Should Sleep-Deprived Surgeons Be Prohibited From Operating Without Patients' Consent?

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Introduction

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The effects of sleep deprivation on performance of physicians has been widely studied ever since the death of Libby Zion in 1984, the subsequent campaign by her parents and others to regulate physician work hours, and the passage of the so-called Libby Zion Law by New York State in 1989 [1]. Impetus was added to investigations of the effects of sleep deprivation when the Accreditation Council for Graduate Medical Education (ACGME) adopted similar standards for accreditation of residency programs in the United States in 2003 [2]. While sleep deprivation clearly affects mental and physical functioning, results of investigations of clinical outcomes have been mixed—some finding adverse effects on patient care, others finding no such effects [3–6].

The arguments for regulating work hours of residents have been extended to apply in a more limited way to attending surgeons. In a recent issue of the *New England Journal of Medicine* [7], two medical ethicists and a sleep specialist published a paper that opened with this scenario: "A surgeon on overnight call responds to an 11 PM call from the hospital, where a patient has presented with an acute abdomen. After working up the patient for several hours, the surgeon decides to . . . perform a bowel resection. By the time the procedure is completed . . . it is time for morning rounds. The surgeon has not slept all night and is scheduled to perform an elective colostomy at 9 AM."

The sleep specialists followed the vignette with a series of questions [7]: Does the surgeon have an obligation to disclose to the patient the lack of sleep during the past 24 hours and obtain new informed consent? Should the surgeon give the patient the option of postponing the operation or requesting a different surgeon? Should the hospital have allowed the surgeon to schedule an elective procedure following a night he was scheduled to be on call? Should it allow a surgeon to perform elective surgery after having been awake for more than 24 hours?

After discussion of the effects of sleep deprivation (fewer than 2 hours of sleep in the previous 24 hours), the researchers answered these questions in the affirmative, with these statements [7]: "Patients awaiting a scheduled elective surgery should be explicitly informed about possible impairments induced by sleep deprivation and the increased risk of complications." "They should then be given the choice of proceeding with the surgery, rescheduling it, or proceeding with a different physician." "If patients decide to proceed, they should explicitly consent to do so—in writing, on the day of the procedure, in front of a witness, and ideally on a standardized form designed for this purpose."

In the same issue of the *New England Journal of Medicine*, three leaders of the American College of Surgeons responded to that paper in a letter to the Editor [8], agreeing that sleep deprivation could be a problem for surgeons, but disputing the necessity or wisdom of mandating a signed informed consent document. They argued that, instead, surgeons should be better educated about the effects of sleep deprivation as well as other factors that may affect performance, enabling them to weigh all issues to provide the best patient care. "A call for mandatory disclosure," they stated, "essentially eliminates the necessary judgmental latitude surgeons should possess to determine their fitness for providing optimal patient care" [8].

In the essays that follow, two authors of those publications, Dr Charles Czeisler and Dr Carlos Pellegrini, present arguments on either side of the question of whether sleep-deprived surgeons should be required to obtain informed consent from patients before elective surgery.

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Pro

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More than 40 years ago, Drs Richard Friedman, Thomas Bigger, and Donald Kornfield from Columbia University College of Physicians and Surgeons in New York published a landmark paper as a Special Article in the *New England Journal of Medicine* [9]. In it, Friedman and colleagues reported that sleep deprivation—which was first reported to adversely affect human performance in a classic 1896 study of Patrick and Gilbert from the University of Iowa [10] and had already been documented to impair cognitive and emotional brain functioning [11–22] in healthy human participants more than fifty years ago—also adversely affected clinical task performance of physicians during their first postgraduate year of training in internal medicine. In their 1971 article, Friedman and colleagues [9] reported that physicians-in-training who were acutely fatigued (having slept an average of 1.8 hours the prior night) made 85% more errors detecting cardiac arrhythmias on an electrocardiogram than those same physicians did when they were not acutely fatigued (having slept an average of 7 hours the prior night).

