



# NEWSLETTER

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## Dangers of Postoperative Opioids

*APSF Workshop and White Paper Address Prevention of Postoperative Respiratory Complications*

by Matthew B. Weinger, MD

### Executive Summary

In response to concerns about the safety of the use of patient-controlled analgesia (PCA) in the postoperative period, the Anesthesia Patient Safety Foundation (APSF) held a workshop in San Francisco on October 13, 2006, that was attended by over 100 clinicians, scientists, and medical industry representatives. The attendees listened to a range of relevant expert presentations, broke into small groups to discuss specific issues, and then reconvened to present and discuss the findings. The workshop focused on improved detection of postoperative opioid-induced respiratory depression. Robert K. Stoelting, MD, APSF President, opened with a statement of the workshop goals: 1) reviewing the evidence regarding the risks of PCA; 2) evaluating the value of continuous monitoring of postoperative patients receiving PCA; and 3) developing recommendations that could be promulgated to advance patient safety. He noted that the APSF believed that opioid-induced postoperative respiratory depression is a preventable cause of morbidity and mortality. He further stated that the recognition of patients at increased risk for respiratory depression and utilization of appropriate monitors to detect this side effect of parenteral opioids could significantly improve patient safety.

The available evidence suggests that there is a significant and underappreciated risk of serious injury from PCA and neuraxial opioids in the postoperative period. While some patient populations

(notably those patients with obstructive sleep apnea) appear to be at higher risk, there is still a low but unpredictable incidence of life-threatening, opioid-induced respiratory depression in young healthy patients. Moreover, life-threatening, opioid-induced respiratory depression also occurs with intermittent parenteral injections of opioid analgesics. Data and clinical experience suggest that, while continual respiratory monitoring could detect many cases of life-threatening, opioid-induced depression, current monitoring technologies and clinical practices are insufficiently reliable with both false positives (e.g., monitor false alarms) and false negatives (e.g., low sensitivity to SpO<sub>2</sub> in the presence of supplemental oxygen administration). Nevertheless, the status quo while awaiting the perfect monitor(s) is not acceptable, and the APSF advocates the routine use of continuous postoperative respiratory monitoring in at-risk patients receiving PCA or neuraxial opioids. Although pulse oximetry will monitor oxygenation, it has reduced sensitivity as a monitor of hypoventilation when supplemental oxygen is administered. When supplemental oxygen is indicated, monitoring of ventilation may warrant the use of technology designed to assess breathing or estimate arterial carbon dioxide concentrations.

### Summary of Workshop Presentations

"Respiratory Depression in PCA Patients: What Continuous Monitoring Has Revealed" was presented by Frank J. Overdyk, MSEE, MD, Professor of Anesthesiology and Perioperative Medicine at

the Medical University of South Carolina (Charleston, SC). Dr. Overdyk and his colleagues conducted a study (funded by the National Patient Safety Foundation) of continuous pulse oximetry and capnography in patients receiving PCA at St. Joseph/Candler Health System in Savannah, GA. The institution established alarm thresholds, and the nurses documented their response to any audible alarm. Over 4,000 hours of continuous monitoring were generated by 178 patients, during which there were 4,007 and 2,221 audible alarms for bradypnea (respiratory rate less than 8/minute) and desaturation (SpO<sub>2</sub> less than 90%), respectively. Dr. Overdyk suggested that particularly high-risk groups included the elderly, the morbidly obese, and those patients receiving supplemental oxygen. He noted that PCA patients receiving continuous opioid infusions seemed to have a lower incidence of respiratory depression, which is inconsistent with the current literature. Dr. Overdyk described his team's recent work involving kinetic modeling of opioid plasma levels and the development of predictive heuristic algorithms based on their assumption that opioid-induced respiratory events have a characteristic pathophysiological "signature."

Richard E. Moon, MD, Professor of Anesthesiology and Associate Professor of Medicine, Duke University Medical Center (Durham, NC), presented a talk entitled "Postoperative Pain Control and Respiratory Depression." Dr. Moon stated that the literature shows that 0.1-1.0% of patients receiving PCA have serious respiratory depression. The elderly appear to be a particularly high-risk group (e.g., an apparent incidence of 3.2% in patients more than 80 years old vs. 0.6% in patients less than 45 years old). Patient factors (age, disease status, metabolism, genetic susceptibility, drug interactions) are the most common contributors. He warned that maximal respiratory depression may occur after the PCA lockout interval has passed. Dr. Moon then described the various options for monitoring patients receiving parenteral narcotics. His group is conducting detailed measurements of the respiratory and neurophysiology of postoperative patients receiving parenteral opioids. They are examining respiratory patterns as a predictive parameter; Dr. Moon described how the fractal analysis

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# President Stoelting Summarizes the State of the APSF in 2006

by Robert Stoelting, MD

As President of the Anesthesia Patient Safety Foundation (APSF), it is my privilege to report annually on the activities of the foundation during the past calendar year. I am pleased to report that 2006 has been an active and rewarding year as we pursue safety initiatives (safety during patient-controlled analgesia, technology training) intended to further our mission that "no patient shall be harmed by anesthesia." In addition to safety initiatives, the past year included a greatly expanded investment by the APSF in the support of research, both in the number of grants awarded and the size of the awards. This critically important expansion of research support was made possible by the generous support of the American Society of Anesthesiologists (ASA, \$500,000 annually) and by the full support of two \$150,000 awards by the **Cardinal Health Foundation** and **Anesthesia Healthcare Partners**.

## Safety During Patient-Controlled Analgesia (PCA)

This issue of the *APSF Newsletter* contains a report of the APSF Board of Directors Workshop on "Safety During PCA" held on October 13, 2006, in Chicago, IL. The impetus for this conference was the APSF's belief that opioid-induced depression of ventilation during PCA (and neuraxial opioids) is a preventable cause of morbidity and mortality.

In the view of the APSF, recognition of patients at increased risk for ventilatory depression and utilization of appropriate continuous monitors (pulse oximetry and indicators of arterial PaCO<sub>2</sub>), which are linked to a system to summon a health care professional to the patient's bedside, would improve patient safety during pain management in the postoperative period. Although patients with obstructive sleep apnea (not always recognized) are at the greatest risk for opioid-induced depression of ventilation, it is clear that occasional patients without this perceived risk factor may experience life-threatening depression of ventilation that might be recognized sooner with continuous monitoring.

There is increasing recognition that supplemental oxygen may mask opioid-induced hypoventilation by maintaining oxygen saturation in the presence of impending apnea and carbon dioxide narcosis. Supplemental oxygen should be prescribed only when it is viewed as beneficial by the treating physician.

In addition to the report in this issue of the *APSF Newsletter*, a summary statement of the workshop appears on the APSF website. This summary statement has been given widespread visibility in the publications of the ASA, American Association of Nurse Anesthetists, American Society of Postanesthesia Nurses, and the American College of Surgeons. Distribution of the results of the workshop

among all health care professionals and recognition of the need for continuous monitoring of patients in the postoperative period is critical, as safe pain management following surgery includes more than anesthesia professionals.

## Technology Training Initiative

The APSF Committee on Technology is undertaking a technology training initiative based on the observation that anesthesia equipment is increasingly complex and anesthesia professionals need formalized training in its use. New machines have unique and subtle variations in breathing circuit design, automated checkout, volatile anesthetic delivery, hidden piston ventilators, fresh gas delivery, and ventilation modes. Although the incidence of equipment-related critical events is relatively low, morbidity associated with such events can be quite high. Human error is the leading contributor to equipment-related problems, and is typically magnitudes greater than pure equipment failure. The implication is that we need greater training and facility with our equipment.

The most effective method of introducing new anesthesia equipment into the operating room has not been thoroughly investigated. The Fall 2006 issue of the *APSF Newsletter* addressed the issue of technology training and the difference between mandatory and voluntary participation by anesthesia professionals. The APSF believes that technology training on anesthesia equipment is an important safety issue and will give this initiative high priority in the next year. *Just as I would not fly on an airplane if the pilot announced his/her decision to turn off the audible alarms, I wonder how many of us would fly on an airplane with a pilot who knew as much about the airplane's equipment as we know about our anesthesia machine?*

## APSF Newsletter

The *APSF Newsletter* continues its role as a vehicle for rapid dissemination of anesthesia safety information with Robert C. Morell, MD, as Editor. The *APSF Newsletter* is sent to more than 80,000 recipients including the members of the American Society of Anesthesiologists, American Association of Nurse Anesthetists, American Academy of Anesthesiologist Assistants, and the American Society of Anesthesia Technologists and Technicians. The Spring 2007 *APSF Newsletter* will be a "special 20th anniversary celebration issue" describing past, present, and future achievements and goals of the foundation.

Important issues presented in recent editions of the *APSF Newsletter* include a 2-part series on "Patient Perspectives Personalize Patient Safety" and "Dealing with Adverse Events" (Winter 2005-2006 and Spring 2006 issues). Other topics presented in recent

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# Value of Pulse Oximetry Depends on $\text{FiO}_2$

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of inter-breath intervals of these patients correlated with mean end-tidal  $\text{CO}_2$ . He recommended that strategies to prevent opioid-induced respiratory depression should include patient triage, appropriate dosing, genetic screening (in the future), and bedside monitoring.

“Using Smart Pumps and Continuous Monitoring to Reengineer the PCA Process” was presented by Ray R. Maddox, PharmD, Director of Clinical Pharmacy, Research and Pulmonary Medicine at St. Joseph’s/Candler Health System of Savannah, GA. Dr. Maddox noted that PCA device-related patient injuries reported to the FDA were more prevalent than those for large volume infusion pumps (LVP), despite a much lower overall usage rate. In 2004, the FDA Maude database contained reports of 22 deaths and 106 Adverse Drug Events (ADE) associated with PCA use and 17 deaths and 390 ADE for LVP. Dr. Maddox then discussed the potential benefits of incorporating dose-checking (“smart pump”) technology into PCA pumps. Finally, he described the results of the use of “smart” PCA pumps linked directly to  $\text{SpO}_2$  and  $\text{PETCO}_2$  monitoring at his hospital. The Smart PCA technology averted 52 PCA-related potential dosing errors (as evidenced by alterations in programming after device alert) in 225 patients receiving PCA. Dr. Maddox described some post-surgical patients where respiratory depression was detected within the first 6 hours on the ward after transfer from the PACU *before any PCA doses had been administered*. He also described cases of averted potential negative outcome due to PCA by proxy. Many perceived “nuisance” alarms proved to be real events. In some cases, a patient’s status changed rapidly, and this would have been difficult to detect in a timely manner by standard-of-care intermittent monitoring. Respiratory depression appeared to be at least as common in patients receiving epidural PCA. Finally, Dr. Maddox found that nurses required substantial education to interpret results of continuous capnographic monitoring. To assist in interpretation and consequent clinical decisions, the hospital incorporated respiratory therapists into their multidisciplinary postoperative pain management team.

Michael W. Jopling, MD, Chairman of Anesthesiology at Mt. Carmel St. Ann’s Hospital (Columbus, OH), discussed “Capnography Based Respiratory Monitoring Outside the Operating Room.” Dr. Jopling’s community hospital has 6 years’ experience using capnography on their inpatient wards. He argued that the JCAHO’s emphasis on pain as a vital sign had the unintended adverse consequence of setting patients’ expectations to be “no pain after surgery.” As a result, more patients may be receiving excessive analgesics. He also emphasized that all types of parenteral opiates can cause significant respiratory depression citing, as an example, the need for patients to be monitored



Matthew B. Weinger, MD

for 48 hours after DepoDur™ injections. Dr. Jopling described 2 problems with relying on correct opioid dosing to prevent opioid-induced respiratory depression: 1) for any given level of pain, there may be a 20-fold variance in individuals’ opioid dose requirements; 2) pain is often variable or episodic (e.g., kidney stones). He went on to emphasize that pulse oximetry is a poor monitor of ventilation if a patient is breathing supplemental oxygen. For example, if a patient is receiving 40% oxygen, the  $\text{PaCO}_2$  could be 150 mmHg and the  $\text{SpO}_2$  could still be 100%. At his hospital, they use a small portable combined capnograph/pulse oximeter along with improved technology for sampling  $\text{PETCO}_2$  in un-intubated patients. Respiratory monitoring is part of their Order Set for postoperative care *and* nurses are allowed to order it independently. All of their clinicians have become believers, although the non-anesthesiologists needed substantial training to be able to effectively implement the system.

