www.apsf.org

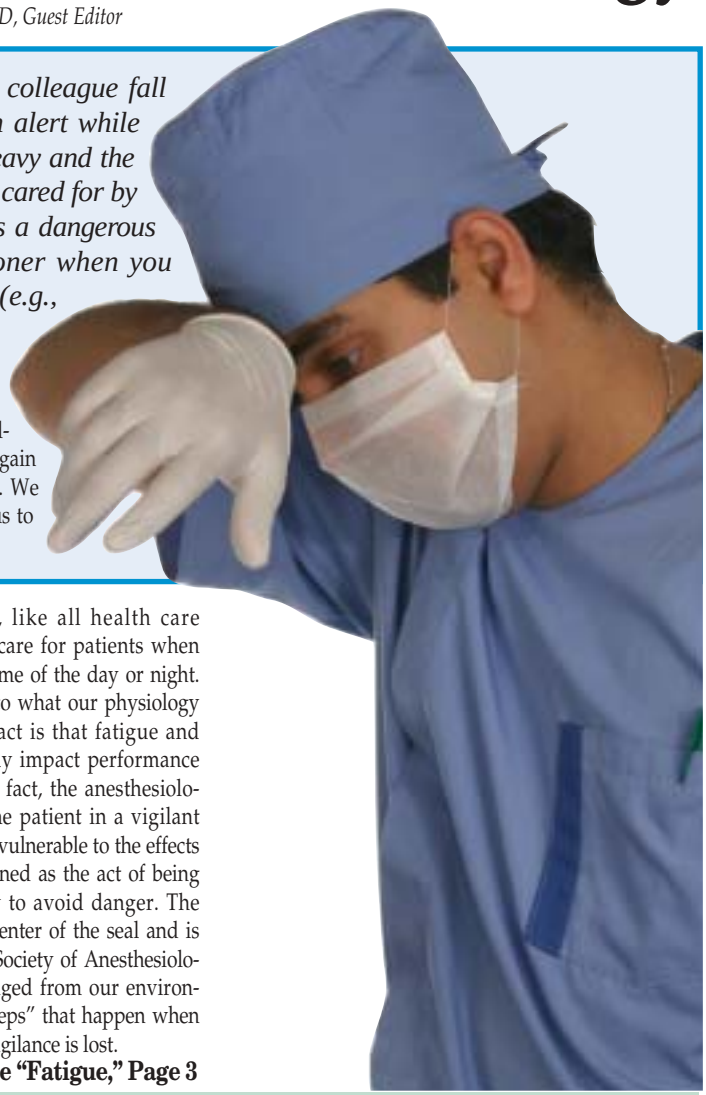
NEWSLETTER

The Official Journal of the Anesthesia Patient Safety Foundation

Volume 20, No. 1, 1-24 | Circulation 75,648 | Spring 2005

Fatigue & the Practice of Anesthesiology

by Steve Howard, MD, Guest Editor



Everyone has seen it. *For example, watching a colleague fall asleep at a meeting or watching an intern struggle to remain alert while holding a surgical retractor. Everyone has felt it. Eyelids get heavy and the environment starts to "grey out." Ask yourself if you desire to be cared for by health care workers who look and feel this way. This clearly is a dangerous situation for our patients. It is also unsafe for the practitioner when you consider the possibility of harm due to occupational injury (e.g., needlesticks) and the increased risk of driving while sleepy.*

This edition of the *APSF Newsletter* will focus on fatigue and the anesthesia care provider. There is renewed interest in this topic, and we have gathered a cadre of individuals who will present important new information on this topic. Anesthesiology has been very forward-looking regarding many aspects of safety, and there is again an opportunity to be at the "cutting edge" in dealing with this pervasive problem. We hope that the material in this issue will encourage others in our field to join with us to change the manner in which we practice and care for patients.

Fatigue and Safety

Fatigue has played a causal or contributory role in some famous accidents.[1] In 1986, the Presidential Commission found that faulty decision-making by sleep-deprived managers contributed to the untoward launch of the space shuttle Challenger. The nuclear accidents at Three Mile Island and Chernobyl both occurred during the early morning hours when our bodies are craving sleep. The grounding of the Exxon Valdez was a monumental environmental catastrophe. The National Transportation Safety Board found that the probable cause of this accident was the fatigue of the person sailing the ship. The National Highway Traffic Safety Administrations estimates that over 100,000 people are killed or injured each year in crashes attributed to drivers who fell asleep at the wheel or were impaired by severe drowsiness. These examples and many others reveal that fatigue is a problem that extends beyond health care and is deeply embedded within our society.

Studies have shown a correlation between the performance effects of sleep deprivation and ethanol intoxication.[2] At 24 hours of continuous wakefulness, psychomotor function was equivalent to a blood alcohol concentration of 0.1%. This is at or above the legal limit for driving in most states. Think of the professional and personal liability of coming to work intoxicated!

Anesthesia providers, like all health care providers, are required to care for patients when they present for care—anytime of the day or night. This is often in opposition to what our physiology demands. An irrefutable fact is that fatigue and sleep deprivation negatively impact performance and mood (see Table 1). In fact, the anesthesiologist's role of monitoring the patient in a vigilant manner may be particularly vulnerable to the effects of fatigue.[3] Vigilance is defined as the act of being alertly watchful, especially to avoid danger. The word "vigilance" is at the center of the seal and is the motto of the American Society of Anesthesiologists. If we become disengaged from our environment (such as the "microsleeps" that happen when we are sleep-deprived), all vigilance is lost.

See "Fatigue," Page 3

Inside:

Check out our new and improved website at

www.apsf.org

- Grant Guidelines
- Search Engine
- Back Issues of Newsletter
- Safety Links
- Sponsor List
- Foundation Information

User-Friendly & Informative!

Contact Information

Anesthesia Patient Safety Foundation
Building One, Suite Two
8007 South Meridian Street
Indianapolis, IN 46217-2922
Telephone: 317-885-6610
Facsimile: 317-888-1482

Administrator:
Deanna M. Walker
E-mail:
apsfoffice@aol.com

President: Robert K. Stoelting, MD
E-mail (President): rstoel7145@aol.com

The APSF continues to accept and appreciate contributions.

Please make checks payable to the APSF and mail donations to:

Anesthesia Patient Safety Foundation (APSF)
520 N. Northwest Highway
Park Ridge, IL 60068-2573

The Anesthesia Patient Safety Foundation Newsletter is the official publication of the nonprofit Anesthesia Patient Safety Foundation and is published quarterly at Wilmington, Delaware. Annual membership: Individual - $100.00, Corporate - $500.00. This and any additional contributions to the Foundation are tax deductible.

The opinions expressed in this *Newsletter* are not necessarily those of the Anesthesia Patient Safety Foundation or its members or board of directors. Validity of opinions presented, drug dosages, accuracy, and completeness of content are not guaranteed by the APSF.

Address all *general, membership, and subscription* correspondence to:
Administrator, Deanna Walker
Anesthesia Patient Safety Foundation
Building One, Suite Two
8007 South Meridian Street
Indianapolis, IN 46217-2922
e-mail address: apsfoffice@aol.com

Address *Newsletter* editorial comments, questions, letters, and suggestions to:
Robert C. Morell, MD
Editor, *APSF Newsletter*
c/o Addie Larimore, Editorial Assistant
Department of Anesthesiology
Wake Forest University School of Medicine
9th Floor CSB
Medical Center Boulevard
Winston-Salem, NC 27157-1009
e-mail: apsfeditor@yahoo.com

Rested Residents Make Fewer Errors

"Fatigue," From Page 1

Fatigue and Health

People who work irregular overnight shifts are at increased health risks.[4] Gastrointestinal and cardiovascular complaints increase, and there is some evidence to suggest that long, strenuous work is also associated with obstetric complications (e.g., preterm delivery, pregnancy-induced hypertension). Immune function, carbohydrate metabolism, and endocrine function are impaired to some degree. One study revealed an increased mortality with severe shortening of daily sleep—sleep of <4 hours increased likelihood of death by a factor of 2.8 in a 6-year follow-up period.[5] The health effects of chronic sleep deprivation are insidious and their impact may not manifest fully for years.

Physiology of Fatigue

Sleep Homeostasis

Sleep homeostasis can be thought of as sleep balance. Every adult has a genetically hard-wired sleep requirement that does not change with age and cannot be trained. The average sleep need for adults is over 8 hours per 24 hours, and most in our society do not achieve this requirement. In fact, surveys done by the National Sleep Foundation reveal that we are a society of chronic under sleepers by over an hour per night. Sleep is a physiologic drive state similar to hunger or thirst. When sleep requirements are not met a "sleep debt" ensues and sleepiness becomes manifest. The only way to pay off this sleep debt is by acquiring adequate sleep. Laboratory studies of chronic partial sleep deprivation provide important information to practicing clinicians.[6] Research has shown that sleeping 6 hours or less per night over 2 weeks results in cognitive performance deficits equivalent to 2 nights of total sleep deprivation. Data on subjective sleepiness (how sleepy the subjects felt) suggest that subjects are largely unaware of their level of impairment; this may explain why the impact of this level of chronic sleep deprivation is assumed to be benign.

Many anesthesiologists and nurse anesthetists are chronically sleep-deprived at baseline and periodically push the envelope further by performing call duties, thus layering acute sleep deprivation on top of a significant sleep debt. When the clinician works on the day after a busy on call night, a potentially catastrophic situation can exist.

Normal aging affects sleep.[7] Disruptions become more frequent, the amount of slow wave (restorative) sleep decreases, and sleep becomes less consolidated. Since sleep needs remain essentially unchanged, the result is daytime sleepiness. This can be countered by daytime naps, but few working people are able to take naps in our society.

Table 1: Fatigue Effects on Human Functioning

- Cognitive slowing
- Impaired vigilance
- Increased performance variability
- Neglect of non-essential activities
- Learning of new information decreases
- Problem solving decays
- Memory degrades
- Motivation declines
- Sleep intrudes into wakefulness

Consecutive Hours of Wakefulness

As hours since the last sleep episode accrue, the physiologic pressure to acquire sleep increases. Extending work shifts past 17 consecutive hours increases the likelihood of errors in laboratory[6] and clinical settings.[8] In a recent study reported in the *New England Journal of Medicine*, interns rotating in the intensive care unit were evaluated on two different schedules.[9] The traditional schedule allowed for work of up to 30 consecutive hours, while the intervention schedule limited the number of consecutive hours to <17. In this well designed study, residents on the reduced schedule obtained more sleep and made 36% fewer errors. The intervention group also showed fewer "attentional failures," which were actual electroencephalographic (EEG) episodes of sleepiness during patient care.[8] These findings match those of many laboratory studies: wakefulness for periods of over 16 hours predicts performance lapses.[6]

Circadian Factors

Humans have a circadian timer that regulates many body processes such as temperature and hormone secretion, but for this discussion the 24-hr sleep-wake cycle is of importance. The circadian clock is located in the suprachiasmatic nucleus of the hypothalamus. The daily light/dark variation entrains this clock to the 24-hour day. We are programmed for 2 periods of decreased alertness every 24 hours: between 3-7 AM and 1-4 PM. The lowest point in this cycle occurs during the early morning one, making it the period of greatest vulnerability to fatigue-related performance impairment.[10]

As we know from shift work and transmeridian air travel, the circadian pacemaker is resistant to change. This is the primary reason for the inability of humans to readily adapt to shift work and why jet lag occurs. For example, workers on the night shift attempt to function when their clocks are primed for sleep. When they attempt to sleep during the day, their clock is programmed for wakefulness. Opposing this normal rhythmic pattern of day-awake and night-asleep is made more difficult because our society's activities are strongly linked to this pattern. Some errands and family responsibilities can only be performed during the day, making adaptation to shift work difficult.

Sleep Disorders

Over 80 sleep disorders have been described. Common complaints include insomnia, excessive daytime sleepiness, and abnormal movements or breathing during sleep. Some of these disorders are relatively common and have documented negative effects on wake performance. The most common sleep disorders are obstructive sleep apnea (OSA), insomnia, and periodic limb movements. Shift work sleep disorder has gained attention recently and has an approximate incidence of 10% in night and rotating shift work populations.[11]

OSA is of special significance because it is prevalent in the population (at least 3-5%), but still underdiagnosed. It is associated with the risk factors of obesity (BMI >27), habitual snoring, and large neck circumference, and is most commonly found in middle-aged males. Excessive daytime sleepiness is a common complaint of patients with OSA and occurs because of the cyclical awakenings caused by airway obstruction during sleep. People with OSA have great difficulty getting restorative sleep because it is like having a pager go off 100 times during each night. The incidence of automobile accidents increases in people with OSA, and experiments reveal impairments that are equivalent to ethanol intoxication.

Other Factors That Affect Waking Function

Depressant and stimulant drugs, whether prescription drugs or substances of abuse, have obvious effects on alertness and performance. In low to moderate doses, caffeine can transiently improve alertness and performance. Social interaction, rest breaks, and exercise can all improve subjective alertness and performance. These factors have no effect on the underlying physiologic level of sleepiness. Other performance shaping factors include chronic or acute illness, boredom, noise, extremes of temperature, and lack of environmental stimuli.

Literature Review

There have been many studies on the effect of sleep deprivation and fatigue on the mood and performance of health care personnel. Extensive reviews on this topic have been published in the last 5 years and the following highlight the important findings.[12,13]

See "Fatigue," Next Page

Lack of Sleep Also Endangers Anesthesia Providers

"Fatigue," From Preceding Page

Subjective Reports

Anesthesia personnel report working long hours, often without taking breaks. In these surveys, over half the respondents reported having committed an error in judgment due to fatigue and feel that fatigue impairs patient safety.

Mood

Mood is found to be consistently worse as work hours are extended and with work done at night. Levels of anger, hostility, tension, bewilderment, confusion, fatigue, anxiety, and depression increase while measures such as vigor and happiness decrease. No studies have been done to evaluate how these mood shifts impact patient care, but they likely play a role in decreased job satisfaction and the occurrence of burnout.

Performance

Meta-analyses have been performed concerning the effects of sleep loss on performance.[14] These analyses suggest that sleep deprivation impairs cognitive performance and mood with less effect on motor performance. Known performance effects include reduced vigilance, impaired memory, prolonged reaction time, and poor communication. Performance also becomes more variable—one moment performance is adequate, followed by perceptual disengagement from the environment at sleep onset. Performance is zero upon drifting into sleep.

Sleep During Patient Care

Ambulatory EEG and videotape of clinicians have been used to quantify sleep in field and simulator studies. "Attentional failures" are greater in interns working 30-hour duty periods when compared to shorter work shifts.[8] Studies of anesthesiologists providing care to a simulated patient reveal similar data.[15] Based on detailed videotape analysis of "sleepy behaviors" (eyes closing, head nodding, and actual sleep), the most impaired anesthesiologist in this study had these behaviors for over 30% of a 4-hour case! These studies support what is commonly seen in the operating room, the classroom, and in conference rooms in hospitals around the world. People manifest severe levels of sleepiness at critical time periods.