Moreover, Friedman and colleagues [9] documented changes in the mood of the acutely sleep-deprived physicians. Such physicians not only felt much greater fatigue when they were acutely sleep deprived than when they were not, but also felt significantly greater sadness and less joy, vigor, surgency, and social affection and exhibited significantly elevated physiologic, perceptual, and cognitive abnormalities. The researchers noted that the psychological deficits they observed in physicians routinely deprived of sleep in the workplace were similar to the deficits observed by other investigators in volunteers deprived of sleep in laboratory studies. Of the physicians studied, 86% reported "difficulty in thinking" when they were acutely sleep deprived; 71% reported depression; 64% reported hyperirritability; 43%, depersonalization and inappropriate affect; and 36% reported recent memory deficit. To illustrate, Friedman and colleagues [9] quoted one of the resident physicians, who reported, "I am so tired I forget what the name is on the chart I am writing in. As a result, I write progress notes in the wrong charts and try to correct myself in the morning." Friedman and colleagues, who limited their study to physicians-in-training who had been working 31 to 36 hours at the time of testing but noted that such physicians routinely worked as many as 60 consecutive hours on weekends, concluded that "only a limited amount of sleep loss can be sustained by an intern (Post-Graduate Year 1 [PGY-1] resident physician) before emotional and intellectual functioning deteriorates" [9].

Publication of the Friedman study [9] in the *New England Journal of Medicine* precipitated a major change in the scheduling of physicians in training—although ironically not the elimination of the routinely scheduled extended duration (≥24-hour) work shifts that the investigators found degraded the performance of physicians. Moreover, the publication did not precipitate the elimination of the 60- to 84-hour work shifts that resident physicians routinely worked, until at least 2003, on weekends at many institutions nationwide [23]. Instead, the frequency with which the traditional extended duration work shifts were scheduled was reduced from an average of three extended duration shifts per week to an average of two extended duration shifts per week, without reducing the duration of those extended duration shifts at that time. On certain rotations, many institutions continued to schedule residents to work three extended duration shifts per week. The principal rationale used to justify the continued tradition of scheduling physicians and surgeons to work extended duration shifts during both training and practice has been continuity of care. Simply put, the main rationale used to justify more than 24-hour shifts at the time—which was later formally tested and disproven in a randomized controlled trial [24]—was that it was better for a patient to be cared for by a tired physician who has followed his or her care since admission to the hospital than by a more rested physician who may be less familiar with the course of the patient's most recent illness. Yet no such rationale can be invoked to justify beginning an elective surgical procedure on a new patient when a surgeon's performance is impaired by sleep loss. Moreover, surgeons are required by law to obtain informed consent before elective surgery, after having disclosed what a reasonable patient would consider to be the "material risks" associated with the procedure. To evaluate the premise that sleep-deprived surgeons should thus be required to disclose such sleep deprivation and then obtain a patient's informed consent before operating, it is important to consider the current evidence linking sleep deprivation to human performance in the context of the ethical and legal principles of informed consent for elective surgery. Some parts of this review are taken from earlier publications [3, 24]. In framing my own position on this question, I do need to concede at the outset that I can only support the premise in the case of elective surgery. Given that laws in most jurisdictions and the principles of informed consent allow surgery without any informed consent in emergency situations, I cannot support this premise in the case of emergency surgery.

Sleep Loss and Performance Impairment

A great deal of evidence links sleep loss with performance impairment. Many factors influence the ability of healthy persons to sustain effective waking neurocognitive performance: biological time of day (ie, circadian

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phase), length of prior wakefulness, nightly sleep duration, and proximity of the last sleep episode [3, 24, 25]. While the effects of these circadian and homeostatic sleep regulatory processes can be modified by environmental conditions, physical activity, and pharmacologic agents (ie, caffeine or nicotine during night wakefulness or hypnotics during day sleep), they cannot consistently overcome the impact of adverse circadian phase and sleep deprivation on performance. Repeated interruptions of sleep, such as is experienced by physicians when they are on call, can lead to sleep deficiency by degrading the restorative quality of sleep. Such repeated interruptions of sleep are thought to contribute to the excessive daytime sleepiness associated with sleep disordered breathing, which induces many brief arousals during the night. Interestingly, just being on call itself disturbs sleep, even when the person is not called [26]. Misalignment of circadian phase with the work/sleep schedule, cumulative sleep deficiency, lengthy prior wakefulness, or recent awakening can create an imposing biological force that can overpower a person's ability to remain awake and attentive while caring for patients [3, 24, 27, 28]. The effects of these four factors can lead to impaired neurocognitive performance, including memory consolidation, and deterioration of waking performance marked by increased rates of attentional failures [29, 30]. These consequences are particularly evident while attempting to sustain attention for a continuous duration of time (eg, for 10 to 20 minutes or more). Sleep-related performance decrements can lead to impaired job performance and higher rates of errors, accidents, and injuries. In the absence of sleep, in the latter half of the night near the habitual wake time, elevated homeostatic drive for sleep interacts with the circadian peak of sleep propensity to create a critical zone of vulnerability [25].