Ann S. Lofsky, MD, a staff anesthesiologist at St. John’s Hospital (Santa Monica, CA) and Anesthesia Consultant and Governor Emeritus to The Doctors Company (Napa, CA), discussed “Obstructive Sleep Apnea and Postoperative PCA Opioids.” Based on a review of claims data, she identified obstructive sleep apnea (OSA) as a significant factor for anoxic brain injury and death in patients receiving opioid analgesia. She reviewed the physiology of sleep apnea and noted that the neural efferent system responsible for maintaining a patent upper airway is depressed by 2 things: rapid-eye movement (REM) sleep and opioids. Not all patients with OSA are obese males and OSA may not be diagnosed prior to surgery. In The Doctors Company database, there were 8 claims since 2000, which included sleep apnea (or symptoms suggestive of undiagnosed OSA) and postoperative respiratory arrest. Dr. Lofsky emphasized that respiratory rate is not a reliable monitor of ventilation

in sleep apnea patients because episodes of obstruction are not usually associated with slow respiratory rates, and there is often chest movement without ventilation (due to airway obstruction). Episodes of critical obstruction can occur intermittently and yet be associated with severe hypoxia. She advocated the following preventive measures: flagging charts of patients with a diagnosis of OSA, having patients already on continuous positive airway pressure (CPAP) use it while hospitalized, and monitoring all OSA patients as long as they are receiving opioids. Dr. Lofsky asserted that respiratory monitoring does not always need to be high-technology—in some cases, an apnea monitor and a sitter may be sufficient.

John B. Downs, MD, Professor of Anesthesiology at the University of South Florida (Tampa, FL) argued in his presentation, “The Pulse Oximeter as a Monitor of Ventilation,” that  $\text{SpO}_2$  is an effective method to detect hypoventilation in almost all situations *if the patient is breathing room air*. Under this circumstance, if ventilation were cut by 50% then  $\text{SpO}_2$  will decrease significantly in only 2-3 minutes.<sup>6</sup> In contrast, the same decrease in ventilation will increase  $\text{PETCO}_2$  to 70 mmHg in about 1 hour, but, if the patient is breathing as little as 25% supplemental oxygen,  $\text{SpO}_2$  may not decrease. Dr. Downs then reported on a study of postoperative bariatric patients in which comprehensive respiratory data were collected every 4 seconds. Most of these patients received supplemental oxygen, and this could mask severe hypoventilation. Dr. Downs went on to try to debunk the conventional wisdom that supplemental oxygen is both beneficial and desirable. He stated that in pigs, one needed to decrease  $\text{SaO}_2$  to 40% of normal (22 mmHg) before oxygen consumption started to decrease, and cardiac problems did not appear until  $\text{SpO}_2$  was less than 20%. He further noted that as desaturation occurs, the diffusion gradient from capillary to mitochondria is maintained.

Robert A. Caplan, MD, presented a “Closed Claims Analysis of Cases Involving Postoperative PCA and Neuraxial Narcotics.” Dr. Caplan is Professor of Anesthesiology at the Virginia Mason Medical Center (Seattle, WA) and is a member of the APSF Executive Committee. The ASA Closed Claims database currently contains about 7,000 closed claims (as of 2001). There were 144 cases with acute pain management claims (2% of all claims)—this is a new and increasing source of claims in the last decade. Using strict inclusion criteria, Dr. Caplan identified 15 cases involving PCA and 16 involving central neuraxial narcotics (CNN). Respiratory event onset was in the first 24 hours in 50% of PCA and 62% of CNN claims. About 60% of these 31 patients died, 13% had permanent brain damage, and approximately 25% had no permanent injuries. Care was judged appropriate in only half of the claims. Assuming proper and effective

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# Group Discussions Yield Recommendations For Detection and Prevention of Respiratory Depression

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use of monitoring, the trained case reviewers felt that better monitoring could have prevented the event in 73% of the PCA and 56% of CNN cases.

## Comparison of Existing Technologies to Monitor Oxygenation and Ventilation

Table 1 summarizes and clarifies the workshop findings on the comparative value and potential role of different monitoring modalities for the detection of opioid-induced respiratory depression.

## Summary of Small Group Discussions

The workshop attendees broke up into 4 smaller groups; each group was facilitated by a patient safety expert. Using the presentations as well as their extant knowledge and experience, each group was asked to address the following question: “If we accept the premise that opioid-induced respiratory depression during patient-controlled analgesia is a preventable cause of morbidity and mortality, what steps can the APSF recommend to improve patient safety?” To guide the discussion, 8 more specific questions were posed (Table 2). A synopsis of each group’s findings follows.

Group 1 was moderated and presented by Paul A. Baumgart, Vice President, Respiratory Care Products, GE Healthcare (Madison, WI), and Vice President of the APSF. This group felt that patients should be evaluated for risk factors related to postoperative pain management during their preoperative evaluation. While maximal prevention should be undertaken for the higher risk patients, the group advocated continuous monitoring of ventilation for all postoperative patients receiving opioid analgesics, regardless of the route. The group supported the “zero tolerance” position suggesting that the cost of a single adverse incident at a facility would offset all costs of monitoring.

Nursing plays a critical role in postoperative patient monitoring. Better education is needed to increase awareness about the risk of PCA and other pain control therapies. Additional care providers such as respiratory therapists could augment nurses’ vigilance. But since postoperative ward patients cannot be continuously attended, additional (electronic) monitoring is necessary. Adverse trends suggesting hypoventilation should automatically pause the opioid administration and simultaneously notify the caregiver. The alarm must be heard. How this is done (whether at the bedside, at a central station, via telemetry, via pagers, etc.) should be appropriate to the physical layout and staffing of the care environment.

Group 2 was moderated and presented by David M. Gaba, MD, Associate Dean for Immersive

and Simulation-Based Learning, and Professor of Anesthesiology, Stanford University, and Director of the Patient Simulation Center of Innovation (PSCI) at the Palo Alto VA Healthcare System (Palo Alto, CA). Dr. Gaba is also the Secretary of the APSF. Group 2 felt very strongly that we should strive for “zero tolerance”—no patient should suffer an injury due to postoperative respiratory depression from parenteral or neuraxial narcotics. Therefore, we need to develop more effective continuous monitoring strategies linked to a *system* of timely and effective response (likely requiring enhanced nursing surveillance as well as the involvement of respiratory therapy and other personnel). Continuous monitoring should be applied to all patients receiving parenteral or neuraxial opioids (or opioids via a new but equivalent route of administration). However, initially, it may be necessary to provide such monitoring only for higher risk patients; those who are 1) known or suspected to have central or obstructive sleep apnea—enhanced preoperative screening for such patients should be considered; 2) elderly; 3) receiving other CNS-active drugs; and 4) have pre-existing respiratory compromise.

The group felt that there is currently no single ideal monitor (or combination of monitors). Yet, many in the group believed that *any* monitoring was better than no monitoring. Patients should currently be monitored with more than one concurrent modality; while effective monitors of alveolar ventilation are superior to monitoring only arterial blood oxygenation, both ventilation and oxygenation should be monitored. Assessing level of sedation along with level of pain would also be useful.

The prevention of opioid-induced respiratory depression should include education of patients and families about realistic expectations for pain control and risks, as well as education and training of clinicians about analgesia and respiratory physiology.

Research is required to identify causes, risk groups, and effectiveness of prevention and treatment of respiratory depression. As new information becomes available, the implementation, prevention, and treatment strategies can be optimized. The dissemination and implementation strategy for addressing this problem should include an APSF position statement; education and training; modified patient-care protocols including expanded use of non-opioid analgesic techniques; and engagement of other parties that conduct direct or indirect implementation of patient safety change, such as the Institute for Healthcare Improvement and JCAHO.

Group 3 was moderated and presented by Julian M. Goldman, MD, Assistant Professor of Anesthesiology and Biomedical Engineering, Massachusetts General Hospital and Harvard University (Boston, MA). This group believed that it was not possible to reliably identify those patients at higher

risk, and, therefore, all patients receiving parenteral opioids should be monitored. They felt that the nurse as an intermittent monitor of respiratory depression was inadequate and, at a minimum, a reliable continuous apnea monitor should be used. However, they recognized that no single current monitoring technology was optimal. They were very concerned about the high rate of false alarms and advocated research to address this important problem. If monitoring detected possible opioid-induced respiratory depression, the infusion should be stopped and a “call for help” should be issued. Dr. Goldman noted that such an implementation had been explicitly excluded in the international closed-loop control medical device standard currently under development. The group also advocated that any solution should address maintenance and training issues. Finally, the group suggested caution in moving forward too quickly because this might limit much needed research.

Group 4 was moderated and presented by Michael A. Olympio, MD, Professor and Vice-Chairman of Education, Department of Anesthesiology, Wake Forest University School of Medicine (Winston-Salem, NC). Dr. Olympio is the Chair of the APSF Committee on Technology and a member of the APSF Board of Directors. This group felt that of all patients receiving parenteral or neuraxial opioids (or procedural sedation), the ones at the greatest risk could not be reliably distinguished from low risk patients, and, therefore, they advocated that all patients be treated equivalently. For example, to declare patients with sleep apnea at-risk, would by definition exclude patients with undiagnosed or unlabeled sleep apnea, who are also at-risk. And to declare young healthy patients at low risk would exclude those who received high doses of opioids while awake and then lapsed into a hypoventilatory state while asleep. Despite concerns about the costs and infrastructure required to monitor all patients, this group was adamant about standard monitoring, as historically accomplished with other devices (ECG, pulse oximetry) despite similar concerns.

Thus, every patient receiving parenteral opioids should be monitored with, at a minimum, pulse oximetry and a continuous measure of respiratory rate. The group suggested that current monitors of expired carbon dioxide had significant limitations in their ability in un-intubated patients to accurately display a true capnogram and to determine an accurate end-tidal value. Longer term, the goal was to develop and universally implement a monitoring strategy that would 1) reliably determine and effectively report hypoventilation and/or apnea; 2) distinguish hypoventilation from apnea; and 3) distinguish central apnea from obstructive apnea.

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# Opinions Summarized and Tabulated

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Table 1. Summary of Opinions about Current Methods of Detecting Opioid-Induced Respiratory Depression

Method	Primary Measures	Sensitivity*	Specificity†	Reliability‡	Response Time	Frequency of Measurement	Cost	Comments
Clinical observation§	Oxygenation & Ventilation	Variable	Variable	Variable	Variable	Intermittent	Variable	Depends on observer skill and observation frequency
Chest wall impedance	Ventilation	Low	Low	Low	Moderate	Continuous	Modest	May be non-specific in airway obstruction
Respiratory rate	Ventilation	Low	Moderate	Moderate	Moderate	Intermittent/Continuous	Variable	May not be helpful in patients with obstructive sleep apnea (OSA)
Tidal volume	Ventilation	Moderate	Moderate	Low	Moderate	Continuous	Modest	Unreliable technology
SpO <sub>2</sub> (when giving supplemental FiO <sub>2</sub> )	Oxygenation	Low	Moderate	High	Slow	Continuous	Modest	Desaturation may be late and then very rapid
Venous blood gas	Oxygenation & Ventilation	High	Modest	High	Slow	Intermittent	High	Depends on prior clinical observation or fortuity
Arterial blood gas	Oxygenation & Ventilation	Very High	Very High	Very High	Slow	Intermittent	High	Depends on prior clinical observation or fortuity
Minute ventilation	Ventilation	Moderate	Moderate	Low	Moderate	Continuous	Modest	Unreliable technology
SpO <sub>2</sub> (without supplemental FiO <sub>2</sub> )	Oxygenation & Ventilation	High	High	High	Fast	Continuous	Modest	Alveolar gas equation predicts a drop in SpO <sub>2</sub> even with modest hypoventilation
PETCO <sub>2</sub> (unintubated)	Ventilation	Moderate	High	Moderate	Fast	Continuous	Modest	High PETCO <sub>2</sub> significant but dependent on sampling. Underestimates PaCO <sub>2</sub> . Some believe only reliable as measure of respiratory rate
PETCO <sub>2</sub> (intubated)	Ventilation	Very High	Very High	High	Fast	Continuous	Modest	Not viable option on ward

\* Sensitivity is test positivity in the presence of abnormality (i.e., [True positives]/[True positives + False negatives]).  
 † Specificity is test negativity in the absence of abnormality (i.e., [True negatives]/[True negatives + False positives]).  
 ‡ Reliability is the consistency of meaningful data, particularly when abnormalities are present.  
 § Clinical observation includes signs of sedation, decreased level of consciousness, respiratory rate, depth, and pattern, airway obstruction, cyanosis, etc.