Driving Studies

A growing number of studies describe an increased risk of drowsy driving in health care providers. A recent study from the *New England Journal of Medicine* found that interns were 2.3 times as likely to report a crash after working an extended shift.[16] They calculated that for every extended work shift scheduled in a month, the risk of a motor vehicle crash increased by 9.1%. This is compelling real-world evidence of how lack of sleep leads to decreased alertness and impacts our abilities to perform.

Steve Howard, MD, Guest Editor

To summarize, we face many challenges in our current health care environment. As you will read in the accompanying articles in this special issue of the *APSF Newsletter*, finding solutions to the issues that revolve around fatigued health care personnel are not simple and clear-cut. We owe it to our patients and ourselves to come to work optimally prepared. We can lead the way for all of health care by helping to solve the problem.

Dr. Howard is a Staff Physician at the VA Palo Alto Health Care System and Director of the Patient Safety Center of Inquiry at VA Palo Alto. He is also an Associate Professor of Anesthesia at the Stanford University School of Medicine, Stanford, CA.

References

1. Mitler MM, Dement WC, Dinges DF. Sleep medicine, public policy, and public health. In: Kryger MH, et al., eds. Principles and Practice of Sleep Medicine, 3rd ed. Philadelphia: W.B. Saunders Company, 2000: 580-8.
2. Dawson D, Reid K. Fatigue, alcohol and performance impairment [Scientific Correspondence]. *Nature* 1997;388:235.
3. Weinger MB, Englund CE. Ergonomic and human factors affecting anesthetic vigilance and monitoring performance in the operating room environment. *Anesthesiology* 1990; 73:995-1021.
4. Costa G. Shift work and occupational medicine: an overview. Occup Med (Lond.) 2003;53:83-8.
5. Kripke DF, Simons RN, Garfinkel L, Hammond EC: Short and long sleep and sleeping pills. Is increased mortality associated? *Arch Gen Psychiatry* 1979;36:103-16.
6. Van Dongen HP, Maislin G, Mullington JM, Dinges DF. The cumulative cost of additional wakefulness: dose-response effects on neurobehavioral functions and sleep physiology from chronic sleep restriction and total sleep deprivation. *Sleep* 2003;26:117-26.
7. Bliwise DL. Normal aging. In: Kryger MH, et al., eds. Principles and Practice of Sleep Medicine, 3rd ed. Philadelphia: W.B. Saunders, Co., 2000: 26-42.
8. Lockley SW, Cronin JW, Evans EE, et al. Effect of reducing interns' weekly work hours on sleep and attentional failures. *N Engl J Med* 2004;351:1829-37.
9. Landrigan CP, Rothschild JM, Cronin JW, et al. Effect of reducing interns' work hours on serious medical errors in intensive care units. *N Engl J Med* 2004;351:1838-48.
10. Van Dongen HP, Dinges DF. Circadian rhythms in fatigue, alertness, and performance. In: Kryger MH, et al., eds. Principles and Practice of Sleep Medicine, 3rd ed. Philadelphia: W.B. Saunders, Co., 2000: 391-9.
11. Drake CL, Roehrs T, Richardson G, et al. Shift work sleep disorder: prevalence and consequences beyond that of symptomatic day workers. *Sleep* 2004;27:1453-62.
12. Weinger MB, Ancoli-Israel S. Sleep deprivation and clinical performance. *JAMA* 2002;287:955-7.
13. Owens JA. Sleep loss and fatigue in medical training. *Curr Opin Pulm Med* 2001;7:411-8.
14. Pilcher JJ, Huffcutt AI. Effects of sleep deprivation on performance: a meta-analysis. *Sleep* 1996;19:318-26.
15. Howard SK, Gaba DM, Smith BE, et al. Simulation study of rested versus sleep-deprived anesthesiologists. *Anesthesiology* 2003;98:1345-55; discussion 5A.
16. Barger LK, Cade BE, Ayas NT, et al. Extended work shifts and the risk of motor vehicle crashes among interns. *N Engl J Med* 2005;352:125-34.

Performance-Enhancing Drugs Present A Double-Edged Sword

by Ralph Lydic, PhD

I thank Steven K. Howard for the invitation to contribute to this *APSF Newsletter* consideration of fatigue as a potential detriment to anesthesia safety. The editorial assignment was to outline arguments against use of performance-enhancing drugs as a counter-measure for excessive physician fatigue. Advances in neuroscience and economic imperatives ensure the increasing relevance of performance-enhancing drugs. This is a topic presently characterized by a paucity of objective data, unscientific argument, and hypocrisy. Some performance-enhancing drugs are willingly accepted, yet other drugs are condemned. Most clinical facilities now maintain a "smoke-free" environment. One can easily envision the outrage that would be elicited by proposals for a "caffeine-free" environment. Caffeine is the most widely consumed performance-enhancing drug. Recent reviews suggest that rapid cessation of caffeine intake causes a "clinically significant distress or impairment in functioning" that warrants "inclusion of caffeine withdrawal as an official diagnosis" by the World Health Organization (ICD-10) and the American Psychiatric Association (DSM-IV).[1] This article highlights some conventional arguments against the healthy individuals' use of drugs that enhance performance (steroids), arousal (modafinil), and cognition (nootropics).

Anabolic steroids enhance performance but have negative side effects that illustrate the counter-argument of excessive medical risks. The International Olympic Committee relies on a World Anti-Doping Agency (WADA) for drug testing. The need for WADA is illustrated by German court convictions of former East German government officials who sponsored use of performance enhancing steroids by their Olympic athletes. In March 2005, leaders of a laboratory co-operative are scheduled to stand trial for a number of charges including the alleged synthesis and sale to elite athletes of a previously undetectable steroid called tetrahydrogestrinone (THG). High profile athletes exert an enormous influence on younger, aspiring athletes. A second argument against performance-enhancing drug use is that it encourages drug use by others. Dr. Linn Goldberg, professor of medicine at Oregon Health and Science University, reported on the 10 December 2004 radio show *Talk of the Nation* that about one million teenagers in the US currently use anabolic steroids.

Modafinil is a schedule IV, wake-promoting drug (www.provigil.com). Modafinil is approved to treat "unusually sleepy people" who have been

diagnosed with narcolepsy, obstructive sleep apnea syndrome, and shift work sleep disorder. Modafinil's mechanisms of action and long-term effects are unknown. Modafinil is distinctly different from stimulants such as methylphenidate, amphetamines, and cocaine. Elite athletes were quick to discover modafinil. In November 2004, the U.S. Olympic gold medal for the 1600 meter relay was revoked and given to France because US athlete Calvin Harrison tested positive for modafinil. The International Associations of Athletics Federations and WADA consider modafinil a performance-enhancing drug. Thus a third argument against the use of performance-enhancing drugs is the long-standing legal precedent of condemnation by the international athletic community.

Discovering molecules that enhance cognition (nootropics) comprises one of the most exciting areas in drug development. There is uniform support for use of these drugs as therapeutic agents. Nootropic drugs will also be used by healthy individuals as enhancing agents. Perceptions about the appropriateness of performance-enhancing drug use is contextual. The International Associations of Athletics Federations and WADA consider drug use as cheating. In contrast, the Defense Advanced Research Projects Agency (DARPA) actively supports performance-enhancing drugs for military use. The DARPA website notes that, "Sleep deprivation is a fact of modern combat. Current operations depend on a warfighter's ability to function for extended periods of time without adequate sleep." By changing only 2 words in the DARPA quote, one can describe a performance challenge often encountered by health care providers.

Performance outcome also influences attitudes concerning drug enhancement. The 2003 tragedy in which Canadian ground troops were killed by US pilots who had taken amphetamines has been interpreted as a condemnation of performance-enhancing drugs. For decades, US astronauts have used amphetamines therapeutically to suppress nausea and to enhance performance. Concerns over drug use have never sullied celebrations of a successful space mission. Likewise, if a clinical case goes well, and the anesthesia provider has taken a performance-enhancing drug, the probability of repercussions is low. One can easily envision a very different response to the same scenario terminating in a negative clinical outcome. Ultimately, performance-enhancing drug use will be decided not by editorials or ethicists but by the drug-using public. For performance-enhancing drugs, presently there is no rational code, but there is a clear coda: the genie is out of the bottle.

Ralph Lydic, PhD, is the Bert La Du Professor and Associate Chair for Research in the Department of Anesthesiology at the University of Michigan, Ann Arbor, MI. *He is supported by grants HL57120, HL40881, and HL65272 from the National Institutes of Health, Bethesda, MD, and by the Department of Anesthesiology.*

Reference

1. Juliano LM, Griffiths RR. A critical review of caffeine withdrawal: empirical validation of symptoms and signs, incidence, severity, and associated features. *Psychopharmacology* (Berl) 2004;176:1-29.

Ralph Lydic, PhD

Dear SIRS

Cause of Ventilator Failure is Unclear

S AFETY
I NFORMATION
R ESPONSE
S YSTEM

Michael Olympio, MD, Chair of the APSF Committee on Technology and Co-Founder of the SIRS Initiative.

Dear SIRS refers to the **Safety Information Response System**. The purpose of this column is to expeditiously communicate technology-related safety concerns raised by our readers, with input and responses from manufacturers and industry representatives. This process was developed by Drs. Michael Olympio, Chair of the Committee on Technology, and Robert Morell, Editor of this newsletter. Dr. Olympio is overseeing the column and coordinating the readers' inquiries and the responses from industry. **Dear SIRS** made its debut in the Spring 2003 issue.

Dear SIRS:

We would like to report an incident of anesthesia machine failure with possible patient safety implications. After the induction and intubation of an 8-year-old female and during the sterile skin preparation for orthopedic surgery, a loud warning buzzer was heard by the operating room staff, apparently emanating from the Dräger Narkomed 6000 (Dräger Medical, Inc., Telford, PA) anesthesia machine. A "walk-around" of the machine was required in order to isolate the buzzing noise arising from the vicinity of the red ventilator bypass button located below the machine's power switch. Pressing the button caused the buzzing to stop and the Ventilator Override button to illuminate. The display screen of the machine did not appear to be affected by the problem, but during the walk-around the display was not visible to the anesthesiologist. Upon the anesthesiologist's return to the head of the patient, examination of the machine's display (absence of any ventilator information on the Narkomed LCD display and a lack of end-tidal CO_2 on a separate monitor) revealed that the ventilator had stopped functioning. The case start was delayed, and the patient was hand ventilated until the machine was exchanged. The case subsequently proceeded without further incident. Later examination determined that the large sealed power supply, located at the rear of the base of the machine, had failed. This incident exposes, in our opinion, several design shortcomings in the Dräger Narkomed 6000 machine, some of which may pose threats to patient safety.

Power Supply Failure

It is disconcerting that the power supply failure in the present instance led to a failure of the ventilator. Given that the Divan ventilator (Dräger Medical, Inc., Telford, PA.) in the Narkomed 6000 is an electronically controlled, electrically powered piston ventilator, the continuous availability of electrical power must be assured. We think it is reasonable to expect that some sort of "fail-over" back-up system, such as exists in the computer, airline, and shipping industries, would be in place on this ventilator. Such was not the case in the present instance. When the power supply failed, the patient went without ventilation for somewhat less than one minute. We think this episode highlights what we believe is a design shortcoming of the Narkomed 6000 machine: there exists a linkage between the power supply and the reserve batteries such that a failure of the power supply itself also eliminates the ability of the back-up batteries to function. In other words, the machine is protected from external power loss, but not from internally originating power interruptions.

Anesthesia machines in general and the Divan ventilator, in particular, require stable and uninterrupted electrical power in order to function properly. Power supply design is modestly complex; electrical efficiency, heat dissipation, weight, shape, size, and cost must all be considered as the design criteria are set and achieved. The engineering, however, is well understood and the power generating industry is stable and mature. Even so, manufacturers understand that component failures do happen during routine use of complex equipment, and therefore manufacturers attempt to incorporate appropriate design safeguards.

It has been truthfully said that the basic functions of the anesthesia provider are to put air in the lungs and water in the veins. With that in mind, it would seem intuitive that the one function for which the anesthesia machine must have powerful redundancy is ventilation. Dräger has clearly considered the loss of external power in its Narkomed 6000 machine. However, our episode suggests that the potential failure of internal components did not receive the same level of attention. Specifically, we believe it is a machine design fault to have combined the back-up battery system and AC power supply in such a way that the failure of the AC power supply subsystem does not initiate both battery back-up and alarm systems in the same manner as does the loss of external AC power. Instead, the failure of the AC power supply caused a total power failure in the ventilator. This design seems to us to be "counterintuitive" and would suggest that Dräger engineers should readdress this design.

Location of the Ventilator Override Button

One drawback, in our opinion, of the Divan ventilator is that electrically controlled valves have the potential to allow it to reach a state, following a power failure, where manual patient ventilation is not possible. The Ventilator Override button is specifically intended to alleviate this scenario and did indeed do so in the present instance. The location of the button is a concern, however.

While Dräger has taken the trouble to build a bright red light into the button, the button is located low on the left side of the machine, beneath the power switch and behind both the flow sensor assembly and the inspiratory and expiratory valves. In general use, this button may or may not be visible to the operator, depending on his height and position relative to the anesthesia machine. In this instance, the button was not immediately visible to the anesthesiologist because the line of sight was obscured by the aforementioned items.

See "Dear Sirs," Next Page

Invisible "Bellows" Requires Different Mindset

"Dear Sirs," From Preceding Page

The anesthesiologist had to walk completely around the machine and approach it from the left side (as viewed by an operator in the usual position) before seeing the red light.

In sum, the location, appearance, and use of the button do not cause the user to have a high degree of confidence or certainty in its function. It is nearly hidden from sight and ambiguously named and labeled, and the fact that it turns bright red from a light built into the switch makes it somewhat startling to use the first time. The button is, essentially, the last line of defense against electrical failure of the Divan ventilator. The Narkomed 6000 operator's manual states that the button "is provided for use in the unlikely event of a fault which does not allow the clinician to ventilate a patient in normal Manual/Spontaneous Mode or safe state." Good ergonomic design suggests that a rarely used button would be best placed away from the primary lines of sight and reach of a machine operator. However, in terms of patient safety, it is our opinion that a rarely used button intended as a last ditch response to a potentially life-threatening situation should be highly visible, unambiguously labeled, and easily accessible. We believe that future Narkomed anesthesia machines equipped with the current iteration of the Divan ventilator should continue to feature the Ventilator Override button, but that button should be redesigned and relocated to satisfy both ergonomic and safety considerations.

Ventilator Visibility

One of the more controversial aspects of the Narkomed 6000 machine is the placement of the Divan ventilator. The Divan ventilator is located beneath a metal panel which serves as the "table top" for the anesthesia machine, and is thus completely hidden from view. When the Narkomed 6000 machine was first introduced, many experienced anesthesiologists were taken aback at the absence of a visible bellows, particularly in light of the years of controversy over the "hanging vs. standing bellows" issue. Indeed, when this ventilator failed, no specific visible indication that the event had occurred was noted except for the buzzer sound and the red light in the ventilator override button. An inexperienced operator, or one distracted by other simultaneous problems, might have taken significantly longer to notice the failure that occurred in this case. The placement of the Divan ventilator out of the operator's sight contributed to our delay in realizing that ventilator failure had occurred. While there may (or may not) be an increase in reliability afforded by placing the ventilator in a metal cabinet rather than a clear plastic column, the loss of visibility of the ventilator is, in our opinion, a high cost trade-off. We suggest that Dräger reconsider this design and find a way to combine reliable function, safe location and visibility in future machines.