Without sleep, alertness and neurocognitive performance exhibit a steady deterioration attributable to sleep loss, onto which a rhythmic circadian variation is superimposed [24, 25, 31]. During sustained wakefulness, 24 hours of sleep deprivation has been shown to greatly impair neurobehavioral performance and judgment [32, 33], to an extent that is comparable to a level of 0.10% blood alcohol concentration [34, 35, 36]. Acute sleep deprivation impairs judgment, cognitive performance, memory, reaction time, visual-perceptual ability, distractibility, and ability to focus attention; it also increases the instability of waking neurobehavioral functions, the probability of eyelid closure, and the risk of loss of situational awareness, even when the eyes remain open [3, 24, 37, 38]. Ironically, instead of slowing response times to preserve accuracy, sleep-deprived participants increase speed at the expense of making more mistakes (ie, become "fast and sloppy") and take greater risks [33, 39].

Both acute and chronic sleep loss adversely affect postural stability, increase postural sway, and slow visual inputs that contribute to postural control [40–42]. The impact of 48 hours of sleep loss on neurobehavioral performance is very severe, degrading the ability to sustain attention and vigilance and to withhold automatic responses and inhibit inappropriate responses [28, 37, 43]. Chronic sleep restriction, such as losing 2 hours of sleep per night, impairs reaction time and driving performance by an amount equivalent to that induced by alcohol ingestion [34]. As with alcohol intoxication, chronically sleep deprived persons tend to underestimate the extent to which their performance is impaired, despite increasing impairment evident in objective recordings of the rate of lapses of attention [28]. Thus, it would be just as inappropriate to ask a sleep-deprived surgeon whether he or she is able to operate safely as it would be to ask an intoxicated patron whether she or he is able to drive home from a bar safely.

Attentional Failures and Automatic Behavior

Importantly, persons struggling to stay awake in the face of elevated sleep pressure—whether due to acute total sleep deprivation, chronic sleep restriction, or repeated interruption of sleep (due to external interruptions or the presence of a sleep disorder)—are not always able to do so. The instability of the waking state due to sleep loss is associated with the occurrence of so-called microsleep episodes (ie, involuntary sleep episodes $<$15 s long) and sleep attacks (ie, involuntary sleep episodes $>$15 s long) [27], both of which can be classified as attentional failures [30]. In a condition of chronic sleep deprivation, even when work (or wakefulness) is scheduled during an appropriate circadian phase, the probability of a sleep-related neurobehavioral performance failure (attentional failure) while working or driving is markedly increased. Of course, once a person has lost the struggle to stay awake and makes the transition from wakefulness to sleep, however briefly, driving performance is much worse than that of a drunk driver, as the person is unresponsive to the environment throughout the duration of the microsleep episode or the sleep attack.

Remarkably, sometimes drowsy persons linger in an intermediate state between sleep and wakefulness. The operator of a motor vehicle in this sleep-related condition—which probably represents a transitional state in which part of the brain is asleep while part of the brain remains awake—may maintain full pressure on the accelerator pedal and proceed for a considerable distance, even negotiating gradual turns and exhibiting goal-directed behavior, but fail to heed stop signals or respond appropriately to traffic conditions in a timely manner. This intermediate state, which has been termed automatic behavior syndrome, often results in a complete loss of situational awareness and judgment [44–46]. In the case of a motor vehicle driver, this can unfortunately involve driving toward the flashing hazard lights of disabled vehicles in a highway breakdown lane rather than steering clear of those vehicles. A striking example of automatic behavior associated with operation of a motor vehicle for an extended duration of time was documented on film, when the husband of a motorist who was nearly driven off the highway by a drowsy driver called 911 to report the drowsy driver and then videotaped the drowsy driver as she drove for 30 minutes on US Interstate 25 in