The ideal monitoring device(s) should be simple, modular, interchangeable, and usable in all types of patients. They should also communicate effectively to the health care provider accurate and timely information. The monitor should not solely present otherwise complex graphical data (e.g., capnography waveforms) because some bedside caregivers will not be able to interpret such data correctly. The monitoring systems should be partially linked to PCA or PCEA devices so that the opioid infusion would automatically stop and concurrently notify the responsible caregiver(s).

After a vigorous debate, the Group concluded that these recommendations were realistic and feasible, and that money spent up-front for the monitoring technology would significantly reduce serious morbidity and mortality. One more death from pain relief could not be tolerated, and the question should actually be rephrased as, “Can we afford **not** to monitor these patients?” The group concluded that the final recommendations should be widely promulgated as a mandate.

## Additional Audience Discussion

Dr. Matthew Weinger (Vanderbilt University) moderated a general audience discussion that amplified several general topics.

## RISK

Dr. Moon (Duke) suggested that *oral* opioid administration may be responsible for a significant number of respiratory events. Dr. Stoelting (APSF) reiterated his concern that the recent zeal to render

Table 2. Guiding Questions for Small Group Discussions

1. Which patients are at the greatest risk?
2. What is the role of monitoring?
3. Desirable characteristics of monitoring devices (e.g., should they be portable, networked, wireless)?
4. Should monitor results (potential at risk conditions) be linked to PCA infusion technology?
5. Should recommendations apply only to high-risk patients?
6. Should recommendations/solutions apply to other than PCA (e.g., neuraxial, chronic pain management, out-of-hospital care)?
7. Are the proposed solutions/recommendations realistic, feasible, widely available, and cost-effective?
8. How should the resulting recommendations be disseminated?

# APSF Issues Recommendations for Monitoring

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patients pain-free following surgery has resulted in an increase in opioid-related adverse events. Patients may have unrealistic expectations regarding postoperative pain while many doctors and nurses may feel more obligated to maximize analgesia (based on interpretation of JCAHO statements). He has repeatedly heard of situations in which PACU nurses had to stimulate patients to ask them if they were having pain before they could be transported to the ward. The awakened patient might give a 7 response to a 10-point pain scale, placing the nurse in a dilemma of recording this score or giving more analgesic drug to a patient who was clinically comfortable and resting so the PACU record will indicate an “acceptable” pain score upon discharge.

## ANALGESIA ALTERNATIVES

A participant stated that we do not use enough non-opioid analgesic adjuvants such as local anesthetic infiltration/regional blocks and non-steroid anti-inflammatory drugs. Drs. Weinger and Morell suggested that patients with obstructive sleep apnea may be safer going home on oral analgesics than staying in the hospital and receiving parenteral opioids. Dr. David Gaba (Stanford University) advocated a better-coordinated multidisciplinary approach to postoperative pain management. Dr. Maddox (Georgia) noted that transdermal and inhaled opioids are new technologies soon to be commercially available and their risks may also prove to be significant.

## MONITORING

Denise O'Brien (Michigan) asserted that nurses remain the lynchpin of effective intervention and the group should support increased postoperative nursing surveillance. Another participant noted that this meant increased nurse staffing levels with its associated recurring costs. John Downs opined that pulse oximetry monitoring of all postoperative patients will be a standard of care within 3 years. He didn't think the additional cost of monitoring technologies will be an impediment to their implementation and cited the rapid intraoperative and PACU adoption of pulse oximetry. Steven Barker (Arizona) suggested that there was currently no ideal ventilation monitor and advocated consideration of electronic auscultation of breath sounds. Julian Goldman (Boston) reiterated that his group felt that because none of the current monitors are adequate, they could not make a specific recommendation regarding monitoring. However, he went on to ask, “What would you want for your relative, if they were receiving PCA postoperatively?” Another participant suggested that within

the next 5 years every postoperative patient would be monitored for both ventilation and oxygenation. Dr. Stoelting (APSF) stated that we cannot afford to wait another 5 years for the perfect monitors because too many healthy 16-year-olds will have been injured in the interim.

## Recommendations

In light of these findings, the APSF recommends the following actions:

1. We advocate widespread acceptance of the goal that *no patient shall be harmed by opioid-induced respiratory depression in the postoperative period.*

After more than 20 years of clinical experience, there remains a significant and still underappreciated risk of serious injury from PCA and neuraxial opioids in the postoperative period. While some patient populations (notably those patients who are elderly, have concurrent cardiorespiratory or CNS disorders, or obstructive sleep apnea) appear to be at higher risk, there is still a low but unpredictable incidence of life-threatening, opioid-induced respiratory depression in young healthy patients. The APSF advocates that health care providers should have “zero tolerance” of respiratory morbidity and mortality associated with opioid use in the postoperative period because these events should be completely preventable.

2. Even though current methods of detecting and preventing opioid-induced respiratory depression have limitations, we believe that *continuous monitoring using available technologies could still prevent a significant number of cases of patient harm.*

While we recognize the limitations of existing monitoring technologies for detecting opioid-induced respiratory depression, the APSF believes that the benefits of their use outweigh the costs, especially in those patients judged to be at highest risk. Thus, we advocate the use of continuous monitoring of oxygenation (generally pulse oximetry) and of ventilation in non-ventilated patients receiving PCA, neuraxial opioids, or serial doses of parenteral opioids.

3. *Thus, immediately, we urge health care professionals to consider the potential safety value of continuous monitoring of oxygenation (pulse oximetry) and ventilation in patients receiving PCA or neuraxial opioids in the postoperative period.*

Although pulse oximetry will monitor oxygenation during PCA, it may have reduced sensitivity, as a monitor of hypoventilation, when supplemental

oxygen is administered. When supplemental oxygen is indicated, monitoring of ventilation may warrant the use of technology designed to assess breathing or estimate arterial carbon dioxide concentrations. Continuous monitoring is most important for the highest risk patients, but depending on clinical judgment, should be applied to other patients.

In the short-term, resistance to change, incomplete solutions, and economics will invariably slow adoption of universal monitoring of postoperative patients. Thus, available monitoring resources will need to be directed to those patients at greatest risk of opioid-induced respiratory depression. In particular, continuous monitoring should be strongly considered in any patient with significant OSA receiving PCA or neuraxial opioids.

4. It is *critical that any monitoring system be linked to a reliable process to summon a competent health care professional to the patient's bedside in a timely manner.*

Even the best monitoring system will be of limited value if the response to the incipient event is ineffective. When the monitoring system alarms, the message must rapidly get to a clinician capable of responding in a timely and appropriate manner. Because staffing constraints necessitate only intermittent presence of clinicians at the bedside of un-intubated postoperative patients receiving parenteral opioids, reliable alerting methods (e.g., audible alarms, central stations, pagers, etc.) are required. Moreover, the responding clinician must be trained to effectively recognize opioid-induced respiratory depression and to intervene appropriately. A mechanism must be in place to allow a bedside clinician to rapidly call for additional help if needed. To effectively manage rare cases of opioid-induced respiratory arrest, the facility must have a well-trained rapid response (or code) team.

5. A widespread program should be initiated to *educate providers and patients about the risks of life-threatening respiratory depression associated with the postoperative use of parenteral opioid analgesics.* Many clinicians, and the lay public, do not appreciate the risks of respiratory depression associated with postoperative parenteral opioid analgesics. Education of providers who prescribe and administer parenteral opioids in the postoperative period is apparently variable and incomplete, providing an opportunity for the APSF, and for anesthesia care professionals, to increase general knowledge and awareness.

See “Opioids,” Next Page

# Research and Education Are Needed Now

## “Opioids,” From Preceding Page

6. Governmental agencies and non-governmental entities should *provide increased support for scientific research* to

- a. Identify those patient populations at the greatest risk of life-threatening, postoperative, opioid-induced respiratory depression. While there are published data on the incidence of opioid-induced respiratory depression in various patient populations, prospective controlled studies could identify the independent relative-risk of critical contributory factors. The relationship of OSA and opioid-induced respiratory depression deserves special attention.
- b. Develop optimal respiratory monitoring technologies, algorithms, and alarms. Near-term research should focus on the development of algorithms that integrate data from several information sources (e.g., pulse oximetry and capnography). Other areas of research should include better signal/artifact detection, new sensor technologies, improved gas sampling methods, and computer-aided diagnosis. An important contribution will be lower cost, portable, wireless respiratory monitors.
- c. Evaluate the impact of different technologies, duration of monitoring, notification modalities, and systems of response. Research should address the reliability and positive predictive value of different monitoring devices and strategies as well as methods of notifying the clinician responders. The most effective interventions are likely to be multi-modal. For example, an intervention might include the routine use of continuous monitoring technologies, electronic notification of front-line clinicians, a rapid response team as a back-up, and simulation-based training of responders.

The APSF is optimistic that further research will improve our ability to utilize effectively continuous monitoring of oxygenation and ventilation in the postoperative period. However, the status quo while awaiting the perfect monitor(s) is not acceptable, and we urge the use of continuous postoperative monitoring of oxygenation and ventilation in appropriate patients without delay.

7. Although detection of postoperative opioid-induced respiratory depression is important, *prevention may be a more effective strategy*. Thus, we also advocate efforts to

- a. Evaluate interventions to reduce the risk of postoperative, life-threatening, opioid-

induced depression including the use of alternative analgesic drugs and modalities.

Research should continue to investigate the comparative effectiveness, safety, and acceptance of perioperative use of local anesthetic infiltration, non-opioid analgesics (especially non-steroidal anti-inflammatory agents and alpha-2 agonists), and analgesic adjuvants. The development of clinically useful opioid analogues with reduced respiratory depressant properties, long a dream of opioid pharmacologists, should continue to be pursued. Finally, studies showing potential value of coadministration of opioid antagonists to reduce opioid agonist side effects (e.g., pruritus, nausea) should be extended to respiratory depression.

- b. Implement, as appropriate,
  - i. Additional clinician training in the prevention, diagnosis, and management of opioid-induced respiratory depression as well as appropriate patient selection for post-procedure PCA and neuraxial opioid therapy. Such training should include ward nurses and appropriate ancillary personnel (e.g., respiratory therapists), based on the systems in place in a specific facility. The most effective training will be experiential—e.g., using clinical scenarios and simulations to reinforce the desired skills and behaviors.
  - ii. Optimized processes of care and medication management systems to assure the occurrence, at the point-of-care, of the 5 Rs for opioid therapy—Right patient, Right drug, Right dose, Right route, Right time. Such processes and systems need not rely on expensive complex technologies. In fact, data suggest that errors can be most effectively reduced by **simplifying** processes through evidence-based re-engineering that actively involves front-line clinicians and strives to reduce the total number of steps required to accomplish any one task. Although the evidence is still equivocal regarding the cost-to-benefit relationship of institution-wide implementation of current electronic medication management systems, such as computerized physician order entry (CPOE) and bar code medication administration (BCMA), targeted use of electronic safety systems in high-risk medication administration may prove to be more cost-effective.

- iii. Improved design and implementation of safe and usable opioid infusion pumps including PCA pumps containing dose-

error reduction (so-called “smart”) technology. Modern parenteral infusion pumps are complex, and lethal overdoses associated with use errors are disturbingly common. Dose-error reduction software alone will not prevent these events. A particularly attractive feature may be the ability to automatically terminate or reduce PCA (or PCEA) infusions when monitoring technology suggests the presence of opioid-induced respiratory depression. To facilitate such capabilities, we strongly endorse the efforts to develop international standards for device interoperability and device-device communication.

In summary, the available evidence suggests that there is a significant and underappreciated risk of serious injury from PCA and neuraxial opioids in the postoperative period. While some patients may be at higher risk, there is still a low but unpredictable incidence of respiratory events in young healthy patients, some of which are related to medical errors associated with infusion technology. Moreover, life-threatening respiratory depression also occurs with intermittent parenteral injections of opioid analgesics. Continuous respiratory monitoring could prevent many cases of life-threatening, opioid-induced respiratory depression. Current monitoring technologies and clinical practices remain suboptimal, being plagued by both false positive (e.g., monitor false alarms) and false negative (e.g., low sensitivity of SpO<sub>2</sub> in the presence of supplemental oxygen administration) alarms. Nevertheless, the APSF advocates the routine use of continuous respiratory monitoring in at-risk patients receiving PCA or neuraxial opioids.

