of systematic reviews | "ACGME" in Title, Abstract or Keywords ("resident" in Abstract or registrar in Abstract) and duty in Abstract and hour in Abstract and restriction in Abstract | 17 | 0 |
| Conference Papers Index | residents AND 80 AND hours | 9 | 1 |
| Dissertations & Theses | (residents) AND (80) AND (hours) (residents) AND (work hours) | 39 | 2 |
| EMBASE | resident AND 80 hours limited to human and 2008-2009 | 6 | 6 |
| EMBASE | (workload OR "work schedule" OR "work schedule tolerance" OR fatigue OR "mental fatigue" OR "work hours" OR "personnel staffing" OR scheduling) AND (sleep OR "sleep deprivation" OR "sleep disorder" OR "circadian rhythm" OR chronobiology) AND (residency OR "education, medical, graduate" OR "internship and residency" OR "night float"), limited to 2005-2009 | 163 | 163 |
| ERIC | exp Graduate Medical Education/ limited to yr "2007 - 2009" | 58 | 0 |
| Proceedings First | Residents AND 80 hours | 2 | 0 |
| PsycInfo | residents and 80 and hours limited to 2008-2009 | 43 | 18 |
| PubMed | (80 hour AND residents) | 256 | 87 |
| PubMed | Related articles search related to Fletcher et al., and related articles on relevant related articles | 94 | 94 |
| PubMed | (workload OR "work schedule" OR "work schedule tolerance" OR fatigue OR "mental fatigue" OR "work hours" OR "personnel staffing" OR scheduling) AND (sleep OR "sleep deprivation" OR "sleep disorder" OR "circadian rhythm" OR chronobiology) AND (residency OR "education, medical, graduate" OR "internship and residency" OR "night float"), limited to 2005-2009 | 95 | 95 |
| Web of Science (Current Contents) | "80 hours"AND medical AND education + related articles search on relevant articles, limited to 2008-2009 | 27 | 24 |
| Overall | All above combined, duplicate articles removed, limited to 2008-2009 | | 196 |

For searching residency program organization annual meetings (searches conducted in July 2009)

| <i>Data source</i> | <i>Search strategy</i> | <i>Retrieved</i> | <i>Included</i> |
|---|--|------------------|-----------------|
| American Surgical Association | "duty hour" and "resident", 2005-2009 | 3 | 1 |
| Association of Program Directors in Surgery | "duty hour" and "resident", 2006-2009 | 2 | 2 |
| American College of Surgeons | "duty hour" and "resident" | 137 | 0 |
| American College of Obstetrics and Gynecology | "duty hour" and "resident" | 78 | 0 |
| Association of Professors of Obstetrics and Gynecology / Council on Resident Education in Obstetrics and Gynecology | "hour" and "resident", 2009 | 33 | 6 |
| Association of Program Directors in Internal Medicine education conferences | "duty hours" and "resident", 2006-2009 | 0 | 0 |
| American College of Physicians | No abstracts available | 0 | 0 |
| Association of Family Medicine Residency Directors | "duty hours" and "resident" | 3 | 0 |
| American Academy of Family Physicians | "duty hours" and "resident" | 76 | 0 |
| National Conference for Family Medicine Residents and Students | Poster presentations, 2008-2009 | 0 | 0 |
| American Association of Directors of Psychiatric Residency Training | "duty hours" and "resident", 2004-2009 | 0 | 0 |
| American Psychiatric Association web site | "duty hours" and "resident" | 0 | 0 |
| Association of Academic Psychiatry | Annual meeting agenda, 2009 | 0 | 0 |
| American Academy of Pediatrics | "duty hours" and "resident" | 29 | 3 |
| Academic Pediatric Association web site | "duty hours" and "resident" | 0 | 0 |
| Association of Pediatric Program Directors | Annual meeting abstracts, 2005-2009 | 4 | 4 |

Appendix B: Literature published in 2008-2009 and reviewed

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Appendix C: Conceptual frameworks identified in the study of duty hour regulations

| Framework | Type | Outcomes | Predictors | Relationships | Limitations |
|---|--------|---------------------------|---|---|--|
| Sleep deprivation (IOM report) | Theory | Resident skills | Quantity and quality of sleep General human performance | Lack of quality sleep leads to worse performance. Changes in duty hours can increase quality sleep and improve performance | Limited evidence for link between sleep, fatigue, and fitness for duty in residents specifically (but see Philibert, 2005) |
| Swiss cheese (Fletcher, Parekh, et al., 2008; J Reason, 1990; J. Reason, 2000). Also the basis for HFACS. | Theory | Patients medical outcomes | Hazards Systems to prevent harm cheese Active failures and latent conditions allowing failure holes Resident fatigue as a particular limitation of the health care system | Safety is compromised when multiple systems fail simultaneously. Fewer duty hours lead to less resident fatigue, which limits the chance of the resident system failing together with others | Understanding of framework by its users varies considerably (Perneger, 2005). |