Denver [47]. Sleep deprivation degrades reaction time, impairs judgment, memory and vigilance, reduces attention span, increases distractibility, and raises the risk of attentional failures, automatic behavior, falling asleep at the wheel, and motor vehicle crashes, with drowsy driving accounting for an estimated 20% of motor vehicle crashes and serious crash injuries [48–50].

Cognitive performance is markedly degraded during the transition from sleep to wakefulness [51]. The extent to which this phenomenon, which is called sleep inertia, interferes with neurobehavioral performance is related to the depth of the prior sleep episode [52]. Thus, agents that interfere with sleep, such as caffeine, can mute the effect of sleep inertia [53]. The adverse impact of sleep inertia on performance can exceed the impact of total sleep deprivation [51]. Persons who are subjected to acute total sleep deprivation or chronic sleep restriction often experience very deep sleep, which will increase the effects of sleep inertia [52]. Upon awakening from sleep, they will often be confused and may even lack situational awareness. Sleep inertia can greatly degrade the performance of on-call physicians or surgeons when they are called upon to perform clinical tasks immediately upon awakening [51].

Young physicians in training who were randomized to work extended duration (>24-hour) shifts experienced twice as many attentional failures [30], and on average made 36% more serious errors caring for patients in intensive care units, including 55% more serious medical errors that reached the patient and 468% more serious diagnostic mistakes, as compared with the same physicians when they were scheduled to have many more handovers in care while working no more than 16 consecutive hours in intensive care units [54]. Most of the serious medical errors committed by the physicians who obtained less sleep were not knowledge-based mistakes, but rather were slips and lapses (ie, failure to carry out correctly an intended plan of action) [4]. Nationwide, we found that, on average, physicians averaging 2.6 hours of sleep during the prior 24 hours had a 168% increased risk of a motor vehicle crash driving home from such extended duration shifts than from shifts that afforded them an opportunity to obtain consolidated sleep averaging 7 to 9 hours in duration [23]. When performing procedures during the daytime, these young physicians had a 73% increased risk of a percutaneous injury after their 20th hour of work than during shifts that averaged less than 12 hours in duration [55]. In another study, the impairment of physicians on schedules in which sleep was restricted to an average of 2 to 3 hours in the prior 24 hours was comparable to the effects of elevated blood alcohol concentrations [56].

We have studied the risks of complications in patients operated upon for elective surgery by experienced attending faculty physicians after those physicians had performed surgical procedures on the night before the elective surgery. Daytime elective procedures that followed overnight emergency procedures occurring between midnight and 6:00 AM were matched with 1 to 5 daytime elective procedures performed by the same physician that did not follow an overnight procedure. Faculty attending surgeons performing elective procedures during the daytime who had a sleep opportunity of less than 6 hours between cases during the prior on-call night had a significantly increased rate (+170%) of procedural complications (ie, adverse events occurring as a result of care during an operation and likely attributable to the performance of the attending surgeon) [57].

Informed Consent and Disclosure

The standard of risk disclosure is based on the principle of patient autonomy, which has been stated in this way: "Physicians must have respect for patient autonomy. Physicians must be honest with their patients and empower them to make informed decisions about their treatment. Patients' decisions about their care must be paramount, as long as those decisions are in keeping with ethical practice and do not lead to demands for inappropriate care" [58].

In most jurisdictions, over the past 30 years, the standard of risk disclosure regarding informed consent has shifted from what a reasonable physician would expect to know (the "reasonable physician" standard) to what a reasonable patient would expect to know (the "reasonable patient" standard) [59]. The principle of patient autonomy is a fundamental principle underlying informed consent, and it requires that physicians respect the right of the patient to make voluntary and informed health care decisions. The patient-centered standard for informed consent "emphasizes patient autonomy by requiring that risk disclosure be conducted to satisfy what an ordinary reasonable person in the patient's particular position would want to know . . . . [this precedent] 'marks the rejection of the paternalistic approach to determining how much information should be given to patients' " [59].