*Dr. Matthew B. Weinger holds the Norman Ty Smith Chair in Patient Safety and Medical Simulation at Vanderbilt University School of Medicine (Nashville, TN), where he is a Professor of Anesthesiology, Biomedical Informatics, and Medical Education and a staff physician at the VA Nashville Medical Center. Dr. Weinger is also the Director of the Center for Perioperative Research in Quality, Director of the Simulation Technologies Program of the Center for Experiential Learning and Assessment, and the Co-Director of the Middle Tennessee Center for Improving Patient Safety. Dr. Weinger is a Member of the APSF Executive Board of Directors and also the Co-Chair of the Human Factors Engineering Committee of the Association for the Advancement of Medical Instrumentation (AAMI) which is responsible for developing U.S. national standards for medical device user interfaces.*

*Disclosure: Dr. Weinger has an equity interest in Fluidnet, LLC.*

# APSF Expands Research Support

## “President,” From Page 62

issues of the *APSF Newsletter* include *Complications of Cervical Epidural Blocks*, *System Fixes Needed to Prevent Drug Errors*, *Oxygen May Mask Hypoventilation—Patient Breathing Must be Ensured*, *Relevance of Black Box Warnings*, and the *Technology Training Initiative*.

Begun with the Summer 2006 issue of the *APSF Newsletter*, a special section entitled *Question and Answers* publishes safety questions submitted by readers and responses from members of the APSF Committee on Technology. The “Dear SIRS” (Safety Information Response System) column in the *APSF Newsletter* continues to provide rapid dissemination of safety issues related to anesthesia equipment as provided by readers. This column is coordinated by Drs. Olympio and Morell.

## Communication

The APSF website ([apsf.org](http://apsf.org)) is coordinated by Jeffrey B. Cooper, PhD, APSF Executive Vice President for Strategic Planning, and George A. Schapiro, APSF Executive Vice President for Development. All *APSF Newsletters* are available online. The APSF website now has a question survey document for anesthesia professionals to register their opinions on patient safety topics. The survey document has been developed by the Committee on Education and Training chaired by Richard C. Prielipp, MD.

The APSF and the ASA Committee on Patient Safety and Risk Management cosponsored a joint patient safety booth at the ASA annual meeting in Chicago in October 2006. The booth content was developed by Drs. Joan M. Christie and Robert A. Caplan.

## Data Dictionary Task Force (DDTF)/International Organization for Terminology in Anesthesia (IOTA)

As of June 2006, 2334 of 2558 terms had SNOMED ID numbers. In addition to anesthesia terms, Dr. Terri G. Monk, Chair of the DDTF/IOTA working group, is leading a committee to develop terminology standards for the perioperative period. The mission of this group is to merge all the existing standards for the perioperative period and to eliminate the overlap and redundancy that presently exist in perioperative terminology.

The DDTF/IOTA working group continues to work on the development of a standard schema for the anesthetic record. The goal is to create a standard XML schema for the anesthetic record. This will enable anesthetic records to be exchanged between diverse information technology systems and users while ensuring semantic inter-operability and traceability.

Dr. Monk is leading the effort to obtain federal funding for work that will support the further development of the terminology/schema for the specialty. Activities of the DDTF/IOTA have been entirely supported by APSF and the vendors of information technology systems (see APSF website for list of vendor supporters). In October 2006, Dr. Monk’s group was successful in obtaining funding from the VA Health Services Research and Development Merit Review Board. The goals of the funded study are to analyze archived data from disparate automated information systems and develop preliminary data standards that will allow the merging of data from disparate automated information systems. Ultimately it is hoped that these data will facilitate study of the role of intraoperative variables amenable to interventions by the anesthesia professional (heart rate, blood pressure, temperature, oxygen saturation, depth of anesthesia). Currently, there is only sparse evidence to support the impact of such interventions, reflecting the fact that hand-written anesthesia records make it difficult to aggregate data on intraoperative physiology across large numbers of patients.

## Research

The Committee on Scientific Evaluation chaired by Sorin J. Brull, MD, received 35 grant applications in 2006 for awards to begin in January 2007. In October 2006, the committee recommended funding of 5 research awards at the \$150,000 level. Two of the grants are supported in full by awards from the Cardinal Health Foundation and Anesthesia Healthcare Partners. I take exceptional pride along with my colleagues in endorsing this level of patient safety research support from the APSF. Since the inception of the APSF grant program, nearly 400 grant applications have been reviewed by the APSF. When the first grants were funded in 1987, funding for patient safety research was virtually nonexistent. Since 1987, the APSF has awarded 68 grants for a total of more than \$3.5 million. The impact of these research grants is more far-reaching than the absolute number of grants and total dollars as APSF-sponsored research has led to other investigations and the development of a cadre of anesthesia patient safety investigators.

## Financial Support

Financial support to the APSF from individuals, specialty and component societies, and corporate partners in 2006 has been most gratifying. This sustained level of financial support makes possible the undertaking of new safety initiatives, the continuation of existing safety initiatives, and increased research funding. In 2006, the APSF awarded \$750,000 in research dollars to patient safety investigators representing more than 50% of the APSF income for the year.

Anesthesia is unique in American medicine in having a foundation dedicated to anesthesia patient safety, and this is reflected by the vision and support of the ASA since the formation of the APSF in 1985.

As in the previous annual report, I wish to reiterate the desire of the APSF Executive Committee to provide a broad-based consensus on anesthesia patient safety issues. We welcome comments and suggestions from all those who participate in the common goal of making anesthesia a safe experience. There remains much still to accomplish and everyone’s participation and contributions are important.

Best wishes for a prosperous and rewarding 2007.

Robert K. Stoelting, MD  
President

See Grant  
Application  
Guidelines  
and Instructions  
on Page 84  
and on the  
APSF Website at  
[www.apsf.org](http://www.apsf.org)

and

Check out the  
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answer and view  
results!



# Grant Program Funds Five Awards

by Sorin J. Brull, MD

The Anesthesia Patient Safety Foundation (APSF) is pleased to report that it continues to attract outstanding applications for funding. The educational focus of the APSF includes innovative methods of education and training to improve patient safety, development of educational content with application to patient safety, and development of testing of educational content to measure and improve safe delivery of perioperative anesthetic care.

The application process continues with an electronic, online submission format that was introduced in 2005. The applications, as well as all the required attachments, are uploaded to the new APSF redesigned website ([www.APSF.org](http://www.APSF.org)), a process that facilitates the application review by members of the Scientific Evaluation Committee, improves the timeliness of response, and facilitates transmission of reviewer feedback to the applicants. The Scientific Evaluation Committee members continue to modify and perfect the electronic application and review process.

This year, the Scientific Evaluation Committee is very pleased to report on several significant developments in the APSF Grant Program. The first is an increase in funding from \$75,000 to **\$150,000 per accepted application**, an amount that now includes up to 15% for institutional overhead. The second development is the inauguration of the **Cardinal Health Foundation Research Award**, made possible by the generous unrestricted donation (\$150,000) by the Cardinal Health Foundation that will support investigations in the areas of education and training or clinical research in medication safety. The third is the continuation of the **APSF/Anesthesia Healthcare Partners Award**, started in 2006 and made possible by a partial (\$100,000) unrestricted grant. In addition to the *Clinical Research* and *Education and Training* content that is the major focus of the funding program, the APSF continues to recognize the patriarch of what has become a patient safety culture in the United States and internationally, and one of the founding members of the foundation—Ellison C. "Jeep" Pierce Jr., MD. The APSF Scientific Evaluation Committee continues to designate each year one of the funded proposals as the recipient of this prestigious nomination, the **Ellison C. Pierce, Jr., MD, Research Award**. The award carries with it an additional, unrestricted prize of \$5,000.

For the year 2006 (projects to be funded starting January 1, 2007), 5 grants were selected for funding by the APSF Scientific Evaluation Committee (for names of committee members, please refer to the list in this issue). The APSF Scientific Evaluation Committee members were pleased to note that they reviewed 32 applications in the first round, 12 of

which were selected for final review at the American Society of Anesthesiologists' (ASA) annual meeting in Chicago, IL. As in previous years, the grant submissions addressed areas of high priority in clinical anesthesia. The major objective of the APSF is to stimulate the performance of studies that lead to prevention of mortality and morbidity from anesthesia mishaps. A particular priority continues to be given to studies that address anesthetic problems in healthy patients, and to those studies that are broadly applicable and promise improved methods of patient safety with a defined and direct path to implementation into clinical care. Additionally, the APSF is encouraging the study of innovative methods of education and training to improve patient safety, and methods for the detection and prevention of medication errors.

The APSF Scientific Evaluation Committee met during the ASA annual meeting on October 14, 2006, in Chicago for final evaluation of the proposals. Of the 12 finalists, the members of the APSF Scientific Evaluation Committee selected 5 awardees:



**Greg Stratmann, MD, PhD**—Assistant Professor in Residence, Department of Anesthesia and Perioperative Care, University of California at San Francisco.

Dr. Stratmann's submission is entitled "*Effectiveness of three clinically applicable strategies to improve the safety of neonatal anesthesia.*"

**Background:** Neonatal anesthesia causes neurodegeneration in many animal species, including monkeys. The investigator's preliminary data suggest that neonatal rats are unable to compensate for this neuronal loss by increasing the formation of new neurons (neurogenesis) from neural stem cells. In fact, the authors previously found that isoflurane is toxic to neuronal stem cells in culture, and in neonatal rats *in vivo*. Decreased neurogenesis by itself causes cognitive decline and a permanent cognitive deficit in rats at 5 and 8 months after neonatal anesthesia. The **purpose** of this study is to

prevent the cognitive decline following anesthesia in neonates. The authors will test the clinical effectiveness of 3 easily applicable strategies to reduce anesthetic toxicity in neonatal rats. Dr. Stratmann will first establish a hierarchy of toxicity of the most clinically relevant anesthetic agents; second, the investigators will determine the safe duration of 1-MAC isoflurane exposure; and third, they will test whether erythropoietin, administered before general anesthesia, can prevent the neurodegeneration and the decrease in neurogenesis, while normalizing long-term (4 months) cognitive outcome. Dr. Stratmann and his colleagues will use a combined approach, including assessment of anesthetic toxicity of different agents and durations of exposure in neonatal neural stem cell lines *in vitro*, and neonatal rats *in vivo*. They further propose to quantify apoptosis, neural progenitor proliferation, progenitor cell survival, neuronal differentiation (neurogenesis), and cognitive outcomes by employing sophisticated immunocytochemical techniques and 2 sensitive neurocognitive testing modalities.

**Implications:** Collectively, this novel and comprehensive approach (that includes both cellular and molecular biology as well as long-term cognitive outcome assessment) will allow the identification of strategies with high clinical applicability that will improve the safety of neonatal and pediatric anesthesia.

In addition to receiving the requested funding of \$150,000 for this project, Dr. Stratmann is also the recipient of the **Ellison C. Pierce, Jr., MD, Research Award**, which consists of an additional, unrestricted grant of \$5,000.



**Karen J. Roetman, MD**—Attending Anesthesiologist, Department of Anesthesiology, Virginia Mason Clinic, Seattle, WA. Dr. Roetman's research proposal is entitled "*Safety of postoperative opioid analgesia*"

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# 2006 Grants Reach \$750,000

## “Awards,” From Preceding Page

*in patients with Obstructive Sleep Apnea: What are the risks and how can the risks be safely managed?”*

**Background.** Obstructive Sleep Apnea (OSA) is an increasingly common medical problem encountered by anesthesia providers, and the relationship between obesity and OSA suggests that the frequency with which we encounter patients with OSA is likely to continue to increase for the foreseeable future. Of particular concern to clinicians caring for OSA patients is the issue of how to safely provide adequate postoperative analgesia. The underlying question is whether the combined effects of sedative hypnotics, volatile anesthetics, and opioid analgesics will increase the risk of obstructive episodes, and decrease the likelihood of arousal in order to clear the airway when obstruction does occur.