On-Screen Ventilator Failure Alarm/Notification

The LCD display screen of the Narkomed 6000 is one of the machine's most attractive features. The flexibility of such a display is unparalleled; it is intuitive and informative. One must wonder then why there was not a very large, very noticeable alert on the display indicating that there had been a major failure. Interestingly, exactly this type of alarm does appear if an external power failure occurs or the back-up battery system is engaged for any other reason.

The diagnostic information available to our technical staff after the incident reveals that the system was aware that there had been a power supply failure. We propose making this vital information accessible to the clinician. We would like to suggest that Dräger add an intrusive, informative, and possibly even instructive on-screen alarm in case of any significant detectable internal or external power failure. This software upgrade should be installed in the field as soon as possible.

Power Supply Failure History

In the publication of a power supply failure in the same model anesthesia machine in September 2003,[1] Dräger was reported to have redesigned and replaced the power supply in all affected machines in the US and Canada. The earlier published failure was tracked to a specific design flaw allowing contact between a capacitor can and a circuit board tracing. Analysis of the power supply in the current instance is pending, but the circumstances of our power supply failure vary significantly from the earlier reported incident, in which there was a "pop" and smoke emanated from the power supply. The machine serial number in the present instance is within the range of all the serial numbers of machines affected by the earlier power supply recall (Dräger correspondence), but this specific machine was not affected by the recall.

Incident Tracking

Ventilator failure in an anesthesia machine is a potentially devastating device mishap. Although it does not appear that FDA incident tracking is mandated by this incident (there was no death or injury), one could consider that such tracking might give Dräger the ability to cast a wider net as the company attempts to discover whether the power supply/ventilator failure presented here is indeed an isolated incident or is the sentinel event in a chain of potential adverse outcomes.

Albert R. Davis, MD
Bruce Kleinman, MD
W. Scott Jellish, MD, PhD
Loyola University Medical Center
Maywood, IL

Reference

1. Usher AG, Cave DA, Finegan BA. Critical incident with Narkomed 6000 anesthesia system. *Anesthesiology* 2003;99:762.

Check out the Virtual Anesthesia Machine Website and the APSF Anesthesia Machine Workbook at www.anest.ufl.edu/vam

Dear Sirs Response

Manufacturer Analyzes Incident, Provides Feedback

Response:

Dräger Medical is grateful for the opportunity to respond to the concerns identified by the clinical staff at Loyola University Medical Center. Dräger Medical considers patient safety to be paramount, and Dräger Medical's history of equipment innovation is evidence of this commitment to patient safety.

Reported Problem

Dräger Medical was contacted regarding the reported condition by a biomed from the facility. The biomed reported that during a case the Divan ventilator was noted to lose power and the display information went blank. An audible alarm was noted and the monitor screen for the anesthesia machine continued to function. The user depressed the ventilator override button and manually ventilated the patient on the machine until the machine was replaced. Upon replacing the anesthesia machine, the biomed performance tested the device and was unable to reproduce the reported occurrence. The biomed replaced the power supply to be cautious.

Findings

The power supply was returned to Dräger Medical for evaluation. Performance testing found the power supply to function normally.

Assessment

The fact that the rest of the system remained active indicates that this was likely not a power supply failure. This was confirmed when the power supply was returned, and the failure analysis found the power supply to function normally.

It would appear from the report that a condition may have arisen in which an alarm was posted by the Divan. The Divan ventilator does have an internal audible speaker that is activated during an atypical hardware or software condition.

The Divan Ventilator incorporates safety software that monitors the function of the ventilator during the power-on self-tests, as well as during normal use. In the event that the safety software monitors a fault condition, the Divan may post an error message on the Divan Control Panel display and an audible alarm. Upon posting the message, the Divan ventilator may configure a warm start or configure itself into Safe State. Safe State automatically configures the Divan for manual or spontaneous ventilation and the next power-on self-test cannot be aborted. A warm start by the Divan would cause the ventilator to momentarily reset, power off, and then on. The reset will take approximately five to ten seconds and then the Divan ventilator will resume ventilation at the user set parameters.

The ventilator override button was designed in the event that an unforeseen condition occurs that the safety software does not recognize. Activating this button removes power from the ventilator forcing it into Safe State which allows for manual or spontaneous ventilation.

Power Supply Failure

The author's concerns about the design of the power supply are unfounded. The functionality and behavior that the author is proposing is indeed how the system works. The Narkomed 6000 is designed to primarily function on AC power. In the absence of AC power, the anesthesia machine will function on back-up battery power for a minimum of 30 minutes with a fully charged battery. The anesthesia machine will inform the user that AC power is no longer present by a visual message and audible alarm.

The author expresses concern about the dependence of the ventilator on electrical power. The dependence of the NM6000 series anesthesia machine on electrical power is no different than previous anesthesia machines manufactured by Dräger Medical, which include the Narkomed product line of anesthesia machines. The Narkomed products also require AC electrical power to function during automatic ventilation.

On-Screen Ventilator Failure Alarm/Notification

Current software released for the NM6000 anesthesia machine does incorporate such features as discussed into the alarm structure. In an AC power failure condition, the device posts an advisory alarm message, "AC Power Fail," plus a single audible tone. A dialog box is also displayed on the screen with a warning tone. Upon activation of back-up battery power, the device will function for a minimum of 30 minutes from a full charge. Prior to depletion of battery power and machine shut down, a battery low message will be posted indicating that approximately 10 minutes of power are remaining. Prior to use, the power on self-test will post appropriate indications to the user regarding the power status to the device. The system will post a message indicating the status of the device as functional, conditionally functional, or non-functional.

Power Supply Failure History

The power supply returned from Loyola was not within the suspect population for the recall that has occurred. The power supply recall was issued for 151 machines. All facilities with machines that were affected by the recall were properly informed and had their power supplies replaced. The recall started November 01, 2002, and was completed February 28, 2003.

Ventilator Override Location

Customer input and design determined the current location of the ventilator override switch to the ventilator on the machine. The switch is clearly labeled (see Figure 1), and the defined use is provided to the user in the Operator's Manual.

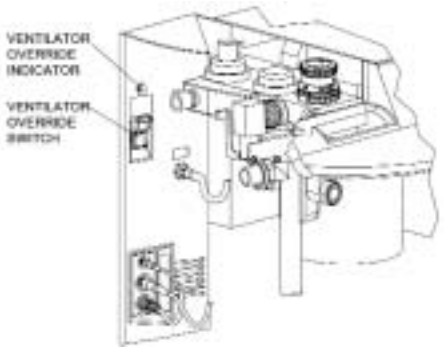


Figure 1: General Location of Ventilator Override Switch

Ventilator Visibility

Dräger Medical recognizes that the location of the ventilator is a significant change for the user versus past designs. As such, Dräger Medical offers as an option, a top cover for the ventilator with a transparent window to allow the user to easily visualize movement of the piston ventilator.

Incident Tracking

Dräger Medical complies with post market surveillance and the medical device reporting regulations.

We appreciate all feedback regarding the features and functionality of Dräger anesthesia workstations. This feedback is important in helping to identify potential performance issues and also helps to incorporate new features that our customers require. Additionally, anesthesia machines are not all the same, and patient safety may be managed through various means and systems. As anesthesia machines are required to perform more complex functions, machine features and usage are always changing. As a result, it is recommended that all staff undergo initial and periodic refresher training to ensure a high level of proficiency for all types of anesthesia machines. Dräger Medical makes its personnel available to help in the continuing education of its customers.

Robert Clark
CareArea Director
Perioperative Care
Dräger Medical, Inc.

Cure for the Dopey Doc?

by Brian E. Smith, MD

I was on call last night, and I was lucky. Although I worked moderately hard for 19 hours, the final 5 were spent dozing off and on in a noisy, cold "sleep" room. Departing for a 7:00 am department meeting, I promptly locked my lab coat and my keys in the call room. A quick change of scrubs made me feel a little fresher, until I spilled a dribble of my morning double espresso on them. I found myself searching for the right word a few times during the meeting, not unusual as I age, but a noticeably more common problem today. I was lucky again after the meeting; while most of my colleagues went to face a challenging day in the OR, one fewer outpatient rooms on the schedule spared me from placing a patient's life in my hands. My group once eschewed working post-call; with declining reimbursement from profitable insurance conglomerates, it is now considered an economic necessity to maintain the status quo. I have to finish writing this article and get some sleep; I have 2 cardiac cases tomorrow, which means a 4:45 am wake-up time.

The concept of performance-enhancing drugs has gotten significant press lately, and the buzz is overwhelmingly negative. Professional athletes searching for a competitive edge are vilified as cheats in the rare instances that they have been caught using anabolic steroids. However, like many other effective tools, performance-enhancing medications used correctly could decrease suffering and improve life: lost in the hype about steroids are potential benefits to society of a wide range of medications unrelated to steroids, and in my view, not at all analogous. Let's focus on one.

Modafinil is a pill that improves mental alertness through a novel mechanism, probably involving dopamine reuptake. It does not have the adrenergic side effects of amphetamines; in fact, most subjects cannot readily perceive the difference between active drug and placebo. It does not decrease the user's ability to recover sleep when an opportunity arises, and does not deliver a rebound effect. It does improve performance on a host of laboratory tasks, including tests of vigilance, memory, mood, and attention, as well as real-world tasks such as flying combat aircraft. The military has a compelling interest in performance and fatigue because combat operations are typically 24/7, and the stakes are extremely high for the participants. Hence, there is serious, ongoing research on the use of modafinil by sleep-deprived aircrews, and the results are encouraging. Modafinil works nearly as well as dexedrine and better than caffeine in maintaining performance during severe sleep deprivation. It does have occasional side effects including headaches and nausea, and undoubtedly more will be found. However, sleepiness is not only detrimental to our patients; it is not entirely benign for the practitioner. Research shows that the sleep-deprived anesthesiologist drives home at least as impaired as one legally intoxicated with ethanol.

One could argue that the work hours of critical health care providers should be regulated; society should make the investment to train and pay enough personnel to provide the same level of expertise to everyone, whenever their need for care arises. However, that is not the case. Sleepy people are keeping people asleep. Before it was confirmed scientifically, it was widely known empirically. Anesthesiologists and nurse anesthetists in busy clinical practices are excessively sleepy. Fatigue affects performance. While we know it empirically, this is a bit more tedious to establish scientifically, but progress is being made. Morbidity and mortality are at stake. In 1999, the Institute of Medicine report described a previously underappreciated number of deaths that were attributable to medical error. I have no doubt that these incidents are more common when the practitioner is fatigued, and my early morning follies today indicate that I was ill-prepared to deal with simple tasks, much less the complex, rapidly evolving catastrophes that my surgeons and patients occasionally conjure up. Unlike professional athletes, whose primary goal may be to win personal fame and fortune, our goal is to maintain vigilance against disaster for our patients. We have an ethical duty to maximize our potential and to carefully and pragmatically consider any reasonable aid that presents itself.

Cognition is complex, and delivering anesthesia is not the same as flying a plane. Exactly how modafinil improves performance is not known, and its effects on memory, problem solving, mood, motivation, interpersonal interactions, and a variety of other factors important to the practice of anesthesia have not been fully investigated. Perhaps modafinil will prove to diminish management of complex diagnostic decision-making, or worsen multi-task management. However, we have the means of testing performance in realistic simulators, so we could begin to answer these questions. College students are taking modafinil to cram for finals. Journalists are using it to combat jet-lag on overseas assignments. Residents are using the drug to maintain alertness while on call. It seems reasonable to study this new frontier of patient (and practitioner) safety, to potentially arm ourselves with both well crafted shifts, good sleep habits, strategic napping, and a safe pharmaceutical to be used when absolutely necessary, to help us maintain our motto: "vigilance."

Dr. Smith is an attending anesthesiologist at the Washington Township Hospital in Fremont, CA, and serves as an Adjunct Assistant Professor in the Department of Anesthesiology at the Stanford University School of Medicine, Stanford, CA.

Managing Fatigue 24/7 in Health Care: *Opportunities to Improve Safety*

by Mark R. Rosekind, PhD

If only it were that simple: just tell people to get their 8 hours of sleep and develop perfect work schedules, or invent a "magic bullet" that eliminates fatigue, manages the safety risks, and is effective for everyone. Managing the fatigue-related risks in health care is much more complicated. Health care tasks can be very different, so there are diverse operational requirements. The people themselves are very different, so individual differences related to age, gender, experience, sleep need, and many other factors vary widely. The sleep and circadian physiology that underlies fatigue, sleepiness, and performance decrements are complex. Historical precedents are difficult to change, and longstanding practices can be resistant to progress. All of health care is contending with the economics associated with the modern practice of medicine, and addressing any significant patient safety issue will involve cost/benefit scrutiny.

These real-world challenges clearly show that effectively managing fatigue in any 24/7 operational setting is a complex endeavor, with no single or simple solution. Given our human physiological design that includes a requirement for sleep and the powerful control and effects of the circadian clock, it is impractical to believe that fatigue can be eliminated from around-the-clock activities. However, there is no question that the safety-related risks associated with fatigue and impaired alertness can be managed better than current practice.

An extensive scientific literature exists that demonstrates the risks and costs associated with fatigue in health care.[1,2] It is clear that health care providers suffer from acute sleep loss, cumulative sleep debt, prolonged periods of continuous wakefulness, and circadian disruption. This physiological disruption is associated with decreased alertness and performance and an increase in errors and risks, including provider car crashes.[1-3] No doubt, ongoing research will further define these risks and elaborate the additional outcomes of fatigue in medical practice. However, it is critical to now move beyond just documenting that fatigue is present in 24/7 health care activities and has negative effects on performance and safety. It is time to test and implement effective strategies and approaches that will manage the known risks associated with fatigue in health care.