Legally, physicians must disclose "material risks," which include impairment of the physician caused by any use of drugs, disease, or alcohol that increase the risk of an operation—such risks must be disclosed to the patient [59]. In the past, most deliberations regarding informed consent have focused on whether or not the informed consent adequately described the risks inherent in the surgical procedure itself and have not focused on the risks associated with the procedure being done in the hands of that particular health care provider at that time. Surgeons are understandably resistant to attempts to change the standard of informed consent from the published risks associated with various procedures to surgeon-specific and site-specific risks, for fear that it would open up a Pandora's box, including the issue of violating the privacy rights of a surgeon to protect information about his or her own medical history [60, 61]. Evidence is accumulating, however, that many factors, including prior experience of the surgeon, whether the hospital has a high or low volume of similar cases, and the availability of electronic medical records, affect the risk of operative complications and adverse events during hospitalization [59]. It is within this context that we must view the premise that is the subject of today's debate, namely, that sleep-deprived surgeons should not be allowed to operate without the patient's consent.

Given the principle of autonomy and the patient-centered standard of disclosure, physicians have a duty to disclose to the patient any condition of the treating physician that an ordinary reasonable person in the patient's particular position would likely consider a material risk (ie, would likely consider to be significant) and therefore want to know. The key question, then, is not whether physicians or surgeons view extended duration work hours and consequent sleep deficiency to be a material risk for the patient, although many do, or even whether or not scientific evidence compiled by medical scientists demonstrates unequivocally that extended duration work hours are a material risk for patients, though it does.

The key question is whether an ordinary reasonable person in the patient's particular position would likely consider extended duration work hours and consequent sleep deficiency to be a material risk and whether the patient would therefore want to know if his or her surgeon had been working for 24, 48, or 72 hours straight before undertaking an elective surgical procedure.

Several national polls have indicated what patients want to know. For example, one poll asked about the subjects' response if they learned that the doctor who is about to perform their surgery has been on duty for 24 consecutive hours [62]. Respondents reported that they would be very likely (65%) or somewhat likely (21%) to feel anxious about their safety; moreover, 60% of respondents reported that they would assume that it was very unlikely (31%) or somewhat unlikely (29%) that the surgical procedure would go well. Thus, 6 of 7 Americans would likely consider the status of a surgeon who has been on duty for 24 consecutive hours to be a material risk, and 6 of 10 believe that this would likely adversely affect the outcome of their surgery. Therefore, it is the surgeon's duty to disclose that condition and seek the patient's consent to operate in that condition before proceeding with the operation. Furthermore, respondents reported that they would be very likely (45%) or somewhat likely (25%) to ask for a different surgeon if they learned that the doctor who was about to perform their surgery had been on duty for 24 hours. So, 70% of Americans indicate that knowing that a surgeon who was about to perform their surgery had been on duty for 24 consecutive hours would influence their medical care decisions: it is the surgeon's duty to disclose that condition and seek the patient's consent to operate in that condition before proceeding with the operation. Confirmatory results were found in recent studies [63, 64].

The Boards of Directors of the Sleep Research Society and the National Sleep Foundation endorsed model legislation in 2005 that would establish "a requirement for physicians who have been awake for more than 22 of the prior 24 hours to inform their patients of the extent and potential safety impact of their sleep deprivation and to obtain consent from such patients before providing clinical care or performing any medical or surgical procedures." Given the extensive evidence that various aspects of neurobehavioral performance, including judgment regarding one's impairment, are degraded to a degree that is, on average, comparable to a blood alcohol concentration of 0.05–0.10 g/dL when persons are awake for 24 hours [34, 35, 36, 65], and that the average physician-in-training is impaired by an amount equivalent to a blood alcohol concentration of 0.05 g/dL when working frequent extended duration shifts [56], patients have a right to be informed if their physician has been on duty for 24 hours or more and the right to decide whether to take the risk of receiving care from that provider.

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Carlos A. Pellegrini, MD

Should a surgeon who has been awake for 22 of the previous 24 hours not be allowed to operate without the patient's written informed consent? My position is that informed consent is not the right solution.