**Purpose.** This grant proposes to conduct the first prospective, blinded, randomized, controlled investigation of ventilatory problems experienced by patients with OSA who receive opioid analgesics in the postoperative period. In addition, the study will identify risk factors for perioperative ventilatory problems in patients with OSA, and will investigate the validity of the recent ASA guidelines for the perioperative care of patients with OSA. The study will use an ambulatory polysomnography system to continuously record arterial saturation, respiratory effort, nasal/oral airflow, EEG, and EKG throughout the postoperative period in patients with OSA, and in matched controls.

**Significance.** Current estimates are that the incidence of OSA in western populations is 5-9% and that the number of surgeries performed in the USA is approximately 40 million per year (data from ASA library staff); thus, as many as 3.6 million patients with OSA present for surgery each year. Added to this number are the patients who undergo “procedural sedation” each year and those who will “screen positive” for potential OSA using the ASA’s screening guidelines, even though they do not have the disease. Thus, the data derived from this study are likely to be applicable to at least 5 million patients each year in the United States.

In addition to receiving the requested funding of \$150,000 for his project, Dr. Roetman’s application was designated as the **Cardinal Health Foundation Research Award**, made possible by an unrestricted, \$150,000 grant from the Cardinal Health Foundation.



**Kirk Hogan, MD, JD**—Professor, Department of Anesthesiology, University of Wisconsin, Madison, WI. Dr. Hogan’s research proposal is entitled “*Anesthetic and surgical risk factors for Alzheimer’s Disease in adult children of persons with Alzheimer’s Disease.*”

**Background.** Since 2001, the Wisconsin Registry for Alzheimer’s Prevention (WRAP) has enrolled adult children of persons with Alzheimer’s Disease (AD) for serial clinical, neuropsychological, biochemical, and neuro-imaging evaluations in order to correlate variation in the onset and progression of AD in a high-risk population sample with biomarkers of AD. Shortly after the inception of WRAP, the potential for deleterious consequences of surgery and anesthesia in months to years after an operative procedure became a new focus of research, arising in large part from the original and sustained efforts of the APSF. The **purpose** of the present proposal is to test whether anesthetic and surgical risk factors associated with postoperative cognitive impairment contribute to AD in participants at heightened susceptibility by virtue of family history (i.e., one or both parents with proven AD), and genetic predisposition. A key feature of WRAP is that upon registration, all participants provide consent for re-contact antecedent to entry into new trials. Taking advantage of this study design, current and future WRAP participants will be approached for consent to enter their anesthetic and surgical records into the WRAP database (850 persons in the positive family history [FH+] group, and 350 persons in the negative family history [FH-] control group). This information will be scored for variables known or suspected to be associated with cognitive dysfunction in the postoperative interval.

**Significance.** If successful, this investigation will identify genetic, acquired, and environmental predictors in perioperative care that predispose a substantial proportion of otherwise healthy patients at risk for AD to adverse and potentially avoidable neurologic outcomes. No other study has evaluated anesthetic and surgical risk factors for dementia in a population enriched for participants with a positive family history.

In addition to receiving the requested funding of \$150,000 for his project, Dr. Hogan is the recipient of the **APSF/Anesthesia Healthcare Partners Research Award**, made possible by an unrestricted educational grant in the amount of \$100,000.



**Jason M. Slagle, PhD**—Assistant Professor of Anesthesiology, Vanderbilt University Medical Center, Nashville, TN. Dr. Slagle’s research proposal is entitled “*The impact of performance-shaping factors on anesthesia care task distribution, vigilance, workload, and non-routine events.*”

The **purpose** of this project is to 1) elucidate the incidence, type, and etiology of various performance-shaping factors including those that may be potentially disruptive or informative; and 2) delineate the effects of these factors on anesthesia providers’ task performance, vigilance, and workload, and on the occurrence of non-routine events (NRE). A NRE is any event that deviates from optimal care for a specific patient in a specific clinical situation. Video will be captured and behavioral task analysis (i.e., time-motion analysis), as well as workload and vigilance assessments, will be conducted for each observed case. At the end of the case, the anesthesia provider will be queried using an established instrument as to whether any NRE occurred during the case. During real-time observation and off-line video-analysis, the authors will identify and classify intraoperative events and tasks including their timing, type, and source of initiation and termination (self or external). Multivariate models will be used to assess the effect of different types of environmental influences and provider-initiated activities on clinical task distribution, workload, vigilance, and NRE occurrence.

**Significance.** The proposed work will provide a detailed description of the nature and impact of the effects of these performance-shaping factors, thus allowing future practices and policies to be guided by objective evidence rather than opinion. The findings will also contribute to future redesign of the OR environment, anesthesia equipment, information technology, and curricula.

The requested funding in the amount of \$149,965 is made possible by a grant from the APSF.

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See 2007 Grant Application Guidelines and Instructions on Page 84 and on the APSF Website at [www.apsf.org](http://www.apsf.org)

# Applicants' Proposals of High Quality

"Awards," From Preceding Page



**Jenny W. Rudolph, PhD**—Assistant Professor, Health Services Department, Boston University School of Public Health, Boston, MA. Dr Rudolph's research proposal is entitled "*Does a standardized electronic protocol for anesthesia handoffs improve information transfer and reduce the potential for adverse events?*"

**Background.** Transfer of patient care from one provider to another, or "handoffs," are both a source of vulnerability and resilience in health care organizations. The nascent literature on handoffs lacks consensus on the benefits versus liabilities of structuring the transitions using tools such as checklists and information systems. To help address this gap, the proposed study examines the impact of a standardized protocol on information sharing between incoming and outgoing anesthesia

providers, and the impact of this information on the subsequent management of a case. Previous handoff research in health care, aviation, and other high hazard industries indicates that effective handoffs are like a highlighter pen on a page of text: the outgoing provider emphasizes, and the incoming elicits, what is most salient about the current situation. Conveying and inquiring into every detail overwhelms both the outgoing and the incoming providers; however, leaving out crucial details restricts the incoming anesthesia provider's knowledge of the patient, as well as his or her ability to effectively hand off information at the next transition of care. Previous handoff and memory research also suggests that chunking information in a familiar way (for the profession) with "most important first," enhances the likelihood that important information will be conveyed and not be forgotten.

Drawing on these insights, this study proposes to study the following research question: "What is the impact of a standardized protocol on the number and organization of facts about patient history, intraoperative events, and postoperative plans that are communicated during the handoff?" Using descriptive data generated by this question, the authors will test the hypotheses that a standardized protocol: 1) improves the organization of that information; 2) increases the proportion of correct facts remembered by the incoming; 3) increases the degree of correspondence in organization between what is communicated during the handoff, and what the incoming recalls; and 4a) increases the rate

at which the incoming addresses adverse clinical states subsequent but related to handoff information, and 4b) reduces the time it takes to begin addressing subsequent adverse clinical states related to handoff information.

**Significance.** This study explicitly addresses leading APSF goals: It is a study that influences how clinicians approach perianesthetic problems for relatively healthy patients; it is broadly applicable across anesthesia as a specialty; is directed at improving methods to enhance patient safety, by reducing potential clinical errors during handoffs of care; and has a defined and direct path to implementation by adopting structured handoff protocols.

The requested funding in the amount of \$149,969 is made possible by a grant from the APSF.

On behalf of APSF, the members of the Scientific Evaluation Committee wish to congratulate all of the investigators who submitted their work to the APSF, whether or not their proposals were funded. The Committee members hope that the high quality of the proposals and the important findings that will undoubtedly result from completion of these projects will serve as a stimulus for other investigators to submit research grants that will benefit all patients and our specialty.

*Sorin Brull is Professor of Anesthesiology at the Mayo Clinic, Jacksonville, FL, and a member of the APSF Executive Committee and Chair of the APSF Scientific Evaluation Committee.*

## Transparent Reality Simulation on the Web

by Sem Lamptang, PhD

The Virtual Anesthesia Machine (VAM) website has diversified and now offers other simulations in addition to those of the anesthesia machine and its pre-use check. The simulation portfolio at <http://vam.anest.ufl.edu/wip.html> includes pharmacokinetics (propofol and fentanyl), compliance to prescribed drug regimens, bag valve mask ventilation, the physics of anesthesia, continuous veno-venous hemodialysis (CVVH), perioperative hemostasis, thromboelastography, coronary circulation, and airway devices. The simulations fall into 3 categories: free public access (n = 17), free registered access (registration required; n = 3), and paid access to an instructor area (n = 11). The latter section was created as part of ongoing efforts to become a non-loss, self-funded program. To facilitate collaborative content creation, a newly-implemented wiki section allows anyone, after registration, to create and edit web pages on that section of the website <http://vam.anest.ufl.edu/wiki>.

Traffic on the VAM website continues to grow (>5 million hits/yr; ~ 650 visitors/day, >28,000 registered users worldwide). Support from the APSF (funding to develop an anesthesia machine work-



book and a simulation of the FDA 93 anesthesia machine pre-use check), private foundations, industry, and the University of Florida's Department of Anesthesiology has allowed the VAM team to stay intact and continue offering free simulations to the global anesthesia community.

*Dr. Lamptang is a Professor of Anesthesiology and Director of the Center for Simulation, Advanced Learning and Technology at the University of Florida. He is also a member of the APSF Committee on Education and Training as well as the ASA Committee on Simulation Education.*

# Safety Abstracts Abound at 2006 ASA

by Steven B. Greenberg, MD, FCCM, Glenn S. Murphy, MD, Jeffery S. Vender, MD, FCCM

Over 1000 abstracts were presented at the 2006 American Society of Anesthesiologist Annual Meeting in Chicago, IL. This brief review will summarize a few of the key abstracts related to patient safety.

## Sedation in Non-Operating Room Settings

The safety of administering sedation (primarily propofol) outside of the operating room was one focal point addressed in this year's abstracts. One retrospective trial (A1695) examined 74 pediatric patients undergoing sedation (propofol or ketamine) for a variety of procedures in the emergency room. Wide variability in dosing of sedatives was recognized due to different physician practices. Hallucinations, hypoxemia, and inappropriate arousal were found in 13.5% of patients. The author concluded that complications associated with providing sedation in the emergency room are not inconsequential, and that standardization of administration needs to take place. Another study (A1584) looked at 40 patients undergoing colonoscopies with anesthesiologists delivering propofol. Airway interventions (>2 interventions per patient) were required in 70% of patients. This study suggests that, even in experienced hands, airway interventions are still required. A retrospective study (A1691) compared nurse administered sedation with physician-administered sedation in pediatrics. Although physicians managed more critically ill patients, nurse administered sedation was associated with increased PACU length of stay and prolonged, deeper sedation times.

Prediction of sedation failure was examined in at least 2 abstracts. In a review of over 39,000 pediatric sedation encounters (A354), the presence of an anesthesiologist substantially reduced sedation failures. Abstract A1395 was an observational study of sedation in 50 non-randomized adults undergoing upper endoscopic ultrasound under videotape scrutiny. Standard care (opioid and benzodiazepine) given by an endoscopist resulted in less effective and efficient sedation compared to when an anesthesiologist administered propofol. These studies mention the need for anesthesiologists providing sedation in these environments.

A new automated propofol delivery system was assessed during GI endoscopy cases (A1586). Forty-eight patients undergoing colonoscopies or upper endoscopies had propofol titrated to a desired clinical effect. An electronic data acquiring system checked vital signs, alarms, respirations, and altered propofol dosing. Three patients experienced significant desaturation (<90%) and 18 subjects had apnea spells >30 seconds. Despite the limitations of the technology, the automated system's response

resulted in recovery of all subjects to normal respiratory parameters without an anesthesiologist's intervention. Proponents of this technology argue that it may mitigate the need for high physician costs, while reducing complications and improving safety in these non-standardized settings. However, the relatively small number of subjects studied, and the significant incidence of desaturation and apnea raise valid concerns.

## Obesity/OSA

The U.S. is experiencing an obesity epidemic with an associated high incidence of undiagnosed patients with obstructive sleep apnea. Several abstracts focused on addressing this crucial topic facing anesthesiologists. In a retrospective trial (A989) of 116,035 subjects, patients who were overweight or obese were at a significantly increased risk of airway difficulty, failed intubation, and reintubation ( $P<0.05$ ). Another large retrospective study (A992) involving approximately 19,000 patients noted an association between an increased occurrence of perioperative events when comparing obese patients to non-obese patients ( $P=0.003$ ). Obese patients may indeed suffer from a higher incidence of perioperative complications and, therefore, require ICU admission. Another retrospective study (A987) involving 248 patients undergoing gastric bypass devised a scoring system to predict which obese patients would need an ICU admission. The following categories: BMI, comorbidities, performance status, pulmonary status, and age were assessed and given a score of 0, 1, 2, or 3 based on increasing risk. Although sensitivity was low (41%), a score of  $\geq 10$  gave an adequate specificity of 88% to predict ICU admission. This scoring device may aid anesthesiologists in predicting which patients may need ICU care, thereby, minimizing inadequate or overuse of limited resources.