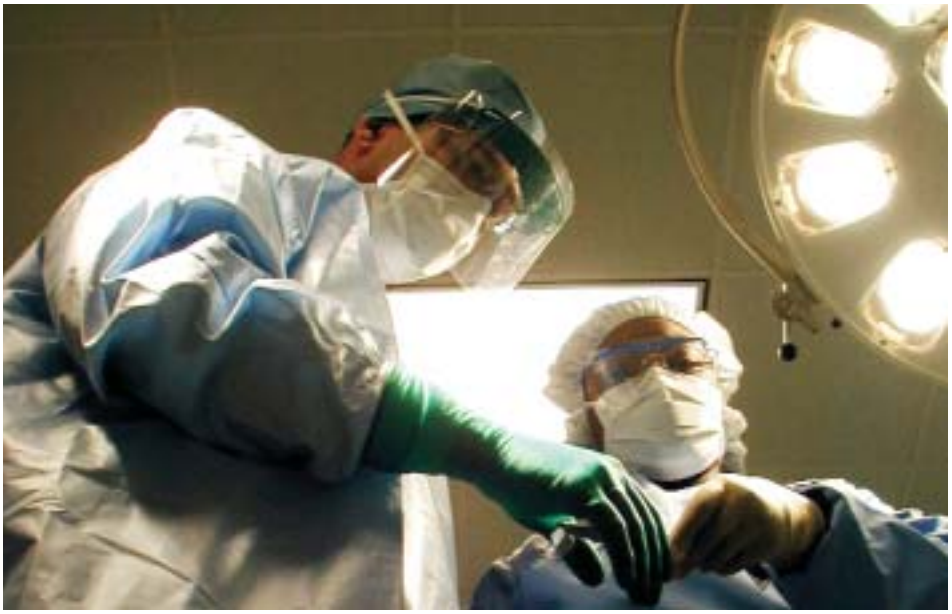
Classically, the most widely used approach to address fatigue in operational settings is through "hours-of-service" (HOS) regulations. Typically, these regulations establish specific off-duty requirements intended to provide rest opportunities and duty time limitations to prevent extended periods of work and wakefulness. An HOS approach also might address total work hours in a certain number of days or an identified number of days off for recovery. In some HOS structures, the work time within a duty period also has specific limits, for example, drive time for commercial truck operators and flight time for commercial pilots. Recently, the Accreditation Council for Graduate Medical Education (ACGME) utilized this same historical approach to establish intern and resident work hour limitations. There is no question that "HOS" are necessary but insufficient to effectively manage fatigue-related risks. This is true because allowing people to work without limitations will clearly

Mark R. Rosekind, PhD

engender fatigue, and providing minimal off-duty periods to prevent acute sleep loss and recovery periods to "zero" cumulative sleep debt are basics of managing fatigue. However, given the complexities previously identified, a general HOS structure cannot be expected to cover every circumstance or individual in health care.

Though an HOS approach is necessary, 2 examples illustrate its limitations. While an off-duty period maybe mandated, this does not guarantee that an individual will obtain required sleep during this time. Whether an individual chooses to remain awake and active, has sleep disturbed by external factors (e.g., noisy environment, sick child), is afflicted with one of the almost 90 identified sleep disorders or a multitude of other possibilities, that individual may not obtain sufficient sleep. Acute sleep loss, regardless of etiology, will degrade subsequent alertness and performance.

Another example involves night work that requires a health care provider to be awake when biologically programmed for sleep by the circadian clock and then attempt to sleep during the day when programmed for wakefulness. Therefore, anyone working through the night is at risk for degraded alertness and performance and the associated errors related to the circadian time of day. Generally, people do not physiologically adjust to night work,[4] and successive nights of work increase safety risks.[5] While light administration has been used successfully in the laboratory to adjust circadian phase,[6] the effective, practical and economically feasible application of this strategy to diverse work settings has yet to be realized. Therefore, the circadian clock will continue to create a physiological fatigue risk for individuals working at night.



See "Managing Fatigue," Next Page

Comprehensive Approach Can Improve Safety

"Managing Fatigue," From Preceding Page

There is no HOS structure in existence that fully addresses this circadian component; in fact, most policies do not incorporate specific circadian elements because they are so complex.

Alertness Management Program

A comprehensive alertness management approach offers the greatest opportunity to address these issues and involves a multi-component program that includes education, alertness strategies, scheduling practices, healthy sleep, and scientific and policy support.[7] An overview of this approach and each component is provided to illustrate the opportunity that a comprehensive alertness management approach offers.

Component 1: Education

Education is the foundation for any effort to address fatigue. At a minimum, the educational component should provide information about the risks associated with fatigue, the physiological mechanisms that underlie fatigue, and available approaches to reduce risks and optimize performance and alertness during operations. Consider that the basis for any significant attitude and behavior change begins with education. Health care provides many such examples where changes in diet, exercise, and smoking begin with educational programs that include information about risks and behavior change. This same approach is a critical first element for any fatigue or alertness management program.

While it is critical to provide an appropriate off-duty sleep opportunity, there is no guarantee that an individual will use the time for sleep. Perhaps the only acceptable approach to address this issue involves providing effective education that portrays the risks associated with not obtaining required sleep before work. It is unlikely that "bed checks" or technological monitoring of individuals to validate sleep will be readily accepted or adopted soon. Similarly, the circadian clock will continue to create physiological risks during the nighttime window of circadian low. It is critical that night workers be informed about this period of reduced alertness and performance, and utilize strategies to manage it.

This education should be provided to all segments within a health care organization. Often, these educational efforts will focus on trainees and physicians. However, nurses, technicians, pharmacists, maintenance personnel, and anyone working irregular schedules are potentially at risk and should be offered, at least, basic fatigue education. Also, a one-time "session" is less likely to create behavior change than information provided in multiple forums and formats and continually over time. Integrating fatigue education into an ongoing program creates the opportunity for this information to become a part of the corporate culture.

Component 2: Alertness Strategies

A second component of a comprehensive alertness management program involves alertness strategies. Beyond just information, the alertness strategies component should include two elements: 1) specific guidance on the effective use of strategies, and 2) establishing appropriate policies and support for implementation of strategies. For example, two well-studied and effective fatigue countermeasures involve planned naps and strategic use of caffeine.[8,9] However, it is critical that individuals understand the basics of their effective use. How long should naps be? What is the best timing? What should be done to avoid sleep inertia? These are important considerations to obtain optimal results from naps. In a similar way, information about the strategic and effective use of caffeine will increase the benefits obtained. For example, what dose is needed to enhance alertness and mental functioning, how much caffeine is contained in different drinks and food, and what will be the best timing for ingesting caffeine as an alertness strategy? Examples of some answers to these questions and other strategy implementation information is available in other sources.[2,7,10]

Another important element of this information should be to assist individuals in discriminating which strategies have a proven scientific basis for their effectiveness and use. When confronted with potential recommendations on "how to stay awake on the job" from a variety of sources (e.g., friends, co-workers, media), what criteria might an individual use to determine their value, efficacy, and safety.

The implementation of alertness strategies often requires policies and corporate support. An explicit policy on the use of planned naps is useful in a variety of ways. First, the policy provides an explicit sanction for the use of planned naps in the context of the work environment. Second, it can delineate specific procedures, timing, and circumstances for its use. Third, it is a mechanism to address any potential concerns about misuse. Beyond policies, corporate support might include the creation of specific nap rooms or some space conducive to obtaining a planned rest period. Also, while some may focus on the use of naps during low workload periods on shift, they can be an invaluable alertness strategy prior to a drive home after a work period. In relation to caffeine, if information about its effective strategic use is provided, then it is critical to have mechanisms in place to make it available when needed.

Similar to the education component, alertness strategies information and policies should be distributed through multiple forums and formats and on an ongoing basis. One example of an integrated education and alertness strategies tool was a video developed on behalf of the American Society of Anesthesiologists.[11] This short video includes some basics of fatigue risks and the underlying physiological mechanisms, and concludes with guidance and modeling of how to apply alertness strategies in a health care setting.

Component 3: Scheduling Policies and Practices

The third component of a comprehensive alertness management program involves scheduling policies and practices. At a minimum, this component should focus on 2 core issues. First, a basic "fatigue" analysis can be conducted to determine from a system's perspective how alertness and performance could be affected by current scheduling policies and practices. This might involve an examination of minimum off-duty times, shift lengths, policies on multiple shifts, consecutive duty periods, recovery opportunities, and other factors. There are at least 14 potential scheduling-related factors that can be evaluated as they relate to alertness and performance.[7] This analysis can identify both strengths and vulnerabilities in current scheduling. Second, based on the system analysis, the scheduling strengths should be reinforced and even extended whenever possible. The vulnerabilities identified present an opportunity to adjust scheduling policies and practices to address fatigue-related risks and enhance alertness and performance.

It should be noted explicitly that scheduling issues are the most complex and contentious elements of any comprehensive alertness management program. Scheduling significantly affects both individual health care providers and the organization. From an individual perspective, scheduling policies and practices will affect income, family, and social activities, and off-duty mood and performance.

Component 4: Healthy Sleep

The fourth component of a comprehensive alertness management program involves healthy sleep. At a minimum, this should involve providing information about the existence of the almost 90 sleep disorders that can be diagnosed and treated. Some of the sleep disorders known to affect health and safety, such as sleep apnea or shift work sleep disorder, should be emphasized.[12-14] Information can outline classic signs and symptoms, as well as, the potential health and safety risks that may be associated. In this context, information should include resources that identify accredited sleep disorders clinics available for referral, and possibly the extent of insurance coverage for these services. Beyond information and referral sources, it is possible to have a work-based diagnostic and treatment program that identifies and treats individuals with sleep apnea.

Component 5: Scientific and Policy Support

The fifth component of a comprehensive alertness management program involves scientific and policy support. A guiding principle for the program

See "Managing Fatigue," Next Page

Leaders Should Acknowledge Fatigue

"Managing Fatigue," From Preceding Page

should be the scientific foundation of all alertness management activities. Whenever possible and available, scientific data should be used to guide and create a foundation for each program component. Whether it is the core material provided in the educational activities or examination of scheduling practices, fatigue-related scientific knowledge can create a basis for guiding action.

A central ingredient of a comprehensive alertness management program involves the integration of activities and multiple approaches to address fatigue. The use of these various components provides a more extensive intervention that acknowledges the complex factors that can create fatigue-related risks. Some issues may be most amenable to educational activities, while others may require explicit changes in scheduling practices or overt sanctioning of certain alertness strategies (e.g., naps). An integrated program will ensure that information in the educational component is consistently represented in the strategies and scheduling activities and that the alertness strategies component is supported by appropriate policy. This integration can be a critical element to the success of a comprehensive alertness management program.

The scientific data are clear: fatigue creates safety and health risks in 24/7 operational settings, including health care. Given the complex factors that underlie fatigue, no single or simple solution can be expected to eliminate fatigue-related risks in health care. There are historical approaches, such as HOS policies, that are necessary, but insufficient to fully address the complexity. However, a comprehensive alertness management approach offers an opportunity to address the complex nature of fatigue and reduce the known risks. As more data demonstrating the safety and health risks continue to emerge, it is critical that health care settings move forward with interventions that address fatigue and promote alertness, performance, and safety. If action is not taken, then health care itself may be viewed as hypocritical when attempting to address these same issues with patients or in other occupational settings. However, the current status of efforts in health care regarding fatigue also represents an important and unique opportunity. By acknowledging and addressing fatigue related risks, health care can be a model for other around-the-clock environments and provide leadership on effective interventions that can improve the alertness, safety, and health of our 24/7 society.

Dr. Rosekind is President and Chief Scientist of Alertness Solutions, Cupertino, CA.

References

1. Gaba DM, Howard SK. Fatigue among clinicians and the safety of patients. *N Engl J Med* 2002;347:1249-55.
2. Howard SK, Rosekind MR, Katz JD, et al. Fatigue in anesthesia: implications and strategies for patient and provider safety. *Anesthesiology* 2002;97:1281-94.
3. Barger LK, Cade BE, Ayas NT, et al. Extended work shifts and the risk of motor vehicle crashes among interns. *N Engl J Med* 2005;352:125-34.
4. Gander PH, Gregory KB, Connell LJ, et al. Flight crew fatigue IV: overnight cargo operations. *Aviat Space Environ Med* 1998;69(9 Suppl):B26-36.
5. Folkard S, Tucker P. Shift work, safety and productivity. *Occup Med* (Lond) 2003;53:95-101.
6. Horowitz TS, Cade BE, Wolfe JM, et al. Efficacy of bright light and sleep/darkness scheduling in alleviating circadian maladaptation to night work. *Am J Physiol Endocrinol Metab* 2001;281:E384-91.
7. Rosekind MR. Managing work schedules: an alertness and safety perspective. In: Kryger MH, Roth T, Dement WC, eds. Principles and Practice of Sleep Medicine. Philadelphia: Elsevier Science, (in press).
8. Committee on Military Nutrition (Institute of Medicine). Caffeine for the sustainment of mental task performance: formulations for military operations. Washington, DC: National Academy of Sciences, 2001.
9. Rosekind MR, Graeber RC, Dinges DF, et al. Crew factors in flight operations IX: effects of planned cockpit rest on crew performance and alertness in long-haul operations. NASA Technical Memorandum #108839. Moffett Field, CA: NASA, 1994.
10. Rosekind MR, Gander PH, Connell LJ, et al. Crew factors in flight operations X: Alertness management in flight operations. NASA Technical Memorandum #1999-208780. Moffett Field, CA: NASA, 1999.
11. Howard SK, Gaba DM, Rosekind MR. Fatigue: Implications for the Anesthesiologist. American Society of Anesthesiologists Patient Safety Videotape Series, Program 29. Park Ridge, IL: American Society of Anesthesiologists, Inc., 1998. Available on the web at: http://www.apsf.org/resource_center/educational_tools/video_library.mspx. (Accessed March 8, 2005)
12. Drake CL, Roehrs T, Richardson G, et al. Shift work sleep disorder: prevalence and consequences beyond that of symptomatic day workers. *Sleep* 2004;27:1453-62.
13. Teran-Santos J, Jimenez-Gomez A, Cordero-Guevara J. The association between sleep apnea and the risk of traffic accidents. *N Engl J Med* 1999;340:847-51.
14. The International Classification of Sleep Disorders (Revised): Diagnostic and Coding Manual. Westchester, IL: American Academy of Sleep Medicine, 2001.

Letter to the Editor

Surgeon Should Give Feedback to His Health Care Team First

To the Editor:

I am amazed by the response to the anonymous surgeon/patient's perioperative experience recounted in the 2004-5 winter issue of the *APSF Newsletter*. I have been in practice for 20 years, in both academic and private practice settings. Currently, I practice in a tertiary care referral center with an anesthesia residency. The overwhelming majority of "anesthesia providers" are dedicated to excellent patient care and very professional in their approach to the patient. I am sorry that this surgeon/patient did not have quite the perioperative experience he was expecting. However, he needs to direct his criticism in a constructive way toward the anesthesia team responsible for his care, and not toward the entire specialty. Interestingly, if I wrote to a surgical newsletter to complain about my surgeon, the letter would probably not be published. I would be told, "Gee, honey, go discuss this with your surgeon." As a specialty we seem to have a collective inferiority complex! But, why? Advances in surgery would not be possible without advances in the field of anesthesiology. Anesthesiologists have pioneered fields like intensive care medicine and pain medicine. The ABA is committed to the continuing education of its members. The residents that I train are as intelligent, dedicated, and hard working as any surgery resident, if not more so. Coming to work is a pleasure, and I consider myself blessed to work with such competent individuals. I have a great suggestion. Let's invite Dr. Phil McGraw to the next ASA meeting. Maybe he can figure out the basis for this collective inferiority complex, because I can't! I can, however, recommend one helpful exercise for those who might still suffer from such a complex. Before you leave for work in the morning, look at yourself in the mirror and tell yourself, "Damn I'm good!"