| Framework | Type | Outcomes | Predictors | Relationships | Limitations |
|--|--------|--------------------|--|---|-------------|
| Resident-reported contributors to patient care mistakes (Fletcher, Parekh, et al., 2008) | Theory | Patient safety | Resident quality of life Patient continuity of care Institution entropy Resident hand-offs Resident experience Resident workload Professional work ethic Resident fatigue | Work hour changes lead to unintended consequences of less time in hospital and improved resident well-being. Work hour changes lead to unintended consequences of more discontinuity and work hours themselves as a goal Improved well-being mitigates factors that lead to patient care mistakes; other consequences aggravate these factors | |
| Deliberate practice (Ericsson, 2004; Omahen, 2009) | Theory | Resident education | Hours of deliberate practice | Reduced duty hours overall can be compensated for by increasing the proportion of time spent in learning | |

| Framework | Type | Outcomes | Predictors | Relationships | Limitations |
|---|--------|---|--|---------------------------------------|-------------|
| Shift worker fatigue (Horrocks & Pounder, 2006; QinetiQ Centre for Human Sciences & Simon Folkard Associates Limited, 2006) | Theory | Resident fatigue, specifically average probability of a high score on the Karolinska Sleepiness Scale | <p>Cumulative fatigue C, based on complete pattern of shift schedules</p> <p>Duty timing T, based on when a particular shift starts and ends</p> <p>Job type/breaks J, based on shift content including activity and breaks</p> <p>Each modeled, and varies from 0-1</p> | $FI = 100 (1 - (1 - C)(1 - J - T))$ | |
| Shift worker risk (Horrocks & Pounder, 2006; QinetiQ Centre for Human Sciences & Simon Folkard Associates Limited, 2006) | Theory | Resident relative risk of accident on a particular shift | <p>Cumulative fatigue C, based on complete pattern of shift schedules</p> <p>Duty timing T, based on when a particular shift starts and ends</p> <p>Job type/breaks J, based on shift content including activity and breaks</p> <p>Each modeled, and varies from 0-1</p> | $RI = C * J * T$ | |

| Framework | Type | Outcomes | Predictors | Relationships | Limitations |
|--|--------|--|---|---|---------------------|
| Shift risk (Folkard & Lombardi, 2006) | Theory | Worker relative risk of accident or incident for a given span of shifts, denoted RR_S . Risk is relative to five 8-hour day shifts with a single mid-shift break | Relative risk for first shift in the span RR_T Additional risk for number of successive shifts CR_N Additional risk for length of shifts CR_L Additional risk for interval between breaks CR_B | $RR_S = RR_T + CR_N + CR_L + CR_B$ | Outside of medicine |
| NORA Long Work Hours Team framework (C. C. Caruso, et al., 2006) | Theory | Workers, immediate negative outcomes: Reduced/disturbed sleep, fatigue, stress, negative mood, dysfunction Long-term outcomes: Worker quality of life, family members of workers quality of life, institutional productivity and injury costs, patient /community safety | Work hours and other schedule characteristics Availability of time for recovery and non-work activities Exposure to job demands and hazards Worker characteristics and job characteristics | (1) Work hours and schedule result in reduced time for recovery and non-work activities as well as greater exposure to job demands and hazards. (2) Reduced time for recovery/non-work and exposure to job demands/hazards lead to immediate negative outcomes (3) These contribute to multiple long-term adverse outcomes for workers, family, employers, and community. Relationships (2) and (3) are moderated by worker and job characteristics. | Outside of medicine |
| Day vs. night work (Bamford & Bamford, 2008) | Theory | Resident quality of life | Start and end times of work shifts | Night work leads to lower quality sleep, worse health, and less work/family balance | |

| Framework | Type | Outcomes | Predictors | Relationships | Limitations |
|---|----------------|---|---|--|---------------------|
| NIOSH report (C. C. Caruso, et al., 2004) | Theory | Worker safety, illness, health behaviors Worker performance | 12-hour or longer, including "on-call" shifts vs. 8-hour shifts | Relative to 8-hour shifts, overtime, extended duty, and on-call schedules were associated with more illness and injury, worse health behaviors, and lower performance. | Outside of medicine |
| Presenteeism (Nielsen & Allen, 2009) | Best practices | Resident safety Patient medical outcomes | Workload Available coverage Professional work ethic | Residents with a strong work ethic and a high work load relative to available coverage will attempt to work even when they are sick. Reporting to work sick leads to risk of contagion for other residents and patients. | |
| Hourly productivity (Jeanmonod, et al., 2008) | Best practices | Resident case volume per rotation Institutional patient admissions | Length of shifts Patients seen per shift hour | Medium-length shifts (e.g. 9 hours) increase resident hourly productivity Increased hourly productivity results in a greater number of patients seen overall and per-resident | |
| Preceptor relationship (Balmer, et al., 2007) | Best practices | Faculty satisfaction | Number of different preceptors e.g. continuity clinic | Duty hour restrictions increase the total number of preceptors residents work with in order to accommodate scheduling needs. Preceptors feel less attached to individual residents and less satisfied with their relationships. | |