In addition to obesity, the diagnosis of obstructive sleep apnea (OSA) and the correlation with difficult intubation was also examined. A prospective trial (A988) was performed involving 1,898 patients over 4 months. Twenty-four percent of these patients were found to be at high risk for OSA based on screening. These patients took an ARES Unicorn home (a device that detects RDI or the number of abnormal breathing events per valid hour of recording time and indicates the severity of OSA). Seventy-six percent of the patients who were in this group and were not already diagnosed with OSA were newly diagnosed with OSA with this model. Study A986 required anesthesiologists to identify 68 patients with difficult intubations and refer them for a sleep study to rule out OSA. Of the 20 patients who agreed to take the sleep study test, 55% of the patients were diagnosed with OSA. This suggests that a difficult intubation may be another harbinger for the diagnosis of obstructive sleep apnea.

## Antibiotic Administration/Contamination of Objects in the OR

Prevention of perioperative infection is a critical patient safety issue. Analysis of 3,623 procedures in relation to antibiotic administration was performed (A140). Appropriate administration within 1 hour of incision occurred in 92% of procedures in which the antibiotics were given in the OR as opposed to 59.8% of the time prior to entering the operating room. This suggests that the optimal administration of antibiotics for patients is most appropriately performed in the operating room.

Two abstracts investigate microbiological growth on objects handled by an anesthesiologist in the operating room. The first study (A944), cultured 5 different objects (oxygen flowmeter on the anesthesia machine, OR bed control, ventilator valve, telephone handle, and the right hand door handle inside the OR) in three different OR settings (trauma, general, and cardiac surgery). Although the most prevalent organism was coagulase negative staphylococcus, alpha streptococcus and *E. coli* were also found. These more pathogenic bugs were most commonly identified in the cardiac surgical operating rooms. This study also noted that more organisms were found in the morning, suggesting that inexperienced or inadequate cleaning personnel may be a factor in promoting pathogenic bacterial overgrowth during the preceding night. Another trial (A948) examined bacterial contamination of computer keyboards and mouse pads in the OR and ICU. By utilizing ultraviolet lamps, it was evident that bacterial growth on these objects existed. Most cultures identified coagulase negative staphylococcus. However, 3 keyboards in the OR as well as 1 keyboard in the ICU were contaminated with MRSA. Ethyl alcohol swabs significantly reduced the overall bacterial load detected. This abstract is a reminder that anesthesiologists should remove their gloves before touching objects and the importance of washing their hands to reduce the risk of spreading infectious organisms to patients.

## Miscellaneous

Airway management is one subject that defines our profession. A large prospective (A1687) trial involving 2,837 adult patients scheduled for general anesthesia with tracheal intubation attempted to identify risk factors for difficult mask ventilation. Following logistic regression, contributing factors included Mallampati >II, age, presence of beard, and history of neck radiation. Impossible mask ventilation was associated with oxygen desaturation in 22% of cases and an increase in difficult intubation. Another study (A555) attempted to establish the incidence of difficult mask ventilation (MV) in 5,434 pediatric general anesthesia cases. The incidence of

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## Abstracts Available on Web

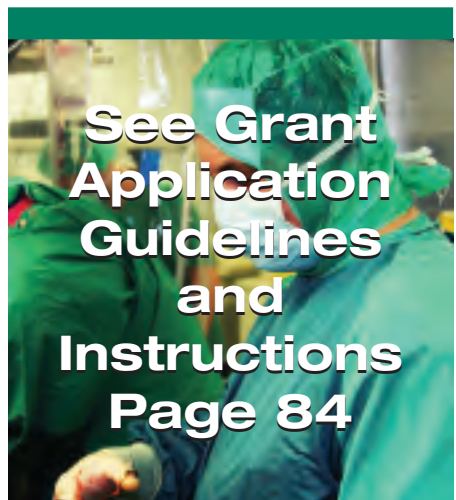
### “Abstracts,” From Preceding Page

difficult or impossible mask ventilation was 0.2%. Although BMI was not shown to be a predictor of difficult mask ventilation, a grade 2-3 (requiring oral airway, inadequate MV, or requiring 2 providers) MV was associated with difficult intubation in ages 2-5 years. This abstract is the first step in identifying the incidence of difficult mask ventilation in a pediatric population. Further studies may look at predictable risk factors for difficult pediatric mask ventilation.

Aprotinin’s safety profile has recently been called into question. A multi-center prospective double blind randomized trial (A383) involving 352 patients attempted to address adverse events associated with aprotinin’s use during total hip arthroplasty. The study reported no differences in postoperative laboratory values (serum creatinine or BUN values) or adverse events (such as deaths, cardiac failure, renal failure, TIA, DVT, or PE) when comparing the aprotinin (APR) and placebo groups. This small study suggests a safe profile for aprotinin during total hip arthroplasty. Another prospective study (A384) evaluated the presence and severity of allergic reactions associated with the use of aprotinin in 1,307 orthopedic surgical patients. The overall allergic reaction rate was 1.3%. However, there was a significantly higher allergic reaction rate in those patients with repeated administration of aprotinin within 3 months of previous aprotinin treatment ( $P < 0.0001$ ).

This brief review highlighted only a small number of the many important abstracts on patient safety presented at the 2006 Annual Meeting. To view other abstracts on patient safety, or to obtain further information on the abstracts discussed in this review, please visit the Anesthesiology website at [www.anesthesiology.org](http://www.anesthesiology.org).

*Drs. Greenberg, Murphy, and Vender are affiliated with the Department of Anesthesiology at Evanston Northwestern Healthcare, Evanston, IL. Drs. Murphy and Vender are also members of the APSF Editorial Board.*



**See Grant Application Guidelines and Instructions Page 84**

## Letter to the Editor

# All Agree—Alarms Must Be Audible

### To The Editor:

I wanted to share an experience with you that may cause you to question the status of patient safety. For nearly 24 years I worked with a large physician/CRNA group. The bulk of my practice was at an outpatient surgery center. It was at that site that I challenged a surgeon about his loud music interfering with patient care; specifically, the music prevented me from hearing my monitors and alarms. He was offended. My attending anesthesiologist, when called to the operating room, agreed with my concern regarding the loud music and explained to the surgeon that it is a requirement to hear the monitors.

Shortly after this occurrence, the medical director of surgery center advised me that I was being moved to another work site due to surgeons being unable to work with me. In fact, it is my belief that the "offended" surgeon used his ability to bring cases to the surgery center to exert pressure to have me no longer assigned to the surgery center. I no longer work for the group. I have no regrets for standing up for "what is right."

I hope this letter influences at least one person, in the future, to stand up for patient safety when challenged by unreasonable demands of a surgeon. The safety of the patient comes first; it is mandated that the monitors and alarms must be audible. Providing a surgeon an environment in which to work is second. This includes background music.

*Iris Horton, CRNA  
London, KY*

### In Response:

In her letter to the editor regarding audible alarms and background noise, Iris Horton, CRNA, offers a striking example of how unprofessional conduct can put a patient’s safety at risk. This nurse anesthetist should be commended for taking a strong stance that the surgeon’s background music be kept to a volume that would allow other health care professionals in the operating room to clearly hear the monitors and alarms. Indeed, all potential distractions and disruptive behaviors pose a threat to patient care.

As a professional organization dedicated to safeguarding the surgical patient and ensuring that operative care is provided in an optimal environment, the American College of Surgeons expects its members to put the interests of patients ahead of their own. As a result, we are strongly encouraging surgeons to disabuse themselves of outmoded conceptions about their role in the operating room. We realize that given the complexity of surgical care today, surgeons can no longer view themselves as “the captains of their ships,” with the rest of the crew on hand simply to carry out their demands—no questions asked. Instead, we are fostering a team approach to patient care, with surgeons listening to and weighing input from all of the team members, including technicians, nurses, anesthesia professionals, and residents. Clearly, any recommendations concerning conditions that affect a team member’s ability to hear monitors or audible alarms would be taken seriously under this approach. We believe that this system will help to improve morale, reduce errors, and increase safety—all of which will provide our patients with better outcomes and healthier lives.

Again, we applaud Ms. Horton’s efforts to advocate for her patient’s safety and anticipate that stories like hers will soon become a throwback to the past.

*Thomas R. Russell, MD, FACS  
Executive Director, American College of Surgeons*

## ENDORSEMENT

### The Council on Surgical and Perioperative Safety

*Endorses the importance of the anesthesia professional being able to hear audible physiologic alarms unobstructed by extraneous operating room noise.*

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# ASA Meeting Exhibits Feature Safety Themes

by John H. Eichhorn, MD

Anesthesia patient safety persisted as a prominent theme in the massive exhibit hall at the American Society of Anesthesiologists Annual Meeting October 12-18 in Chicago. Both the Scientific and Educational Exhibits and also the Technical Exhibits from manufacturers and sellers of anesthesia-related equipment and supplies contained some new approaches to patient safety as well as many familiar themes with a few twists.

In the Scientific and Educational Exhibits, 14 of the 56 entries, 25%, in some way related to airway concerns. This again reinforces the suggestion that airway management remains likely the greatest technical/mechanical challenge for anesthesia professionals, because it is the one central component of practice that has changed the least in the "modern era" of anesthesia, as defined by the widespread adoption nearly 20 years ago of electronic monitors such as oximeters and capnographs to extend the power of human senses and allow much earlier detection of dangerous intraoperative situations. The fact remains that general anesthesia still today very often includes induction of unconsciousness and then paralysis of a patient's ventilatory musculature when there is no specific certainty or even assurance that intubation of the trachea or even positive pressure ventilation will be possible. Accordingly, virtually all anesthesia professionals still today experience "difficult airway" situations with a frequency that depends on their type of patients and practice. Thus, airway tools of a wide variety, airway models, airway simulators, airway educational efforts, and the associated Scientific and Educational Exhibits as well as airway-related products for sale in the Technical Exhibits continue to constitute an appreciable fraction of the displays.

Among the airway related Scientific exhibits, prominently featured was a comparatively low-tech but apparently very useful new device from Belgium consisting of a specially shaped disposable inflatable bag that is placed under a patient's upper torso (particularly a morbidly obese patient) and then inflated and adjusted to maximize the sniffing position (slight extension and increase of the sterno-mandibular distance) in order to align the airway and facilitate direct laryngoscopy (potentially replacing the mound of pillows, sheets, and towels or various foam-type inclines now used for this purpose).

Ohio was strongly represented with 2 exhibits from Cincinnati Children's Hospital on pediatric airway equipment and techniques as well as a display from the Cleveland Clinic about using specialized CT scans to image and analyze airways (not yet by a long shot the long sought-after bedside device to map every patient's airway preop but a step in that direction). Also from the Cleveland

Clinic were 2 other exhibits: one an update for light-wand intubation of a difficult airway with accompanying computerized teaching support and the other a new "stylet forming device" to be used with a video laryngoscope in order to customize the endotracheal tube to a specific patient's difficult airway. Another display from Cardiff, Wales, stressed the interesting problem that various pediatric laryngoscope blades with the same names are actually of different shapes and give different views of the airway, some better than others. In the educational mode, a French computerized virtual airway program was offered as an improved method to teach in 3-D the fiberoptic "navigation" of the difficult airway.

An exhibit from Baylor in Dallas focused on the problem of dealing with difficult airways in remote locations distant from the OR and its resources and personnel. The extensive display highlighted methods to adapt basic, readily achievable techniques for "the outfield."

Another exhibit from Mt. Sinai in New York dealt specifically with topical anesthesia of the airway for awake fiberoptic intubation, emphasizing both traditional and new techniques.

Shifting emphasis, the "difficult extubation" was the subject of an entry from Spain and demonstrated a systematic sequential approach first to support extubated patients, and then, when needed, assist ventilation, attempt reintubation, or establish a surgical airway.