Elizabeth T. Young, MD
New Orleans, LA

Fatigue and Anaesthetists:

The Association of Anaesthetists of Great Britain and Ireland's Approach

by Michael E. Ward, MB BS, MRCS LRCP, FRCA

The membership of the Association of Anaesthetists of Great Britain and Ireland (AAGBI) is totally medical, and currently 95% of the anaesthetists in the UK are members. It has in excess of 9,000 members, including 4,500 full members (consultants in UK terminology is equivalent to attendings in the US), 1,000 members retired from active practice, and the remainder who are staff in training grades. Most reside in the British Isles, but 400 currently work or live overseas (68 are currently in the US).

Annual membership costs are £180 ($338). The roles of the Association are

- to represent the interest of its members
- to provide advice and information to both members and public about anesthetic matters
- to organize regular (twice yearly) national meetings and 40 small seminar meetings annually at its London headquarters to which members have significant discounts
- to publish its monthly scientific journal, *Anaesthesia*, sent free to all members together with its newsletter, *Anaesthesia News*
- to maintain a professional website
- to provide a significant level of automatic injury and life insurance coverage for members during patient transfer
- to provide representation at Westminster and the Department of Health
- to work with the Royal College of Anaesthetists to provide full professional support and maintenance of standards of practice and training
- to publish regular guidelines on professional and ethical matters which form the basis for good practice, known as "Glossies."

Michael E. Ward, MB BS, MRCS LRCP, FRCA

In early 2003 Dr. Ed Charlton (an ex-member of AAGBI Council) wrote to the AAGBI President to draw his attention to an editorial and review article published in *Anesthesiology* on the subject of fatigue in anaesthesia.[1] This was a timely occurrence as changes in work patterns, due to the impending implementation of the European Working Time Directives and the anticipated New Consultant Contract, were expected to have a profound effect on the total weekly working hours and lifestyles of both career grade and non-career grade anaesthetists, as well as other hospital doctors in the UK and Ireland. A paper with a similar message had been published in June 2000 and reported that fatigue was listed as a contributory factor in 152 anesthetic incidents, or 2.7% of all reports.[2]

The Association of Anaesthetists of Great Britain and Ireland

The President raised the matter at the next bi-monthly Advisory Meeting of the Council where I was tasked with setting up a working party to examine the evidence and produce a document to explore the problems of fatigue in anaesthesia and make proposals that could reduce the risks for both patient and practitioner. A scoping meeting of selected Council members met in March 2003 to discuss the proposal, and it was agreed that the project should proceed with other invitees who could add knowledge and experience to the deliberations.

The first full meeting of the new Fatigue and Anaesthetists Working Party took place in May 2003 and, in addition to members of Council and the Association's Trainees section, involved Ed Charlton and representatives of the British Medical Association, an Occupational Health Physician, and the Royal College of Anaesthetists.

The working party met on a total of 6 occasions and produced 8 drafts of the document. Much of the draft revision was done by email iteration and amendment with the formal meetings being reserved for discussion of policy and drawing out the recommendations from the text. When the working party met in January 2004 to review draft 5, it was over 8,000 words long and was fully referenced with 56 citations. It was clearly too long for a traditional glossy and a number of options were considered. It could be published as it was in full, it could be severely abridged, or it could be abridged with the full document and all its supporting references and material available on the AAGBI website.

The last proposal was accepted, and an abridged draft (4,000 words and 21 references) was submitted to Council for final approval in early March 2004. All Council members were able to feedback comments to the April Council meeting, and corrections or amendments adopted there were included in the final document launched in July 2004.

Every Association document when first published has a date assigned for a review, when Council decides whether it should be withdrawn, is still a relevant document, or should be completely revised and republished. These documents are known as "Glossies" because of the glossy cover assigned to them.

What are glossies for? First, they should educate members on topics of relevance to professional practice, but they are not meant as mini textbooks of anaesthesia. Second, they should be useful to the membership as references when discussing professional activities with other specialty groups or managers. It is hoped that, with the support of a glossy, an anaesthetic division may be able to ensure proper provision of support, be it clinical, equipment, secretarial, or administrative to allow safe practice. Some glossies become very powerful tools, such as the "Recommendations for Standards of Monitoring During Anaesthesia and Recovery," which has set the standard, and is broken at the peril of the practitioner. Others such as "Management of Anaesthesia for Jehovah's Witnesses" provide handy pocket-sized reference to less common problems faced by the anaesthetist. The glossy, "Fatigue and the Anaesthetist," can be used to guide members and the management of hospitals into following safe practices with a scientific background in respect to the duration of working hours and recovery from arduous duties. Guidance is also offered on better practices to be followed where turnovers from one anaesthetist or team to another are necessary due to the onset of fatigue or the requirement to relieve a colleague who has

See "Britain and Ireland," Next Page

AAGBI Has Important Recommendations

"Britain and Ireland," From Preceding Page

exceeded safe working hours. It makes a number of significant proposals aimed to protect both the patient and the practitioner.

Principal Recommendations:

- Every anaesthetist should be aware of the problem of fatigue and carry a personal obligation to provide safe and effective service.
- Departments must have a plan to manage staff at all grades who have suffered an onerous duty period and consider themselves unfit to continue work. For example, when a night on call is arduous there must be a mechanism/protocol to allow for replacement/relief of an overtired anaesthetist.
- Job plans which are likely to lead to predictable fatigue should be avoided so that busy nights on call should neither follow nor precede a full working day in the operating room, intensive care unit, or similar duty.
- Job plans of career grade staff should be designed to include flexibly worked fixed theatre sessions without operating sessions allocated to a particular surgeon or service in order to provide regular relief for colleagues.
- Routine rest breaks should be implemented. A "Handover Protocol" should be used before even short rest breaks. A standardised checklist to be used when relieving a colleague should be introduced to avoid omitting vital information about the patient, procedure, anaesthetic technique, and equipment.
- All hospitals should ensure the availability of "on call" rooms for those doctors working night shifts, to enable rest breaks. With the recent introduction of shift working, many hospitals have removed the "duty" or "on-call" rooms as a cost saving measure. The Association believes that such facilities should be reintroduced or protected in order that anaesthetists who get the opportunity to take a rest break during their shift can do so in a suitable environment.
- Management should provide designated rooms adjacent to the operating room for napping and "post-call" sleeping facilities.
- Good quality accommodation should be available for resident on-call staff.
- All staff should have access to good quality refreshments at all times. It is often not possible for anaesthetists to visit the dining hall/cafeteria at the fixed hours of opening due to the unusual requirements of their workload. Alternative refreshment facilities must be provided at these "odd" hours.
- On-call responsibilities should be reviewed for anaesthetists over 45 years of age in conjunction with advice from an accredited specialist in occupational medicine.
- Private practitioners should ensure that a combination of National Health Service and Private work does not lead them to practice when compromised by fatigue.

While the proposals in the document are clearly aimed at anaesthetic working practices, the principles of the findings and recommendations will be just as applicable to surgery or other branches of hospital medical practice.

The "Glossy" has been sent to all members of the AAGBI and interested groups and posted on the AABGI's website.[3] In addition, an expanded version, which goes into some aspects in much greater detail, has also been posted on the website.[4]

Dr. Ward serves as Chair of the Association of Anaesthetists Working Party on "Fatigue and Anaesthetists" and is Former Vice President of the Association of Anaesthetists of Great Britain and Ireland. He is also a Consultant Anaesthetist and Senior Clinical Lecturer in the Nuffield Department of Anaesthetics, Oxford, England.

References

1. Howard SK, Rosekind MR, Katz JD, Berry AJ. Fatigue in anesthesia: implications and strategies for patient and provider safety. *Anesthesiology* 2002;97:1281-94.
2. Morris GP, Morris RW. Anaesthesia and fatigue: an analysis of the first 10 years of the Australian Incident Monitoring Study 1987-1997. *Anaesth Intensive Care* 2000;28:300-4.
3. Fatigue and Anaesthetists. London: The Association of Anaesthetists of Great Britain and Ireland, 2004. Available on the web at: http://www.aagbi.org/pdf/Fatigue.pdf.
4. Fatigue and Anaesthetists (Extended Web Version). London: The Association of Anaesthetists of Great Britain and Ireland, 2004. Available on the web at: http://www.aagbi.org/pdf/Web_Version_Fatigue.doc

ACGME

ACGME Recognizes Dangers of Fatigue

The Accreditation Council for Graduate Medical Education (ACGME) has recently instituted a requirement for "Sleep Loss and Fatigue Management Training" in teaching specifications for all residency programs.

Specifically, it is stated that "faculty and residents must be educated to recognize the signs of fatigue and adopt and apply policies to prevent and counteract its potential effects."

Reminder!

APSF Grant Applications Due

Monday June 20, 2005

- **See website for guidelines and instructions**
- **Applications must be submitted electronically via website**

The Costs of Clinician Fatigue and Its Prevention

by David M. Gaba, MD

In the course of studying and writing about the problem of fatigue in health care personnel, our group and others have suggested a multitude of possible countermeasures. In this Special Issue, a world expert on managing fatigue concerns in a variety of high-hazard industries discusses a number of possible approaches. Many countermeasures seem simple to implement at little cost. Others would require substantial reorganization of the clinical work environment and the clinical workforce. These are thought to have substantial costs associated with them, and many of them have not been studied very thoroughly for efficacy (do they work in the lab?), effectiveness (do they work in day-to-day practice?), let alone for their costs. In this article I will raise a number of questions concerning various costs of countermeasures. Few of the questions can be answered at this point, and none can be answered definitively. Attempting to answer them will be an appropriate component of a long-term strategy to come to grips with the demands of a "24/7" health care industry.

First, the growing literature on the adverse effects of fatigue on clinician performance implies that there are substantial, sometimes hidden, costs to individuals and society already imposed by suboptimal or inefficient patient care and outright errors caused or exacerbated by clinician fatigue. Such costs are difficult to compute. Recent data show unequivocally that error rates were higher by trainees working highly fatiguing schedules vs. those working less fatiguing schedules.[1] Extrapolating the excess errors in the more fatigued group from these studies to the wider clinician population is appropriate, but imprecise. On the one hand, outright errors are only the tip of the iceberg. What about orders that are written a little late, just enough to push discharge from an ICU out another day? What about the clinic or OR schedule that gets behind because people are working just a little slower. On the other hand, not all the costs apparently due to fatigue-induced errors can necessarily be recouped using any of the existing countermeasures. Thus, in the absence of very complex and long-term trials that capture direct and indirect costs due to excess fatigue of clinicians, we cannot be sure of how much money could be saved by limiting clinician sleepiness.

The current situation imposes other societal costs related to the health care workers themselves. There is growing evidence that fatigued trainees are at risk for traffic accidents, particularly when driving home after long and/or overnight duty periods.[2] There is also strong evidence among truck drivers and others that occupational-related illnesses are related to sleep disturbances due to night work. The cost of such accidents, illnesses, and lost productivity is not typically ascribed to fatigue of personnel in the health care system but is a "real" cost that must also be considered.

Malpractice litigation has surprisingly not become a driving force regarding the safety and economic ramifications of fatigue. Sleep deprivation of clinicians involved in litigation has only rarely been a significant issue even though high levels of fatigue are widespread throughout health care. Over many decades, a rise in such litigation has been expected each time the issue is highlighted in the media (e.g., after the Libby Zion case) or with increasing unionization of residents, but so far this has not happened. If it should ever happen, it will certainly amplify the actual costs of fatigue-induced errors or negative outcomes.

Finally, one of the most uniform findings of fatigue studies of health care personnel is that tired clinicians have negatively altered mood, which surely cannot contribute to caring and humane interactions with patients.[3] It is hard to put a cost on callous or insensitive patient care, but the public often seems to place a higher premium on personal attention and caring than on technical excellence. Thus, there are clear and major opportunities to reduce costs and improve care by ameliorating sleepy clinicians. Measuring these costs, or the extent to which they are mitigated by countermeasures, will be very difficult. It is hard to measure the benefits of the "accident that did not occur" (especially when the accidents are uncommon), or gratified patients who otherwise would have been upset with their care. The signals of "safety" are inherently weaker than the signals of "production."[4,5]

Having said that, let us look at the diverse countermeasures that have been suggested, as well as some of the direct and indirect costs they would impose on the health care system. Although these costs have never been measured, and cannot be detailed exhaustively in this article, many of them can be articulated for consideration in any future comprehensive financial modeling of potential fatigue intervention policies.

Education

A seemingly easy countermeasure is to educate clinicians about the science of sleep and the ways in which they can act to protect their health and improve their performance. Educational modalities (videos, lectures, and seminar series) require moderate investment to produce and disseminate. For clinicians to attend such training may pull them out of revenue-producing work, and has to be traded off against other sorts of training that they are required to take. And while the costs may be only moderate, the efficacy and effectiveness remain to be tested.

David M. Gaba, MD

Sleep Hygiene

One typical target of education is to exhort clinicians to make sleep a higher priority in their lives. On the one hand, requiring health care professionals to come to work well-rested is no different from forcing them to come to work sober and drug-free. On the other hand, to some degree this policy shifts the cost "burden" onto individual clinicians who are being asked to give up an hour or two of their other activities–whether moonlighting or spending time with their families–in favor of sleep. While they will also recoup some direct benefits to their health, mood, and possibly traffic safety, in part they are being asked to bear the costs of the health care system's 24/7 demands, rather than having the system bear those costs collectively by hiring more staff.

Fitness for Duty Tests/Standards

The logical conclusion of a variety of countermeasures that attempt to change the pre-shift physiological state of clinicians would be to establish metrics and standards for "fitness for duty." In this case, clinicians who are impaired would not be allowed to work that day or that shift. The costs for implementing such standards could be high. Replacement clinicians would need to be immediately available to substitute for those who are not fit for duty. Measures would have to be taken to ensure that the system is not abused by those wanting extra time off. And, while some causes of sleep deprivation can be avoided by proper sleep hygiene, others (such as the sick child at home) cannot reasonably be prevented even by the most dedicated clinician. In addition, the health care system already copes with absences due to illness, so adding "fatigue impairment" to other more common illnesses might be a tractable marginal cost.

See "Costs," Next Page

Solutions to Fatigue Require Resources

"Costs," From Preceding Page

Work Schedule Changes and Work Hours Limitations

A common countermeasure being imposed around the world, at least for trainees, is limiting total work hours and on duty-periods. The European Union is currently at a 56-hour weekly limit, with other limits on shift duration and rotation. Eighteen months ago, the ACGME imposed regulations on all residency programs in the U.S. that required substantial changes in work schedules. The imposed limit of 80 hours per week is far more lenient than European limitations. Recent studies published in the *New England Journal of Medicine* demonstrate that altering work schedules can decrease error rates.[1] But, the altered schedules require hiring more net clinical employees, or shifting work from trainees to others. Both are relatively expensive solutions. Calculating the costs of changing the schedules is not easy. There are also indirect costs to the system. Medical educators are struggling with how to provide the same training in the fewer hours available. Some solutions to this problem will themselves have costs.