| Framework | Type | Outcomes | Predictors | Relationships | Limitations |
|---|-----------------------------|--|---|--|--|
| <p>Regulation is constraint (“One size does not fit all”)</p> <p>Mentioned in many organizational responses, e.g. (Grady, et al., 2009; Greenberg, et al., 2009)</p> | Model (conceptual metaphor) | Institution ability to adapt, innovate | <p>Rigidity of regulation enforcement</p> <p>Flexibility within regulations</p> | <p>Rigid constraints limit movement (innovation) to within the constraints.</p> <p>If constraint is too tight, movement within the constraints may not be sufficient for innovation.</p> | |
| <p>Sleep-deprived practice is evidence of commitment (Charap, 2004; Lopez & Katz, 2009)</p> | Model | Resident professionalism | | <p>A physician demonstrates dedication through caring for patients regardless of his/her personal discomfort and needs, including fatigue.</p> <p>Often connected to sleep-deprivation as a rite of passage in the development of a physician.</p> | |
| <p>Sleep-deprived practice is a skill</p> | Model | Resident skills | | <p>The ability to practice without adequate rest is learnable and improves through experience in such practice.</p> | <p>Others argue that habituation to stress leads to ethical erosion (Lopez & Katz, 2009)</p> |
| <p>Community Charter of the Fundamental Social Rights of Workers (1989, basis of the 1993 EU Working Time Directive 93/104/EC; doctors in training included as workers by amendment 2000/34/EC)</p> | Model | Resident safety | | <p>Excessive work hours reduce worker safety and health, which are fundamental social rights.</p> | |

| Framework | Type | Outcomes | Predictors | Relationships | Limitations |
|---|-------|---|--|---|---|
| Ethical treatment of workers (Dembe, 2009) | Model | Resident safety Societal ethics Patient safety | | Extended duty may be coercive and deceptive and thus unethical treatment of workers, and may lead to inequities in the labor market. There is a societal interest in protecting workers. The medical profession's ethics prohibit practice in ways that would cause harm to patients. | |
| Fixed pie / zero-sum (Cited by many organizational responses) | Model | Resident education Institution cost to residency program | Funding available for residency program Resident hours available to see clinical cases Length of residency program in years Time available to attending physicians to teach | Total residency resources – funding, hours, years, attending time – are fixed. Reduced hours will need to be made up for by shifting funding from education to clinical care (e.g., to hire physician extenders), or teaching time from attending physicians, or by increasing residency length. | Zero-sum assumption may not hold if additional resources are provided |

| Framework | Type | Outcomes | Predictors | Relationships | Limitations |
|--|-------|--|--|---|---|
| <p>Degradation of skill</p> <p>(American College of Surgeons Task Force on the Resident 80-hour Work Week, 2009; Charap, 2004; Marron, et al., 2006)</p> | Model | <p>Resident skills</p> <p>Patient medical outcomes</p> | | <p>Residents are receiving less training time, and becoming less skilled.</p> <p>Patient outcomes have been maintained because faculty have taken over work previously done by residents.</p> <p>When residents eventually become faculty, however, patient outcomes will decline; alternatively, residents will recognize their limits and be more likely to see subspecialty training, leaving the least prepared residents to become attending physicians in primary care.</p> | <p>Unable to observe until sufficient residents after 2003 have become attending physicians or enter fellowships.</p> |
| <p>Compensatory improvement (IOM report)</p> | Model | <p>Patient medical and non-medical outcomes</p> | <p>Number of handoffs</p> <p>Health care organizations</p> <p>Continuity of care</p> <p>Patient safety</p> | <p>Decreased duty hours increase handoffs.</p> <p>Increased handoffs result in decreased continuity of care which results in risks to patient safety.</p> <p>Health care organizations wishing to maintain safety will devise improved mechanisms for maintaining continuity across handoffs</p> | <p>Little evidence that organizations can or will improve in response to regulatory changes</p> |
| <p>Professional role (aka "shift mentality" (Bamford & Bamford, 2008; Cass, et al., 2003; Charap, 2004)</p> | Model | <p>Resident professional behavior, ethical development</p> <p>Patient continuity of care</p> | <p>Professional attitude putting needs of the patient before those of the physician</p> | <p>Arbitrary limits on duty hours lead residents to see themselves as shift workers, not as responsible for a patient's complete course of care.</p> <p>Residents may be ill-prepared for independent practice post-residency.</p> | <p>Unclear whether attending physicians actually model the desired behavior when practicing with residents (Anim, et al., 2009; Cyr-Taro, et al., 2008)</p> |

| Framework | Type | Outcomes | Predictors | Relationships | Limitations |
|---------------------------|-------|--------------------------|--------------------------|---|-------------|
| Empathy (Higginson, 2009) | Model | Resident professionalism | Resident quality of life | <p>Rest and work/life balance lead to an appreciation of life.</p> <p>Appreciation of life leads to increased empathy with suffering of others.</p> <p>Empathy is a defining characteristic of a physician.</p> | |