While not targeting airway manipulation, an exhibit from UMDNJ-RWJ in New Jersey dealt with a common related problem by featuring a new type of face tent intended to provide supplemental oxygen to sedated patients having upper endoscopy involving a bite block holding the mouth open while avoiding the common problem of CO<sub>2</sub> rebreathing in prior efforts of this type. This display was very near the annual entry from the American Sleep Apnea Association and around the corner from the exhibit of the Society for Airway Management, all of which seemed somehow fitting.

Other safety-related topics covered in the Scientific and Educational Exhibits included an extensive presentation regarding fires during monitored anesthesia care, specifically outlining the cause of these fires and best measures to prevent them. An extensive multimedia display from Milwaukee Children's Hospital highlighted common anesthesia machine mishaps and how to prevent them. Finally, while the potential safety benefits may not be as direct as from some of the other exhibits (but are nonetheless very real), from the same hospital was a provocative display about perioperative interpersonal conflicts and how to manage them. While documentation of anesthesia adverse events

being caused or contributed to by "bad blood" between anesthesia professionals and other types of personnel is understandably hard to come by, it is certainly worth trying to prevent such conflicts that can be distracting and disruptive during anesthesia care.

Continuing the theme from the Scientific and Educational Exhibits to the corporate section, excluding the mega-exhibits from the large national companies with multiple product lines across the entire anesthesia spectrum, there were no fewer than 34 of the technical/commercial exhibits exclusively or largely devoted to equipment and supplies for airway management, again dramatically emphasizing the major role of improving airway handling as an ongoing component of the evolution of anesthesia patient safety. One company offered a new interlocking set of foam pillows, similar in purpose to the inflatable bag noted above, for use in positioning the torso, neck, and head of a difficult airway patient (greatly morbidly obese, for example) in the most favorable manner for direct laryngoscopy. Multiple large displays showed a panoply of all manner of airway tools and equipment. This genuinely dizzying array raises the question that there may be too many competing technologies and varieties of equipment available for there to be adequate investigation of their application, risks, and benefits. Frequently characteristic of the commercial marketplace in medical equipment, it appears that several manufacturers have rushed into production of new tools or technologies that have only been "tested" by their inventor and have never been the subject of peer-reviewed publications or multi-center clinical trials. While this quasi-shotgun approach may be entrepreneurially understandable, it makes for such a possibly bewildering array of choices to average anesthesia practitioners that it seems much easier for them to stick with the familiar Mac 3 or Miller 2 rather than try to figure out what may be better, either in general or in "difficult airway" scenarios. So far, there does not appear to be an organized effort by the profession to sort all this out. Further, clever as some of the new devices may seem, their significant cost is enough potentially to prevent their widespread trial, much less adoption, which likely contributes to the very slow pace of improvement in the prevention of the rare but dramatic unexpected airway problems and even overt emergencies upon induction of general anesthesia.

In any case, there were several updates and variations on the fiberoptic and video-assisted laryngoscopes, several of which were intended for routine everyday use. Some featured eyepieces, but more of them this year offered miniature cameras and video systems, including some that projected to very small screens (1.7 inch diagonal and

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# Airway Issues Persist as Prime Focus

## “Exhibits,” From Preceding Page

attached directly to the laryngoscope handle, which is not much larger than a traditional one), to small free-standing screens that would rest on a stand or the patient’s chest, or to very large video monitors. One relatively large new video-intubation rigid apparatus from an endoscope manufacturer involves a large plastic laryngoscope blade through which an optical/light source bundle fits and rests next to a trough that guides the tube into the larynx under direct video imaging. The 1.5 x 3 inch screen is on the handle and has a sighting target on it that, when superimposed on the cords in the picture, indicates the tube is aimed straight down the larynx. The other manufacturers of fiberoptic bronchoscopes offered added new variations of laryngoscopes incorporating fiberoptics, making new “flexible intubation videoscopes.” Another system featured blades containing integral optics that would fit onto a traditional C battery-powered handle, claiming to give a view around the base of the tongue without the need to displace it as in traditional direct line-of-sight laryngoscopy. A new intubating stylet involves a starting guidewire that is used in the same manner as with the Seldinger technique for a vascular cannula. A new variant of “helpful” endotracheal tube has an integrated articulating tip that bends at the cuff, which is flexed to help approach an anterior larynx without use of a stylet by an internal wire actuated by pulling up on a plastic collar at the connector end of the tube.

Also new this year was a video-enabled laryngeal mask airway with the optics and camera incorporated into a handle similar to existing intubating laryngeal mask airways. The medium-sized screen is attached to the handle by a magnetic latch after the mask is placed in the airway. The manufacturer emphasizes that positive pressure ventilation can be continued during the video-guided intubation attempt, which requires the use of the existing dedicated extra-long endotracheal tubes and then the pusher to allow removal of the handle.

At the other end of the airway-management complexity and technology spectrum was a new product that is nothing more involved than sticky-backed disposable foam tape that is intended to be stuck on a regular steel laryngoscope blade, Mac or Miller, in such a position as to be even with the teeth during laryngoscopy, thus preventing the metal blade from touching teeth and reducing the risk of dental damage. The manufacturer stresses the utility of this remarkably simple “technology,” especially for attempts of new trainees of any type who are starting to learn direct laryngoscopy and endotracheal intubation.

Thematically related to the airway management products was a new emphasis on diagnosing and documenting obstructive sleep apnea preoper-

atively. One company offers a service that involves specific screening for any suspected OSA patient, including a 1-night, at-home test to help make the diagnosis and then a treatment plan as indicated with emphasis on the immediate post-general anesthetic period. Another company offers a product to be used in the preop screening process. It is a disposable battery-powered plastic strip worn overnight with thermal sensors in front of the nose and mouth that senses breathing pattern and efficiency in a manner that allows the indicator to analyze for the presence of OSA, even the night before surgery. The strip “develops” automatically in the morning and reveals a rating for OSA risk that can be incorporated into the anesthetic plan.

The problem of unintended baro- or volu-trama from leaving the anesthesia machine in manual ventilation mode with the APL (“pop-off”) valve completely closed (usually immediately following intubation) while distracted (say, taping in the tube) can now be addressed with a relatively simple new “ventilator safety valve” that goes between the breathing circuit tubing and the absorber head. It will automatically vent gas from the circuit if pressure exceeds 20 cm H<sub>2</sub>O for more than 6 seconds, thus preventing the accidental over-inflation of the breathing bag to dangerously high pressure and sometimes a startlingly large volume.

One other main theme of the technical exhibits was information management systems, for which there were 23 companies displaying products. One new entry comes from New Zealand (American headquarters in Nashville) that has automated patient data and an electronic anesthesia record but whose main focus is patient safety through preventing intra-op medication errors. Special drug carriers and organizers, bar-coded syringes, a bar-code reader, and a touchscreen are all integrated into a system that preliminary studies show decreases intraoperative anesthetic drug errors by 41%. Other systems had the expected screens, software, and printers, all with the similar claim that complete, organized, legible information about the anesthetic is, by definition, a safety benefit.

Other interesting new products with slightly indirect patient safety positive implications were seen among the displays. A spring-loaded color-coded syringe to be used to identify the epidural space with loss of resistance to saline automatically and definitively during slow advancement of a Touhy needle appeared to attract significant attention. Regarding maintenance IV infusions of propofol, either for TIVA or sedation, the propofol blood level can be monitored directly by measuring it in real time in the expired breath using a new detector based on “ion molecule reaction mass spectrometry.” A new twist was the new availability of ultrasound machines for purported anesthesia applications; several companies had such offerings.

Finally, in a different vein, an interesting new product was displayed that visibly identifies vessels under the skin, greatly facilitating the cannulation of either subject veins or arteries. Near infra-red light in a special delivery system is focused on the skin, which shows green with the underlying vessels clearly visible as dark outlines. The initial offering is a roll-around stand with the device (a little smaller than a football) on an articulating arm; however, company representatives state that a hand-held model is in development.

Overall, patient safety remained a key focus of both types of exhibits at the ASA Annual Meeting. This recognizes both the current success in improving safety and also the significant challenges still remaining, such as, for example, in making genuine changes in practice, leading to lower risk of patient injury associated with issues in airway management.

*Dr. John Eichhorn, Professor of Anesthesiology at the University of Kentucky, founded the APSF Newsletter in 1985 and was its editor until 2002. He remains on the Editorial Board and serves as a senior consultant to the APSF Executive Committee.*

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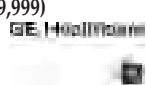


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In memory of Dr. Anthony J. DiGiovanni (Texas Society of Anesthesiologists)  
In memory of Laurie A. Noll, MD (The Coursin family)  
In memory of June Thomas (Sunrise Trauma Anesthesia and Resuscitation Services)  
In memory of Leroy D. Vandam (Dr. and Mrs. George Carter Bell)

## Dear SIRS

# Reader Seeks Standards for Equipment Check

**S**AFETY  
**I**NFORMATION  
**R**ESPONSE  
**S**YSTEM



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

**Dear SIRS** refers to the **Safety Information Response System**. The purpose of this column is to allow expeditious communication of 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 2004 issue.

### Dear SIRS:

I am a retired member of the ASA. I am involved in Q/A in the Department of Anesthesia of Lenoir Memorial Hospital in Kinston, NC.

We have found that there are no specific current standards for checking of equipment prior to the start of an anesthetic. We do have departmental safety requirements that are met.

Are there guidelines or standards of which we are not aware? Please advise me of any current standards. The last standards are 1993 and hence those are out of date. As part of our Q/A we meet JCAHO requirements, hospital policies, and departmental rules and regulations. However, as previously stated, we are looking for national standards regarding equipment check.

Robert J. Dean, MD  
Kinston, North Carolina

### In Response:

While it is common sense and good practice to check equipment prior to using it, there are a few specific guidelines and standards that address this topic, which I have summarized below. The anesthesia literature reminds us that the incidence of pure anesthesia equipment failure is rare, while human error is much more frequent, with a failure to check being most likely.<sup>1-4</sup> Therefore, the real question becomes not "Should we check?" but rather "What, how, and how often should we check, and who should perform the check?"

Operator Manuals from both Dräger Medical, Inc. and Datex-Ohmeda/GE Healthcare contain instructions for preoperative checklists. For example, the Datex-Ohmeda Aestiva has one for "Everyday before the first patient," "Every time a different clinician uses the system," and "Before every patient." The Dräger Fabius Tiro has "Daily" and "Pre-use" checkout forms. Ideally, each anesthesia provider should follow the guidelines and frequency specified in the Operator Manual, but, realistically, this is not the common practice.<sup>5</sup>

The active standard for anesthesia machines/workstations in the United States is ASTM F1850-00 (2005): *Standard Specification for Particular Requirements for Anesthesia Workstations and Their Components*. The specification states that each anesthesia workstation shall have a checklist(s) from the manufacturer to be performed prior to each use. This is in agreement with IEC 60601-2-13:2003, the international standard for anesthesia machines. Both

documents state that attention should be paid to any additional checklists established by regional or national medical associations, or government agencies.

The ASA 2004 Guidelines for Office-Based Anesthesia, Monitoring, and Equipment state that, "All equipment should be maintained, tested and inspected according to the manufacturer's specifications." These guidelines, however, do not specifically address non-office-based locations, but do reiterate the suggestion to follow the manufacturer's recommendations.

The AANA 2002 Scope and Standards for Nurse Anesthesia Practice states in Standard VIII: "Adhere to appropriate safety precautions, as established within the institution, to minimize risks of fire, explosion, electrical shock and equipment malfunction. Document on the patient's medical record that the anesthesia machine and equipment were checked." The interpretation of Standard VIII states, "Prior to use, the CRNA shall inspect the anesthesia machine and monitors according to established guidelines. The CRNA shall check the readiness, availability, cleanliness and working condition of all equipment to be utilized in the administration of the anesthesia care. . . ."

JCAHO Standard EC.6.10 states, "The hospital manages medical equipment risks," with the rationale that, "Medical equipment is a significant contributor to the quality of care. . . . It is essential that the equipment is appropriate for the intended use; that staff, including licensed independent practitioners, be trained to use the equipment safely and effectively, and it is essential that the equipment is maintained appropriately by qualified individuals."