At-Work Napping

Some studies in other industries (and some in health care) show a benefit to at-work napping during long or overnight duty periods.[6] Even short naps of 45 minutes have been shown to be beneficial in some settings, improving alertness and performance.[7] Naps are common for trainees working 24-hour (or longer) shifts, but they are available haphazardly, and during many shifts little if any sleep can be accrued. Scheduled guaranteed naps might be useful for such personnel or even for night shift workers during only 8 or 12 hour shifts. What would it take to provide a guaranteed nap for such workers? In some cases it might be feasible for existing personnel to cross cover sufficiently to allow scheduled naps. In other cases it might be necessary to add one or more individuals on the night shift to provide rotating coverage for the napping individuals. Modeling the costs of on-shift napping will be difficult and will depend heavily on the exact staffing and work demands of each clinical setting. Union rules may play a role in what can and cannot be done with existing personnel versus with additional clinicians.

Post-Shift Napping

Naps taken after the shift is completed might help with the safety of the drive home and might also reduce accumulated sleep debt. If they are voluntary, the only costs are to provide the facilities for departing workers to nap. Experience shows that most workers would prefer to depart tired in order to get home earlier. Those with very long drives home, or those likely to face heavy traffic, may be the most likely to choose to nap rather than depart immediately. Thus, unless the preferences of workers are changed, or the nap is a mandatory use of unpaid time, the post-shift nap is unlikely to be a robust strategy for the workforce as a whole, even though its costs are modest.

Drug Therapy

Many clinicians already use a drug—caffeine—on a regular basis to promote alertness during the night. But caffeine is an imperfect drug and is generally not used very wisely. The new alertness enhancing drug modafinil (approved for the use in patients with narcolepsy, daytime sleep complaints in patients with obstructive sleep apnea, and shift work sleep disorder) may provide an alternative. Whether shift workers should use modafinil on a regular basis is one question (see Dr. Lydic's and Dr. Smith's articles in this issue). But if they should, or if they do, who will pay the costs of the drug? Who will pay the costs of any side effects generated by taking the drug? And what might be the costs of litigation that might arise should medical errors be made that either a patient's attorney, or the attorney of the clinician, ascribe to the use of the drug?

Light Therapy

The application of higher levels of ambient light at the right time periods has been shown in laboratory studies to reset circadian rhythms and could be used to aid shift workers.[8] Special facilities might be needed to allow workers to obtain light therapy at the right time. The timing of light therapy is very critical to its success—thus, as in the case of napping, relief personnel might be required to allow others to obtain light therapy.

In conclusion, one thing is certain. The emerging research indicates strongly that, both before and after the ACGME rule changes for residents, our health care industry and our professions have ignored substantial costs to patients and society due to fatigue-induced errors, poor performance, and automobile accidents by sleepy clinicians. After years of clamoring for change in the work and duty hours for physicians in training, significant but limited changes have been imposed. Further changes seem warranted, for this group as well as for experienced health care personnel. We must acknowledge that these reforms carry a cost. For the strongest interventions, the costs are likely to be high. Modeling the direct and indirect costs is not a simple matter, and must take into account a large variety of factors that may differ strongly in different work settings, and at different institutions. They may also differ based on the health care discipline involved and the administrative structures of the different components of the workforce. Still, cost and policy modeling is a mature art, if seemingly arcane to most clinicians. The time is right for some serious research on the organizational, logistical, and cost implications of the various proposed countermeasures to best inform policy choices. We call on our colleagues in health services research to become interested in the economic and policy implications of the fatigue issue, and help us find the best solutions to protect our patients, and improve our own health in the most expeditious and cost-effective manner possible.

Dr. Gaba is a Professor in the Department of Anesthesia and the Associate Dean for Immersive and Simulation-Based Learning at Stanford University, Stanford, CA.

See "Costs References," Page 22

Anesthesia Patient Safety Foundation

Corporate Donors

Founding Patron ($400,000 and higher)
American Society of Anesthesiologists (asahq.org)

Foundation Patron ($50,000 to $99,999)
GE Healthcare (gemedical.com)

Benefactor Patron ($25,000 to $49,999)
Abbott Laboratories (abbott.com)
Aspect Medical Systems (aspectms.com)
AstraZeneca Pharmaceuticals LP (astrazeneca.com)
Philips Medical Systems (medical.philips.com)
Tyco Healthcare (tycohealthcare.com)

Grand Patron ($15,000 to $24,999)
Baxter Anesthesia and Critical Care (baxter.com)
Dräger Medical, Inc. (nad.com)
Preferred Physicians Medical Risk Retention Group (ppmrrg.com)

Patrons ($10,000 to $14,999)
Endo Pharmaceuticals (endo.com)
Spacelabs Medical (spacelabs.com)

Sustaining Members ($5,000 to $9,999)
Alaris Medical Systems (alarismed.com)
Arrow International (arrowintl.com)
First Professionals Insurance Company (fpic.com)
B. Braun Medical (bbraun.co.uk)
Becton Dickinson (bd.com)
Datascope Corporation (datascope.com)
Kimberly-Clark (kimberly-clark.com)
LMA of North America (lmana.com)
Medical Education Technologies, Inc. (meti.com)
Organon (organon.com)
Roche Laboratories (roche.com)
Smiths Medical (smiths-medical.com)
The Doctors Company (thedoctors.com)
Vance Wall Foundation
Vital Signs (vital-signs.com)

Sponsoring Members ($1,000 to $4,999)
Anesthesia Business Consultants (anesthesiallc.com)
Cerner Corporation (cerner.com)
Cook Critical Care (cookgroup.com)
Docusys, Inc. (docusys.net)
King Systems Corporation (kingsystems.com)
Masimo Corporation (masimo.com)
Oridion (oridion.com)
Somnia, Inc. (somniainc.com)
Trifid Medical Group, LLC (trifidmedical.com)

Corporate Level Members ($500 to $999)
Armstrong Medical, Ltd.
Belmont Instrument Corporation (belmontinstrument.com)
Boehringer Laboratories (autovac.com)
Hoana Medical, Inc. (hoana.com)
Lippincott Williams and Wilkins

Participating Associations
American Association of Nurse Anesthetists (aana.com)

Subscribing Societies
American Society of Anesthesia Technologists and Technicians (asatt.org)
American Academy of Anesthesiologist Assistants (anesthetist.org)

Community Donors

(includes Anesthesia Groups, Individuals, Specialty Organizations, and State Societies)

Grand Sponsor ($5,000 and higher)
American Association of Nurse Anesthetists
American Medical Foundation
Florida Society of Anesthesiologists
Indiana Society of Anesthesiologists
Robert K. Stoelting, MD

Sustaining Sponsor ($2,000 to $4,999)
Alabama State Society of Anesthesiologists
Anesthesia Associates of Massachusetts
Anesthesia Consultants Medical Group
Anesthesia Resources Management
Anesthesia Service Medical Group
Arizona Society of Anesthesiologists
Nassib G. Chamoun
Georgia Society of Anesthesiologists
Indianapolis Society of Anesthesiologists
Iowa Society of Anesthesiologists
Massachusetts Society of Anesthesiologists
Michigan Society of Anesthesiologists
Minnesota Society of Anesthesiologists
Ohio Society of Anesthesiologists
Old Pueblo Anesthesia Group
Pennsylvania Society of Anesthesiologists
Society of Cardiovascular Anesthesiologists

Contributing Sponsor ($750 to $1,999)
Academy of Anesthesiology
Affiliated Anesthesiologists, Inc.
American Society of Critical Care Anesthesiologists
J. Jeffrey Andrews, MD
Anesthesia Associates of Northwest Dayton, Inc.
Anesthesia Services of Birmingham
Anesthesia Service of Eugene, PC
Arkansas Society of Anesthesiologists
Asheville Anesthesia Group
Association of Anesthesia Program Directors
Capital Anesthesiology Association
Frederick W. Cheney, MD
Connecticut State Society of Anesthesiologists
Jeffrey B. Cooper, PhD
John H. Eichhorn, MD
David M. Gaba, MD
Illinois Society of Anesthesiologists
Kentucky Society of Anesthesiologists
Edward R. Molina-Lamas, MD
Madison Anesthesiology Consultants
Maine Society of Anesthesiologists
Maryland Society of Anesthesiologists
Members of the Academy of Anesthesiology
Michiana Anesthesia Care
Missouri Society of Anesthesiologists
Robert C. Morell, MD
Nebraska Society of Anesthesiologists
John B. Neeld, MD
Nevada State Society of Anesthesiologists
New Mexico Anesthesia Consultants
Northwest Anesthesia Physicians
Neshan Ohanian, MD
Oklahoma Society of Anesthesiologists
Oregon Anesthesiology Group
Oregon Society of Anesthesiologists
Physician Anesthesia Service
Pittsburgh Anesthesia Associates
Society of Academic Anesthesia Chairs
Society for Ambulatory Anesthesia
Society of Neurosurgical Anesthesia & Critical Care
Society for Pediatric Anesthesia
South Carolina Society of Anesthesiologists
South Dakota Society of Anesthesiologists
Tennessee Society of Anesthesiologists
Texas Society of Anesthesiologists
Washington State Society of Anesthesiologists
West Jersey Anesthesia Associates, PA
Wisconsin Society of Anesthesiologists

Sponsor ($100 to $749)
Anesthesia Associates of Boise
Anesthesia Associates of Chester County
Anesthesia Associates of St. Cloud
Susan Bender, CRNA
Sorin J. Brull, MD
California Society of Anesthesiologists
Robert A. Caplan, MD
Cardiovascular Anesthesia, LLC
CHMC Anesthesia Foundation
Melvin A. Cohen, MD
Stuart M. Cohen, MD
Colorado Society of Anesthesiologists
Commonwealth Anesthesia Associates
W. Keith Conerly, CRNA
Paula A. Craigo, MD
Glenn E. DeBoer
Walter C. Dunwiddie, MD
Norig Ellison, MD
Jan Ehrenwerth, MD
Barry J. Friedberg, MD
Georgia Anesthesia Associates
Barry M. Glazer, MD
Griffin Anesthesia Associates
Peter Hendricks, MD
James S. Hicks, MD
Dr. and Mrs. Glen E. Holley
Victor J. Hough
Idaho Society of Anesthesiologists
Independence Anesthesia, Inc.
Sharon Rose Johnson
Daniel J. Klemmedson, DDS, MD
Roger W. Litwiller, MD
Thomas T. McGranahan, MD
Medical Anesthesiology Consultants Corporation
Mississippi Society of Anesthesiologists
Roger A. Moore, MD
Ervin Moss, MD
New Hampshire Society of Anesthesiologists
New Jersey State Society of Anesthesiologists
Beverly K. Nichols, CRNA
L. Charles Novak, MD
Denise O'Brien, RN
Jill Oftebro, CRNA
Physician's Accounts Receivable
Mukesh K. Patel, MD
Physician Specialists in Anesthesia
Richard C. Prielipp, MD
Debra D. Pulley, MD
Rhode Island Society of Anesthesiologists
Society for Technology in Anesthesia
Southern Tier Anesthesiologists, PC
South County Anesthesia Association
University of Maryland Anesthesiology Associates
Utah Society of Anesthesiologists
Vermont Society of Anesthesiologists
Virginia Society of Anesthesiologists
Drs. Mary Ann and Mark A. Warner, MD
Matthew B. Weinger, MD
West Virginia Society of Anesthesiologists
Dr. and Mrs. Wetchler
Lawrence Wobbrock, JD
Waterville Anesthesia Associates
West River Anesthesiology Consultants
Woodland Anesthesia Associates

In Memoriam
In memory of Gale E. Dryden, MD (Friends of the Dryden family)
In memory of Margie Frola, CRNA (Sharon R. Johnson, MD)
In memory of Charles L. Maimbourg, MD (Texas Society of Anesthesiologists)
In memory of Walter H. Mannheimer (Texas Society of Anesthesiologists)
In memory of Robert A. Sandoval, MD (Texas Society of Anesthesiologists)
In memory of Morton V. Sinclair (Russell S. Peterson, MD)

Note: Donations are always welcome. Send to APSF; c/o 520 N. Northwest Highway, Park Ridge, IL 60068-2573 *(Donor list current through March 14, 2005)*

Report of APSF Workshop on Postoperative Long-Term Outcome

by David M. Gaba, MD, and Robert C. Morell, MD

Anesthesiologists have long been pioneers in seeking ways to improve the safety of patients. To date, most of our efforts have been directed toward reducing the likelihood of adverse events in the immediate perioperative period. Over the last few years several threads of information have been coalescing that suggest there is another patient safety issue involving adverse outcomes occurring long after the traditional perioperative period. These outcomes are not directly tied to a specific complication of the surgery and may be referred to as "long-term outcomes" of anesthesia and surgery.

The APSF has begun to take an active interest in this topic. In the *APSF Newsletter* (Fall 2003 and Spring 2004), a number of these issues were introduced, along with the hypothesis that the underlying biological mechanism to explain the occurrence of such long-term outcomes might have to do with inflammatory processes triggered in the perioperative period. As detailed in those articles there are a variety of reasons to think that mortality, and presumably morbidity, can be affected by perioperative events, and that inflammation could be a key element in such occurrences.

Because the threads were disparate, from different medical domains, and still uncertain, the APSF decided to convene a multidisciplinary experts' workshop. Following is a brief report of some of the highlights from that workshop. Dr. David Gaba was selected as the principal investigator for the workshop because of his extensive research experience, expertise in patient safety, role as secretary of the APSF, and the fact that he does not conduct research in this particular area. Thirty experts attended the conference in Boston, MA, on September 21-22, 2004. The names of attendees and their biographies are available on the APSF website. The full program for the workshop is also available on the site. The program was divided into 4 sessions including epidemiology of long-term outcomes following anesthesia and surgery, 2 sessions on inflammatory processes and other underlying biological mechanisms, and a final session reviewing the issues discussed and the pitfalls of conducting outcomes research, and debating the best course of action for future research.

The goals for the conference were to:

- Define the problem(s) of long-term outcomes after anesthesia and surgery
- Estimate the scope and nature of the problem(s)
- Assess the state of the science of the putative inflammatory mechanisms
- Identify the most important research questions, and the key gaps between what is being studied and what needs to be studied
- Develop an agenda for possible research
- Determine if existing interventions require greater attention for evidence-based guidelines/practice parameters
- Identify new interventions in need of study
- Develop a plan for dissemination and follow-up.