The rationale for obtaining informed consent from this patient under the circumstances described above is as follows: The operation performed by a surgeon who has not slept for 22 hours imposes a higher risk. The patient has a right to know that there is an increased risk of complications (patient's autonomy). The patient's knowledge of an increased risk will result in actions that mitigate the risk.

Let us examine each of these three assumptions.

Does an Operation Performed by a Surgeon Who Has Not Slept for 22 Hours Impose a Higher Risk?

The issue of sleep deprivation and fatigue and its effects on medical care came to a head in the 1980s after the death of Libby Zion, a patient who had been admitted to a New York hospital and was treated by a resident who eventually claimed that fatigue caused by lack of sleep had impaired his decision-making abilities. Despite the tremendous publicity that this case received and its focus on sleep deprivation, the adjudication of responsibility by the courts in this case was equally divided between the hospital (on behalf of the resident) and the patient, who had not disclosed a previous history of cocaine use [66].

This case fueled interest in the impact of sleep deprivation leading to a considerable number of studies. Those studies can be divided into two general types: those conducted in laboratories under controlled situations, and those conducted by physicians (surgeons in our case) examining the effect of different work patterns on the outcomes of operations. The

majority of the studies performed in controlled situations showed that vigilance, decision-making, and other attributes are affected progressively by acute sleep deprivation of the type under consideration in our case. A few experimental and controlled studies, however, have shown that while sleep deprivation manifested itself in sleepiness scales and increased overall cognitive workload, the subjects were able to perform technical tasks and to learn new tasks after nearly 24 hours of sleep deprivation—something also pertinent to our discussion [67].

Conversely, studies that measured the relationship of sleep deprivation to outcomes of surgery have had varying results. On one extreme is the observation of Rothschild and colleagues [57] that in a subset of surgeons who had had less than 6 hours of "sleep opportunity" before an elective case (measured between the end of an emergency case while on call and the initiation of an elective case), the complication rate rose from 3.4% to 6.2% when compared with cases the surgeons had performed when they had not been on call or operated during the night. Of interest, however, is that, even in this study, when all cases and all surgeons are considered, there were no significant differences in the outcomes of elective operations whether the surgeon had or had not been operating the night before the elective case. The authors themselves acknowledge that they did not know whether or not the surgeons had slept the entire night before the "control" cases when they were not on call, and that there were potential confounders created by the retrospective nature of the study. On the other extreme are the findings of a more recent paper by Chu and colleagues [68] in which the researchers evaluated the effects of sleep deprivation on the outcome of more than 4,000 consecutive cardiac surgical procedures and found no difference at all in the results with sleep deprivation of the kind we are discussing today. In between these two extremes there are other studies that have focused on the effect of reduction of resident work hours and workload of surgeons, and so forth, with varying results and many of these studies showing no effect on the outcome of patients.

At the end of the day, well-controlled studies are impossible to do, and many studies that have looked at physicians' working hours and compared them to outcomes have failed to show an association. It is clear that while controlled studies show a progressive deterioration in our ability to do certain tasks, the failures of the studies to demonstrate influence on the outcome may be related to the fact that those involved use a number of fatigue mitigation techniques (such as physical fitness, periods of short naps, use of coffee, and others), to actually mitigate tiredness. The same has been true for the studies that have examined the effects of the implementation (in 2003) of an 80-hour work week for residents and mandatory periods of rest [5]. Examination of patient outcomes has shown varying results, and the largest cohort examined comprising all admissions to the VA failed to show any difference between the before and after 80-hour eras.

The argument above is not intended to defy logic; acute and chronic sleep deprivation by logic should impact on the surgeon's performance. However, the studies have shown that there is no clear, measurable, reproducible relationship between the number of hours a surgeon has been working and the outcomes of an elective procedure.

The Patient Has the Right to Know—But What?

There is no question that the patient has a right to know everything that may affect the outcome of a procedure that he or she is about to undergo. However, mandating that the surgeon disclose to the patient the amount of sleep that the surgeon had over the preceding 24 hours without a clear measurable effect on the patient's outcome is not indicated. Furthermore, doing so just before an operation, at the time of maximum vulnerability on the part of the patient, is inhumane. Even further, if surgeons believe that they are tired and may not be offering the patient the best operation, surgeons' ethics would insist that the surgeons excuse themselves from doing it. Therefore, asking a surgeon to discuss with the patient the potential for sleep deprivation to affect outcome (assuming the surgeon believed that to be true) at the same time that we ask the surgeon to behave professionally (and therefore abstain from doing the operation) makes no sense to me.

It is not only that this becomes impractical, but if surgeons were to be obligated to disclose whether they were on call and did not sleep, should they also disclose whether they were able to sleep well? Whether they were awake part of the night at home? Whether there are issues of health among family members that kept a surgeon awake or worried? And what about financial worries, marital problems, and so many other issues that are known to affect the ability of humans to concentrate. How far is this disclosure supposed to go [8, 69]?

I understand that it is "convenient" to take something as objective as having been on call versus not having been on call or having performed an operation the night before versus not having performed an operation the night before as elements that can be easily determined and easily measured and put them in the consent. But why do that in the face of a lack of demonstration of a clear effect on outcomes? And if it was clear that it affected outcomes, wouldn't it then be an obligation of the system to protect the patient and the surgeon by prohibiting the performance of the operation? Why would informing the patient be the best solution in this case? What if the patient agrees? Can a system—assuming the information was clear on the effect of complications—accept the patient's wish?

To some extent, the issue of legislating an informed consent should take into consideration societal perception of decisions in general, and of surgeons in particular, as depicted in a recent article [70]. If the surgeons

are perceived as "knights," the motivation that drives them is altruistic, and policies should be quite permissive allowing the surgeons the possibility to lead and to have a voice in the process. If the surgeons are perceived as "knaves," then their motivation is primarily self-interest, and the policies should have a "punitive aspect" with no room for a leading role for a surgeon. If the surgeons are perceived as "pawns," then the motivation plays a lesser role, the person is seen as a passive victim, and the policies ought to be proscriptive providing a protective role. In reality surgical residents have been perceived as pawns, and it is because of that ACGME has developed policies that are proscriptive in the time that residents are allowed to be on call.

Mitigating the Risk

I believe there are many ways to mitigate the potential risks associated with excessive workloads, night call, and sleep deprivation. First, the solutions start with the surgeon. Appealing to professionalism and arming the surgeons with enough information about the effects of sleep deprivation and fatigue would result in the development of strategies by the surgeon. I am not talking about the "last line of defense," namely, the surgeon noting that he or she is fatigued and deciding not to do an operation. I am talking about the adequate planning of the surgeon's life in terms of overall fitness, hours worked, how to accommodate the unpredictability of surgery, and how to best position himself or herself for work. Informed consent is the ultimate expression of professionalism between a surgeon and a patient. Everything that the surgeon believes with some degree of accuracy may bear on the outcome should be discussed with the patient in the most transparent fashion well before the operation is decided upon. A mechanical disclosure of duty hours, while the patient is awaiting surgery, while asking that the patient sign a "specially designed form" as has been proposed, is the antithesis of informed consent and places the patient in an unfathomable position, choosing between a surgeon who is trusted and a totally new person who may not be known to the patient or the family.

The second layer that I see as a solution is the immediate environment in which surgeons performs their work. Groups of surgical divisions or sections in the academic world and surgical partners in private practice in the outside world should be looking out for one another, and they should make their rules as to whether or not elective procedures are allowed to be performed after a night on call. In those cases, local rules for groups and for teams may have much more relevance. For example, if the calls are normally ones that are extremely demanding, then there should be no room for surgeons to schedule elective cases the next day. Conversely, in situations where the call may not be very demanding and where most of the time the surgeon can obtain a good night's sleep, then the scheduling of elective cases maybe more permissive.

Developing high-performing teams, emphasis is placed within a team on the need to have persons that are fit for duty. In this environment, persons are familiar with the concept of "mutual support," situational awareness, and mutual monitoring, and the ability of any member of the team to "stop the line" just before or even during the operation represents another layer of protection and mitigates the risk.