Session 1: Epidemiology of and Risk Factors for Long-Term Outcomes

Robert Lagasse, MD, began by reviewing some of the history of research on short-term, adverse outcomes in anesthesiology, illuminated issues in studying long-term outcomes, and suggested that the advent of Anesthesia Information Management Systems (AIMS) could make it easier to link intraoperative events to both short- and long-term outcomes. Next, Shukri Khuri, MD, described the Veterans Health Administration's National Surgical Quality Improvement Program (NSQIP). Dr. Khuri is a cardiac surgeon who has led the NSQIP project for many years. NSQIP tracks surgical outcomes (typically out to 30 days post-op) for a number of major surgical procedures, in a variety of surgical specialties, across all VA facilities that perform them. The NSQIP database depends on data entered by a specially trained nurse at each site, who is able to leverage the VA's electronic medical record system. Data are collected on a large number of preoperative variables, on a few intraoperative variables (e.g., duration of surgery, surgical procedure), and then on a suite of postoperative outcome variables. The NSQIP database now has more than 1.2 million records and for selected patient groups has assessed mortality out to 10 years. The NSQIP program has expanded to the private sector, first in a set of studies and now in a joint program with the American College of Surgeons–ACS-NSQIP. Finally in this session, Terri Monk, MD, discussed the history of studies of long-term mortality following anesthesia and surgery in different patient populations. She provided an overview of intervention studies such as those using beta-blockade in the perioperative period. She also presented preliminary but provocative data from her original research examining perioperative cognitive dysfunction in patients having general anesthesia. Data on intraoperative vital signs and blinded bispectral index (BIS) data were recorded for these patients as were various postoperative outcomes, including mortality at 1 year. The data on mortality were then subjected to multiple regression modeling to determine which underlying preoperative and intraoperative factors correlated with death at 1 year. Not surprisingly, underlying medical problems were the major risk factors (odds ratio 16.1), as was time spent with a systolic blood pressure less than 80 mmHg (odds ratio 1.04/minute <80). A BIS value <40 was also identified as a significant risk factor. Dr. Monk also described results of a similar study performed on a larger number of patients in Sweden by Lennmarken et al. that also showed that BIS <45 was a statistically significant risk factor. Dr. Monk described all of these results as surprising, since there was no obvious mechanism to account for these findings. In addition, approximately one-half of the deaths in her study were due to cancer, and the correlation of time with hypotension or with BIS <40 to death due to cancer was even harder to explain.

Discussion of Session 1

Robert Stoelting, MD, APSF President, chaired the discussion of Session 1, at which the panel reviewed the epidemiology. There was particular focus on the data from Weldon and Monk's study and from Lennmarken et al. because these results were unexpected. It was acknowledged that these data are preliminary and are strictly observational. Nonetheless, they are provocative data, as they suggest that some factor occurring during the brief period of the anesthetic may be linked to mortality remote from the perioperative time frame. There was spirited debate about these data and what they could mean if they are confirmed with further studies. One suggestion was that the occurrence of BIS <45 represents merely a marker for patients who are particularly vulnerable for some reason. Another possibility discussed was that these patients may have a higher adrenergic state and are subsequently treated with higher levels of

See "Workshop," Next Page

Inflammatory Response May Be Deleterious

"Workshop," From Preceding Page

hypnotics or volatile anesthetics. It was also suggested that the patients with the low BIS values might have a greater or more extended inflammatory response to anesthesia and surgery, although there are no studies yet that have investigated such a putative mechanism. It was widely agreed that these questions will need to be examined in larger studies that specifically investigate these issues.

There was additional discussion of other perioperative factors and treatments that have an impact on long-term outcomes. In particular, the data on perioperative beta-blockers are complex. While there have been multiple randomized trials, and there is a consensus for beta-blockade in patients with known cardiac disease having vascular surgery, whether this is beneficial for broader use is still open to considerable debate.

Sessions 2 and 3 – Inflammation

Potential biological mechanisms for such occurrences were the topics of Sessions 2 and 3. At the beginning of Session 2, Dr. Steffen Meiler proposed a set of hypotheses concerning the perioperative inflammatory/immune response as a potential biological link to long-term outcomes after anesthesia and surgery. Dr. Meiler proposed a "two-hit" model, which states that the inflammatory response to surgery may amplify pro-inflammatory cell mechanisms of certain disease states, such as coronary artery disease, hence contributing to disease acceleration and adverse postoperative events. The evidence that inflammatory processes are critical for the progression of atherosclerosis is undeniable. Similarly, inflammatory processes and infections are known to play a key role in cancer biology (e.g., hepatitis leading to hepatocellular carcinoma). The role of inflammation in the degenerative central nervous system diseases, such as Alzheimers, is more tentative, but a growing body of evidence definitely points in this direction.

Furthermore, Dr. Meiler proposed that certain patients or patient populations may exhibit an exaggerated inflammatory response to surgery and/or delayed resolution to the preoperative immune status. Limited human data are in support of this notion. If true, these patients may be at even greater risk to experience postoperative complications. What would cause an abnormal inflammatory response to surgery is not known, nor are all the factors that might be triggers beyond the surgical procedure itself. Whether anesthetic drugs, other aspects of anesthetic technique, or physiologic occurrences during surgery could be potent triggers for abnormal inflammation is not well established. There are threads of evidence that anxiety, fear, and pain can trigger inflammation.

This led Dr. Meiler to propose that perioperative care is a key nexus for affecting both short- and long-term outcomes. A common goal between anesthesiologists, surgeons, internists, and others will be to identify which patients are at risk, to define adjuvant treatments and modified patient care processes to prevent the negative outcomes, and to apply them throughout the continuum of the perioperative period. According to these models, taking an inflammation/ immune-based approach to dissecting the biological interactions between anesthesia, surgery, and postoperative complications therefore promises to yield important insights.

Last in the session, Rod Eckenhoff, MD, discussed the effects of volatile anesthetics on the oligomerization of brain proteins. This line of research was triggered by the speculation that many neurodegenerative diseases may be caused by the aggregation of normal and abnormal proteins (similar to what occurs in mad cow disease). Halothane and other volatile anesthetics do cause oligomer formation in amyloid precursor protein at clinically relevant levels, and this process lasts a long time. A single exposure of desflurane caused 3 days of differences in protein expression. Other proteins could be affected similarly. One example cited is ferritin, which binds volatile anesthetics at low concentrations. New animal models are being established in rats, which are thought to be a good model system. Finally, although these mechanisms suggest that exposure to volatile anesthetics might be linked to the occurrence of dementia, this conclusion is very speculative at this point.

Discussion of Session 2

The discussion was led by Dr. Carl Rosow. There was extensive discussion about what is meant by "stress," and whether "anxiety," "stress," or other terms really describe the same state. There was further discussion of the diverse responses and timeframes of inflammatory responses that were being discussed. Some inflammatory response is critical for wound healing and warding off surgical infection, yet too much or too prolonged a response might be deleterious. The panel tried to determine whether any existing studies show a definitive link between the kinds of inflammatory mechanisms suggested and postoperative complications. Some threads were drawn from studies of patients having cardiac surgery and cardiopulmonary bypass, but it was acknowledged that no studies to date demonstrate this specific putative linkage. There was discussion of whether one could study the long-term outcome of animals (rodents in particular) that had undergone anesthesia and surgery, while studying their inflammatory responses. There was wide agreement that understanding the subtle issues of long-term outcomes would require both animal and human studies.

Session 3: Inflammatory Mechanisms Redux

Session 3 continued the theme of looking at the basic biological aspects of inflammatory mechanisms. First, Charles Serhan, MD, presented a fascinating description of the active processes that resolve inflammation after it has been triggered. This resolution is not just a "burnout" of the pro-inflammatory functions, but rather has a set of resolution functions that involve resolving mediators. Resolution is thus different than mere "anti-inflammation," and the resolution processes offer another potential target for therapeutic manipulation. Furthermore, anti-inflammatory therapies may sometimes also inhibit the natural pro-resolution pathways, thus delaying or blunting their beneficial effects. Many of the mediators of the resolution phase are lipid mediators, among which are lipoxins, resolvins, and neuroprotectins. Resolvins may be the active ingredients of the beneficial effects of omega3 fish oil and other dietary elements. Similar molecules in the nervous system are called neuroprotectins. Dr. Serhan summarized the potential promise of this line of investigation as offering ways to mitigate the negative effects of inflammation by turning on resolution rather than by attempting to inhibit the pro-inflammatory phase itself. However, turning this basic science into therapies ready for clinical trials will take some time.

Discussion of Session 3

Don Stanski, MD, chaired the discussion of Session 3. There was extensive discussion of how to find the middle ground between the elegant basic science work and the interface to the clinical issues of long-term, post-surgical outcomes. In this regard, there is some work underway to develop more easily run assays for some of the resolution molecules. Another thread was trying to better link the seemingly beneficial effects of drugs like beta-blockers, clonidine, statins, and the underlying bioactive mediators.

An interesting question was raised as to the effects of discontinuing patients' aspirin or non-steroidal anti-inflammatory therapies prior to surgery so as to minimize their effects on platelet aggregation, and thus on perioperative blood loss. A side effect of stopping these drugs could be to promote or unmask a more extreme inflammatory response.

In addition, there was considerable discussion about whether it is beginning to be possible to tease out which patients are most susceptible to short and long-term negative outcomes on the basis of their genotype or biochemical markers, in addition to the traditional risk factor analysis.

Session 4: Wrap Up

Dr. Jeff Cooper chaired this session and reiterated the interest of the APSF in the concept of long-term, postoperative outcome. Active participants in this session included Drs. Dan Sessler and Lee Fleisher who shared their experience, observations,

See "Workshop," Next Page

Working Group Develops Basis for Action

"Workshop," From Preceding Page

and recommendations concerning future investigations. Dr. Karl Hammermeister proposed a "straw man" sequence of investigations to be considered by the panel. This sequence would be to:

- Confirm excess late adverse outcomes (e.g., mortality)
- Identify predictors of late adverse outcomes
- Evaluate mechanisms of excess late adverse outcomes
- Conduct small-scale trials of interventions for excess late adverse outcomes
- Conduct large-scale comparative randomized clinical trials of interventions.

Following this discussion Dr. Cooper called for 3 mini-votes of the participants:

- Do you believe that there IS some relationship between inflammatory processes in the perioperative period and long-term survival?

  A majority of participants voted yes.

- Should an appropriate study be done to measure "excess" mortality resulting from identifiable factors of anesthesia and surgery?

  Again, a majority of participants voted yes.

- Should such a study demonstrating "excess mortality" be completed before any other studies–such as those suggested in the "straw man"–are begun?

  Only a few participants voted yes.

Marcel Durieux, MD, PhD, advocated conducting campaigns of basic research and clinical research in parallel, since useful clinical investigations can be done even before the underlying mechanisms are fully defined in the laboratory. Among the clinical questions that currently seem ready for investigation, he listed:

- Relationship of intraoperative EEG measures to long-term mortality. The panel largely agreed that the data discussed so far are intriguing but very preliminary. He emphasized that the issue is not necessarily "deep anesthesia," but that this might be a marker for patients who have different underlying physiology. We need to find out what causes this relationship, increased requirement, or exaggerated response.
- The development of chronic pain after surgery, and use of "preventive analgesia" to prevent postoperative chronic pain
- Perioperative transfusion and its effect on long-term outcome
- The development of a perioperative hypercoagulable state, which may result in thromboembolism and/or myocardial ischemia.

Some comments were made about possible follow-up activities stemming from this conference. Dr. Khuri indicated that NSQIP is very interested about incorporating AIMS data in NSQIP. Dr. Hunt from CMS indicated that CMS might well be interested in adding additional variables to the database analysis projects that are currently in design.

Dr. Thomas Russell, the Executive Director of the American College of Surgeons, said that it was very clear that the entire team caring for a surgical patient—surgeon, anesthesiologist, primary care physician, cardiologists, oncologists, and many others—needed to engage in serious new efforts to share and coordinate their knowledge, perspectives, and clinical efforts in order to optimize outcomes for the patients. Never again should they satisfy themselves to work solely within their own silos, no matter how expertly.

In summary, the group arrived at a number of threads of agreement and observation, which will now serve as the basis for future analysis and action. These include

1. Historically, surgeons and anesthesiologists have largely felt their actions only have immediate or near-term consequences.Things not directly related to the surgical procedure that occurred "way down the line" (the "long-term outcomes") had to do with the patient's underlying medical conditions and were just bad luck. But the group thought it was distinctly possible that there are things that happen during surgery that have lasting effects and may have a long-term impact on morbidity and mortality.
2. The group acknowledged that there may in fact be excess mortality over the long-term linked to the process of anesthesia and surgery. But the data are extremely sparse, complicated, and have many limitations and pitfalls. The question should be pursued further to find more definitive answers.
3. There should be more studies of large numbers of patients to better identify risk factors for the occurrence of adverse long-term outcomes as well as for short-term complications.
4. Inflammation has been implicated in many disease processes and it is definitely possible that there exists a relationship between inflammation and the long-term outcomes associated with surgery and anesthesia. Much remains to be determined to see if this linkage is present, and if so, its strength and what can be done about it. Studies are needed both on the basic biology of inflammation, and on the specifics of this biology in the setting of anesthesia and surgery.
5. As we collect better data about the nature of postoperative outcome, studies are needed to evaluate the mechanisms, and define possible interventions. This may happen first in small-scale trials, but ultimately large-scale studies, with thousands of patients, will be needed. The benefits of extrapolating existing therapies, such as perioperative beta-blockade, to broader groups of patients requires further study as well.

Dr. Gaba is a Professor in the Department of Anesthesia and the Associate Dean for Immersive and Simulation Based Learning at Stanford University, Stanford, CA. He is also Secretary of the APSF.

Letter to the Editor

Hypoxemia in the Hospital Frequently an Early Sign of Impending Catastrophe

To the Editor:

Dr. Stemp makes an interesting point, albeit with great drama: detection of transient hypoxemia is not nearly as vital to patient outcome as determination of cause. Summarizing the logic of his letter, one would conclude that treating hypoxemia with oxygen but neglecting further investigation enables the undetected respiratory pathology to continue.

His points are legitimate. Most humans outside the hospital tolerate transient hypoxemia without sequelae as it is usually produced by a benign or self-limited process. However, hypoxemia in the hospital frequently is an early sign of impending catastrophe.

Perhaps Dr. Stemp would agree with this conclusion: oxygen should be the first step in addressing hypoxemia, but never the last.

Samuel Metz, MD
Oregon Anesthesiology Group
Portland, OR

American College of Surgeons Collaborates With APSF to Develop Quality Program

The American College of Surgeons National Surgical Quality Improvement Program (ACS NSQIP)

By R. Scott Jones, MD, FACS

Surgical operations, in contrast to medical treatments of chronic diseases, lend themselves to observation by outcome studies. Whether patients live or die, have complications, are cured, have their symptoms relieved, return to work or play, and are satisfied with their care are very important issues vital to the assessment of the quality of surgical care. The Veterans Administration Health System (VA) addressed surgical quality improvement by developing the National Surgical Quality Improvement Program (NSQIP) to employ a prospective, peer-controlled, validated database to quantify 30-day risk-adjusted surgical outcomes.

Dedicated, trained, NSQIP nurses collect specific preoperative, intraoperative, and postoperative data. Statistical analysis of the preoperative data identifies risk factors predictive of outcome. Further analysis calculates the expected outcome of a patient population. The observed outcome/expected outcome (O/E ratio) denotes the risk-adjusted outcome. A low O/E ratio indicates better than expected outcome and a high O/E ratio indicates poorer than expected outcome (mortality, morbidity, or other). The NSQIP O/E ratio, based on valid, reliable data measures the quality of surgical care. This risk-adjustment allows valid comparisons of outcomes among all hospitals in the program. Also, the NSQIP data identifies sources of morbidity and mortality to enable management practices and improvement of the processes of care to reduce morbidity and mortality. After implementation of the NSQIP, between 1992 and 2002, the VA surgical mortality decreased 27% and the morbidity decreased 45%.