The fourth element is the institution itself—and here is where I believe the bulk of the responsibility ultimately will lie. Yes, it will require giving up part of the autonomy that surgeons have had over the years, but ultimately, making use of modern technology, the institution should assure by its rules (eventually applied through the teams) that everyone is "fit for duty."

Systems must change to respond to current knowledge in terms of cognitive workloads and the effect of fatigue on performance. When discussing safety in medicine, we frequently turn to aviation, an industry known for its devotion to safety. Most recently, the Federal Aviation Administration introduced regulations [71] further addressing pilot fatigue. It did so in a multifaceted way that takes into consideration specific factors that affect performance. Extending our comparison of the informed consent, perhaps those who defend that theory would consider it appropriate for the crew to disclose to passengers the number of hours worked, the number of sectors flown, and the degree to which they may be sleep deprived. Instead, the system simply sets rules that precludes crews from flying those planes. Our rules should mandate that hospitals develop system changes to protect patients and surgeons alike that are not based on informed consent but on internal rules founded in the type of work that a given hospital carries on. Every surgeon should take fatigue management courses, and the systems should incorporate fatigue mitigation techniques that are known to work.

The American College of Surgeons' Division of Education has recently created a "committee to enhance peak performance in surgery through recognition and mitigation of the impact of fatigue." It is the intention of this committee to discuss with a number of constituencies (experts on fatigue and sleep deprivation, patients, surgeons, other health care providers, and so forth), all elements that may affect the peak performance of a surgeon, in particular focusing on the recognition and mitigation of the impact of fatigue. The College expects to have a white paper defining today's position once the study has been concluded.

Thus, the idea of obtaining informed consent is, in my opinion, an easy way out. It deflects a responsibility to patients that should be shared by the system, the team, and the surgeons; and it asks the patients to provide, with their signatures, permission to proceed to do something that may not be in their best interest. I believe it is the surgeon, and ultimately the system, who must rise to this occasion and accept the responsibility for the delivery of the best possible surgical care.

Concluding Remarks

Robert M. Sade, MD

Czeisler presents strong and persuasive scientific evidence for detrimental effects of sleep deprivation. He and Pellegrini agree on several points: lack of sleep compromises neurobehavioral performance, and the ethical and legal standards for informed consent require that surgeons disclose to patients all material issues that can affect the outcome of a planned operation. Their main disagreements focus on the nature of the material risks posed by a surgeon's sleep deprivation and who should bear the burden of deciding whether an operation should go forward.

A critical issue in this debate is the real-world question of whether and to what degree attending surgeons' lack of sleep affects the outcomes of their surgical procedures. Czeisler cites a single study of practicing surgeons—his group's recent paper found that complications after procedures were higher when surgeons were on call the night before than when they were not. Their study had several serious flaws; most important was absence of any data on the surgeons' actual time of sleep when on or off call—being on call does not necessarily mean lack of sleep, nor does off call necessarily mean a full night's rest. In response, Pellegrini cites several other studies that have shown no difference in surgical outcomes performed by sleep-deprived versus well-rested surgeons.

None of the available studies has been well controlled. Such studies are needed, but it seems unlikely that we will ever have a randomized controlled trial evaluating the effects on surgical outcomes of various degrees of practicing surgeons' sleep deprivation. In the absence of reliable data, what should be done in the interest of patient safety? That question lies at the heart of this debate.

In the face of uncertainty about the presence or degree of elevated risk to patients, we might wonder whether it is premature to mandate a consent process that is likely to confuse and frighten patients immediately before an operation, a time when they are not well situated to receive new information and make a thoughtful, deliberate decision. Perhaps the weight of making decisions about surgical procedures in the face of the surgeon's suboptimal sleep would best be borne by the institution and the surgical team, as well as by the surgeon. Mandated disclosure and written consent of the patient seem too blunt an instrument to advance the goal of patient safety. The mitigation strategies outlined by Pellegrini might better serve the interests of patients without violating their autonomy and informational needs.

What will policy makers do with the facts, assertions, and beliefs presented in this debate, in this era of increasing regulation of the health care system? The policy of mandated work hours for physicians-in-training has been solidly entrenched for several years—such regulation may lie on the road ahead for practicing surgeons as well.

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