After recognizing the effectiveness of the NSQIP the leaders in the VA arranged for its preliminary evaluation in 3 university hospitals, Emory University, University of Kentucky, and the University of Michigan. The program worked very well in that setting. Then the VA and the American College of Surgeons (ACS) began collaboration for further application of the NSQIP in the private sector. With support from a grant from the Agency for Healthcare Research and Quality (AHRQ) to the ACS the NSQIP was introduced into 11 additional university hospitals. Later data was included from 4 affiliated community hospitals. With 2 years of complete data the NSQIP functions very well in these 18 private sector hospitals.

The private sector hospitals could not use VA resources, facilities, or information systems. For that reason, a private company QCMetrix, developed a web-based data collection system and trained the private sector nurses. The Colorado Health Outcomes Program (COHO) affiliated with the University of Colorado provides biostatistical services, data management, and report preparation for the private sector initiative.

In addition to proven performance in the VA, 4 year's private sector experience has demonstrated the effectiveness of the NSQIP as a quality improvement tool and a source of new clinical knowledge. So the ACS developed a business plan to offer this program, beginning with General and Vascular Surgery, to all interested hospitals. The VA program will continue as the VA NSQIP and the private sector initiative will become the ACS NSQIP.

The ACS NSQIP will contribute to the reduction of surgical mortality and morbidity. The success of ACS NSQIP depends upon several factors. First, the trained, dedicated nurses provide reliable data. The program includes measures of reliability of the data collection so there is minimal variability among the hospitals in the program. Second, each hospital must have a surgeon responsible for the conduct of the program. The surgeon works closely with the nurse and monitors the data. Third, an Executive Committee reviews the reports provided to the hospitals on a regular basis. Fourth, the ACS NSQIP generates Best Practices from the database and makes them available on the website. Fifth, the surgeon and the nurse can review their hospital's data (unadjusted) on the website and compare it with the means of the other hospitals in the program contemporaneously. The website provides a very versatile instrument for drilling down into the database to examine the variables in detail. This database can form the cornerstone of the morbidity and mortality conference and other quality improvement programs in the hospital. All ACS NSQIP data is encrypted when it leaves the participating hospital for management by QCMetrix and COHO. Also, all hospitals are de-identified in the database. All data is confidential. In the semi annual risk-adjusted reports the hospitals can only identify themselves. Confidentiality is maintained for surgeons, hospitals and patients.

The ACS and the APSF recently collaborated to submit a proposal to the National Library of Medicine requesting funds to investigate the feasibility of transferring intraoperative data to the ACS NSQIP database from the Anesthesia Information Management System operating in some hospitals. The availability of intraoperative hemodynamic, metabolic, and temperature data could substantially improve the capacity of the ACS NSQIP to predict and evaluate surgical outcomes. The ACS NSQIP provides an excellent opportunity for surgeons, anesthesiologists, and nurse anesthetists to work together effectively to evaluate and thereby improve surgical outcomes.

The reduction of morbidity and mortality are sufficient justification to employ this program. It has the added advantage of allowing surgeons to fulfill their professional responsibility of self-evaluation. It is also an excellent opportunity for surgeons to work in collaboration with the leaders of hospital administration, anesthesiology, and nursing services to benefit patients.

As representatives of the American College of Surgeons we sincerely hope the administrators, surgeons, anesthesiologists, nurse anesthetists, and nurses of all hospitals choose to introduce, maintain, and use this unique surgical quality improvement tool. Further information about ACS NSQIP can be obtained by contacting mwerner@facs.org, the ACS website at www.FACS.org, or www.nsqip.org.

Dr. Jones is Director, Division of Research and Optimal Patient Care, American College of Surgeons, Chicago, IL, and Professor of Surgery University of Virginia, Charlottesville, VA.

APSF Grant Application
Information Available on Our Website:
www.apsf.org

Letters to the Editor:

Do Not Break Contact With the Patient

To the Editor:

I read with interest, and sadness of course, of the 3 examples of anesthetic accidents in the article "Turn Your Alarms On" in the winter issue of the *APSF Newsletter*.

I have been retired for almost 15 years, but was forcibly reminded by the article of my constant admonition to residents and students: "Do not break contact with the patient."

A precordial stethoscope for all conscious patients and an esophageal one for all under general anesthesia was a constant routine for all my patients. My spiel was,

> "You are either hearing the heart beat or you are feeling it beat at all times. This way, you can turn your back to the patient to draw up meds or write on the chart. You can carry on a conversation with the surgeon, but you never lose input from the heart. The beeping EKG helps, but is not a substitute. The oximeter and capnograph are great, too, but nothing takes the place of listening to or touching the patient."

There is no excuse, of which I am aware, for the anesthesiologist to leave the head of the patient; he or she has no obligation to help anybody do anything; his only obligation is to the patient's safety. This sounds mundane, but I pounded it into my residents.

Monitors are fine, but these 3 accidents would not have happened if my rules had been followed.

Terring W. Herionimus III, MD, FACA, FCCP
Professor of Anesthesiology, Retired
University of Virginia Medical Center
West Virginia University Health Sciences Center

PACU Pulse Ox Tone Touted

To the Editor:

I'm in total agreement regarding the special need to hear the pulse beep tone for pulse oximetry during anesthesia. Anesthesiologists can testify to the importance of the pitch/saturation ratio (and to the fact that the "dive-bombing falling pitch" will never go unnoticed).

However, I'm always amazed that when I take a patient to the PACU, the nurses have turned off all "noise-makers" (is it to have a quiet place for the recovering patients?).

I have often asked them to turn the pulse oximetry beep tone on with my patients. I explain to them they can turn their backs on the patient and still hear the most important beep in the world.

I would like to suggest that the APSF institute a policy for the PACU which is identical to the OR.

Sincerely,

Heddy-Dale Matthias, MD
One Roses Bluff Parkway
Madison, MS 39110
601-856-7074
hdmatthias@jam.rr.com

Reader Softens View of OR Reading

To the Editor:

I am replying to your article in the *APSF Newsletter* and offering you my perspective on the issue. I am in total agreement that the image we project is important, and the image of Dr. Giesecke with his feet propped up on the anesthesia machine presents a poor image.

On the other hand, the level of sensory deprivation can be extremely variable in cases, and the ability to multitask varies among anesthesiologists. In the past, manpower was sufficient, and case volume was large enough that those in need of constant stimulation could just stick with open hearts, AAAs, and so forth. Today, we might do complex cases one day and the next be stuck in a dark room with an ASA 1 or 2 patient for 2-4 hours in a case with almost no potential for blood loss with only a minimal break from a sympathetic colleague.

Reading material downloaded onto a PDA from a site such as Avantgo® is much more discreet and can be done such that monitors can be still in the field of view, keeping someone used to multitasking in complex cases from being lulled into boredom. Useful PDA software such as ePOCRATeS® and other clinical applications make it a common device for clinicians to keep with them.

When I started practice, I only supervised residents and CRNAs in an academic setting and was a staunch opponent of any reading in the OR. In my current practice, I supervise some, but often do cases of varying complexity alone. This experience has caused me to soften my position on this issue.

Mont Stern, MD
East Amhert, NY

References Support Fatigue Concerns

"Costs References," From Page 16

References

1. Landrigan CP, et al. Effect of reducing interns' work hours on serious medical errors in intensive care units. *N Engl J Med* 2004;351:1838-48.
2. Barger LK, et al. Extended work shifts and the risk of motor vehicle crashes among interns. *N Engl J Med* 2005;352:125-34.
3. Veasey S, et al. Sleep loss and fatigue in residency training: a reappraisal. *JAMA* 2002;288:1116-24.
4. Gaba DM. Structural and organizational issues in patient safety: a comparison of health care to other high-hazard industries. *California Management Review* 2000;43:83-102.
5. Reason J. Human Error. Cambridge: Cambridge University Press. 1990:1-302.
6. Dinges DF, Broughton RJ. Sleep and Alertness: Chronobiological, Behavioral, and Medical Aspects of Napping. New York: Raven Press, 1989.
7. Rosekind MR, et al. Crew Factors in Flight Operations IX: Effects of Planned Cockpit Rest on Crew Performance and Alertness in Long-Haul Operations. NASA Technical Memorandum #108839 Moffett Field, CA: NASA Ames Research Center, 1994.
8. Czeisler CA, Dijk DJ. Use of bright light to treat maladaptation to night shift work and circadian rhythm sleep disorders. *J Sleep Res* 1995;4:70-3.

Letter to the Editor

High Airway Pressure Mandates Diagnosis and Remedy

To the Editor:

In the Fall 2004 issue of the *APSF Newsletter*, Dr. Nichols et al. stressed the importance of machine check, especially of the reusable pieces of equipment to avoid a foreign body in the circuit causing high airway pressures (HAP) after intubation. This problem is not uncommon and continues to cause anxiety when encountered.

I am sure many of us follow a pattern of checks when confronting the problem of HAP after intubation. The order of these checks is decided by the preexisting problems of the patient, the machine, and also by previous encounters of a similar nature.

The checks have to be quick (time and life-saving), systematic, and cost-effective. The following sequence, although not exhaustive, may suit most of the circumstances (Figure 1) and is for the benefit of anesthesiologists who have not encountered HAP after intubation, and, it is hoped, will never have to use this algorithm.

On initial notice, it may be a good practice to put one's hand under the drapes and feel for the ETT outside the patient, which may be obstructed by the surgeon's hand or kinked due to the plastic's inherent properties. Following that, perform auscultation of the chest to detect breath sounds. Precordial stethoscopes placed prior to draping come in handy. Rhonchi, or bilateral absent breath sounds, are treated by a dose of albuterol. If the HAP continues, start Ambu bag ventilation. If ventilation is easy, the obstruction is proximal to the ETT. This is approached systematically from either the angle piece and upstream or the ventilator and downstream, not forgetting that some of the causes missed are a stuck O_2 flush valve, wrong vacuum settings in the scavenging system, and leak from ventilator bellows.

The causes of HAP distal to the angle piece are either from the patient or the ETT. With continuing anesthetic, by the intravenous route if necessary, pass a suction catheter down the ETT (Figure 2). This will give some information, depending on how far one is able to pass the catheter. Once the ETT is eliminated as a cause for HAP, the patient causes are approached while having in mind the preexisting problems of the patient and the sequence of events that led to the HAP. This systematic approach avoids changing the ETT unnecessarily with its attendant problems of laryngeal trauma, saves the time of reintubation, and is also cost-effective.

One can suitably modify the scheme shown in the tables for the individual circumstances depending on the degree of suspicion about a particular cause.

Hariharan Shankar, MD
Milwaukee, WI

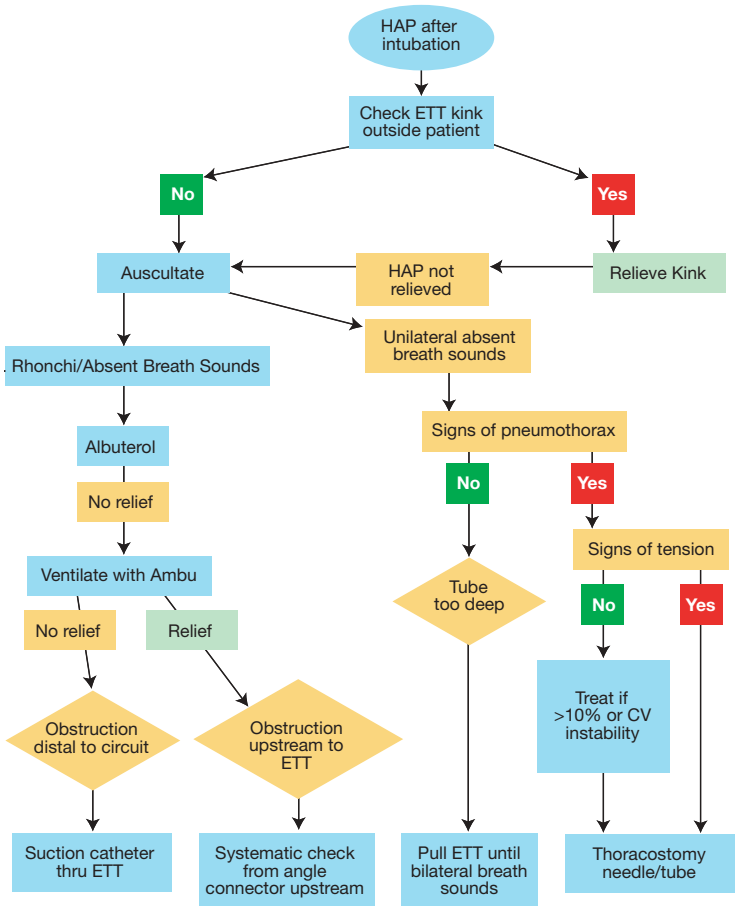


Figure 1: Algorithm for High Airway Pressure After Intubation

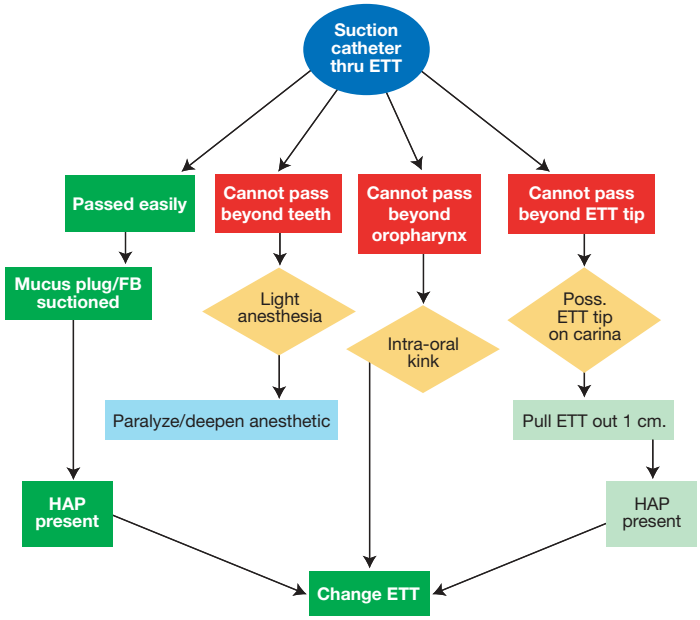


Figure 2: Suction Catheter Placement Leads to Diagnostic Scheme & Management Recommendations

- *Performance Enhancing Drugs*
- *Costs of Fatigue*
- *Management of Fatigue*
- *Great Britain and Ireland's Approach to Fatigue*

Guest Editor: Steve Howard, MD

Dr. Howard is Director of the Patient Safety Center of Inquiry at VA Palo Alto and Associate Professor of Anesthesia at Stanford University School of Medicine, Stanford, CA.

In this issue:

Fatigue & the Practice of Anesthesiology

We have all had to work "dog-tired"—is it safe?

Anesthesia Patient Safety Foundation
Building One, Suite Two
8007 South Meridian Street
Indianapolis, IN 46217-2922

NONPROFIT ORG.
U.S. POSTAGE
PAID
WILMINGTON, DE
PERMIT NO. 1387