In summary, studies show that "failure to check" equipment is causative in many adverse events; the ASTM standard says manufacturers shall include a pre-anesthesia checklist as part of their labeling; the ASA says we should test equipment as per the manufacturer's specifications in office based anesthesia; the AANA says the CRNA shall check all equipment prior to use; and JCAHO says it is the hospital's role to ensure that staff be trained to use equipment safely and effectively. One hopes that, upon publication of the new FDA pre-anesthesia checkout (discussed below) and adoption by both ASA and AANA, this lack of a uniformly accepted practice standard will be addressed. The bottom line is that anesthesia providers should follow the recommendations of their professional organizations and the institutional policy regarding the

See "Checkout," Next Page

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# Practice Alert is Needed and Anticipated

## “Checkout,” From Preceding Page

pre-anesthesia checkout of their equipment. This is the safest practice in my opinion.

*Sincerely,*

Carolyn G. Holland, CRNA, MSN  
Representative of AANA, ASA Task Force on the Pre-Anesthesia Checkout Recommendation  
Visiting Assistant Professor  
University of Cincinnati  
College of Nursing  
Cincinnati, OH

## In Response:

Dr. Dean is correct that there are no current standards for checking anesthesia equipment prior to use. The 1993 document entitled “Anesthesia Apparatus Checkout Recommendations” is only a “recommendation” and was promoted officially by the FDA not by the ASA or AANA. Although the 1993 FDA Recommendations are aging, the steps outlined in that document still apply to much of the equipment currently in use. They are, however, obsolete for the newer designs that have changed the architecture of the system and/or rely upon automated checkout procedures. For that reason, the ASA Committee on Equipment and Facilities formed a task force in 2003 to formulate an approach to pre-anesthesia checkout procedures that is relevant for modern equipment and practice.<sup>5</sup>

I believe that the precedent of the 1993 FDA Recommendations establishes a continuing responsibility to check. Other than brief mentions in the Guidelines for Office-Based Anesthesia, and the 2005 ASA Manual for Anesthesia Department Organization and Management (MADOM, <http://www.asawe-bapps.org/docs/2005MADOM.pdf>, page 109), which states that appropriate checklists “should be” available in a department’s manual, the ASA website does not have anything else in the practice parameters, standards, or guidelines sections.

The task force on revising the pre-anesthesia checkout procedures is in the process of finalizing what we hope will be accepted as a new approach to the pre-anesthesia checkout. Guidelines for designing the checkout have been developed that apply to modern anesthesia delivery systems as well as older, more traditional, equipment. Lessons learned regarding patient safety have been incorporated into the guidelines including an emphasis on checking backup ventilation equipment, ensuring that alarms are functional, and creating redundant checks for critical items to minimize the potential for human error. An important aspect of the new recommendation is to encourage utilizing technicians for some checkout procedures when feasible to reduce the burden on the provider and hopefully improve compliance.

The FDA is once again interested in evaluating and possibly endorsing the new recommendation. Documents will also be submitted to ASA, AANA, and ASATT leadership for consideration and adoption as appropriate into society guidelines or standards. We have learned over the years that failure to check equipment can threaten patient safety. I believe there is little question that appropriate checkout procedures are an important aspect of safe practice. The new pre-anesthesia checkout recommendations will likely be published in the upcoming year. Whether these recommendations are ultimately accepted as practice standards or not, it is incumbent on each individual practitioner to take the responsibility of the pre-anesthesia checkout seriously. The new design guidelines will hopefully become a useful resource to support that goal.

*Sincerely,*

Jeffrey M. Feldman, MD  
Chair, ASA Task Force on the Pre-Anesthesia Checkout Recommendation  
Division Chief, General Anesthesia  
Dept of Anesthesiology and Critical Care Medicine  
Children’s Hospital of Philadelphia  
University of Pennsylvania School of Medicine

## In Response:

Several changes have occurred since the last widely accepted Anesthesia Apparatus Checkout Recommendations were published by the FDA 13 years ago. Anesthesia machines and workstations have become more flexible, user friendly, and now include more design safety features and often so-called “automated” checkout procedures. However, they have also become more complex, with significant differences in design among manufacturers and even among machine models. At the same time, the anesthetic environment has also evolved, to include a larger number of ambulatory and office-based procedures with a higher volume of rapid cases and demands for efficiency.

Both of these developments have decreased the use of the 1993 checklist, and indeed any pre-use check. Lamportang and colleagues, in 2005, found that only 38% of the anesthesia providers they surveyed rated their competence in performing the 1993 FDA checklist as “good” or “excellent,” and less than 25% still perform a pre-use machine check before each procedure.<sup>5</sup> The most frequent reasons cited for not performing a check include, “The checklist takes too long to perform,” “I do not know how to perform a proper pre-use check,” and “My anesthesia machine has an automated pre-use check and does it for me.”

However, the need for a pre-use check is greater than ever. Therefore, the ASA Committee on Standards and Practice Parameters, and the Committee on Equipment and Facilities are drafting a “Practice

Alert.” This alert will emphasize the necessity of 1) adequate training and demonstrated competence in the use of each model of machine a practitioner uses to deliver anesthetics to patients, and 2) a routine pre-use machine check, performed according to institutionally-established standards, prior to each anesthetic. We would expect the submission of this Practice Alert to ASA for approval this year.

*Sincerely,*

Donald E. Martin, MD  
Chair, ASA Committee on Equipment and Facilities  
Professor of Anesthesiology  
Vice-Chair for Academic and Faculty Development  
Department of Anesthesiology  
Penn State University College of Medicine  
Hershey, PA

## Co-Editor’s Note:

Dr. Robert J. Dean of Kinston, NC, has asked a very timely question. There are 2 issues that concurrently developed and merged into the proposed Practice Alert, described by Dr. Martin above. One issue was published in the previous edition of the *Newsletter*,<sup>6</sup> and described the challenges and success of a pilot study on mandated anesthesia machine training. Since that publication, the APSF leadership has described a new Initiative to investigate a widespread implementation of mandated machine training programs. You can read about that Initiative on the APSF Website at [http://www.apsf.org/initiatives/technology\\_training.msp](http://www.apsf.org/initiatives/technology_training.msp). The second issue, of course, was the effort by Dr. Feldman and his Taskforce to re-engineer the checkout recommendations as described above. Thus, it is hoped these concurrent and related safety efforts will soon lead to some version of a Practice Alert, encouraging anesthesiologists to not only check their machine, but also to learn how to operate and understand it thoroughly. As the benefits and feasibility of implementing such training programs are described, one could hope for an emerging Standard of Care.

*Dr. Michael A. Olympio*

*Chair, APSF Committee on Technology*

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NEW

## Q &amp; A

Numerous questions to the Committee on Technology are individually and quickly answered each quarter by knowledgeable committee members. Many of those responses would be of value to the general readership, but are not suitable for the Dear SIRS column. Therefore, we have created this simple column to address the needs of our readership.

**Q** Dear Q&A,

We have a new GE Datex-Ohmeda Aestiva/5 anesthesia machine. The isoflurane Tec 7 vaporizer has a concentration dial in turquoise, but a purple color patch near the filling spout (see photo insert). Isoflurane bottles are, of course, purple. The sevoflurane Tec 7 vaporizer has its dial also in turquoise, but a yellow color patch near the filling spout. Sevoflurane bottles are, of course, yellow.

Since their introduction to the GE market, sevoflurane Tec 7 vaporizers have always had a distinguishing turquoise dial. For me, seeing this same color dial now on the isoflurane vaporizer is very confusing. I surmise that these turquoise colored dials are due to color aesthetics (the GE Datex-Ohmeda logo is turquoise).

To avoid this confusion, it seems reasonable for isoflurane vaporizers to have a purple dial, and for sevoflurane vaporizers to have a yellow dial. This would avoid volatile anesthetic color-coded confusion.

Sincerely,  
Heddy-Dale Matthias, MD  
Madison, MS

**A** Dear Dr. Matthias,

When designing the Tec 7 vaporizer, we recognized the need for easier identification of drug variant as compared to the Tec 5 vaporizer, which only had a very small label on the front cover. Given that goal, we added the agent color along with a generic drug reference to the sight glass area and agent color reference surrounding the agent filler areas. In clinical tests conducted at a major medical center in Chicago, clinicians were easily able to identify the agent variant from across the room (from one corner of the OR to the other).

When determining what color the dial strip and agent concentration dial should be, we chose the teal green for several reasons. One

would be for the Datex-Ohmeda branding guidelines, but the other was for a clinician therapy reference. Under Datex-Ohmeda design guidelines, all clinical therapy touch points were teal green. This color plan appeared on ventilator control knobs and monitor control knobs and was carried onto the vaporizer concentration dial. The idea was that clinician therapy-related touch points would appear in this teal green color. If you recall on the Tec 5 and older vaporizers, the concentration dial and dial strip were black.

From a quality and customer feedback standpoint, we have received no complaints on the Tec 5 variants with the black agent concentration dial or on the Tec 7 with the teal agent concentration dials reflecting inability to identify vaporizer agent variant.

I hope this explanation helps.

Jane Gilbertson  
Global Product Manager  
GE Healthcare, formerly Datex-Ohmeda

**A** Dear Dr. Matthias,

ECRI has never heard of a similar complaint, and no reports are listed in our databases. We tend to agree with those whose responses can be summarized as, "It doesn't seem like a significant problem." Teal/turquoise is the color that Datex-Ohmeda uses in a few places on its otherwise off-white anesthesia units. The D-O response indicates that this color identifies controls that the user would adjust or touch, and while we've seen no discussion measuring the effectiveness of the approach, we've never considered it particularly harmful. The fact is that the color in question isn't related to any existing agent, so we're puzzled that one would make such an association. The standard color-coding is still displayed prominently on the face of the vaporizer, and that's long been a method of identification. Additionally, with any medical gas, the color is one indicator but the definitive indicator is the label; we think similar thinking applies here. The position of

the vaporizer on the anesthesia machine puts the agent color indicators and labeling at about eye level and the teal adjusting knob above eye level making it less likely to confuse the agent and the adjustment. This is reasonable human factors design. Finally, although refilling errors (i.e., filling a vaporizer with the incorrect agent) occur on occasion, we believe that the current scheme of unique connectors, color indicators, and labeling makes an error unlikely even if the user initially mistakes the teal dial as representing a particular agent. The vaporizer picture below is worth a thousand words and might be useful in the newsletter in explaining this question.

Albert L. de Richemond, MS, PE  
Associate Director  
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The GE Healthcare, formerly Datex-Ohmeda Tec 7 Vaporizer with teal concentration dial and agent-specific color coding near the agent filler and sight glass areas. Photo courtesy of GE Healthcare, with permission.

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# A Protocol for the Perioperative Management of Patients With Intracoronary Drug-Eluting Stents

by Lisa T. Newsome, MD, Michael A. Kutcher, MD,  
Sanjay K. Gandhi, MD, Richard C. Prielipp, MD, and  
Roger L. Royster, MD

## History of Coronary Stents

Since the introduction of percutaneous transluminal coronary angioplasty (PTCA) by Gruntzig in 1977, major advancements have been made in the clinical practice of percutaneous coronary intervention (PCI). Puel and Sigwart, in 1986, deployed the first coronary stent to act as a scaffold, thus 1) preventing vessel closure during PTCA, and 2) reducing the incidence of angiographic restenosis, which had an occurrence rate of 30-40%.<sup>1</sup> By 1999, stenting composed 84.2% of all PCIs.<sup>1</sup> Despite the widespread use of these devices, bare metal stents (BMS) have been associated with a 20-30% restenosis rate requiring reintervention.<sup>2,3</sup> Restenosis occurs as a result of neointimal hyperplasia—growth of scar tissue within the stent—due to the proliferation and migration of vascular smooth muscle cells. This phenomenon is clinically evident within the first 6-9 months after stent placement, and occurs in response to strut-associated injury and inflammation.<sup>2</sup>

In addition to restenosis, PTCA and BMS implantation cause exaggerated endothelial injury and inflammation, rendering both the stent and vessel highly thrombogenic.<sup>4,5</sup> A fibrinogen layer covers the stent surface, further inducing platelet activation and thrombosis. Adjunctive anti-platelet medication is crucial in preventing local coronary thrombosis, myocardial infarction (MI), and death.<sup>5</sup> Current recommendations for patients with BMS include dual anti-platelet therapy with aspirin and clopidogrel, which are continued for 6 weeks to allow complete endothelialization of BMS.<sup>6</sup> Wilson et al. in 2002 reported similar findings in patients who underwent noncardiac surgery.<sup>7</sup> The incidence of MI and death were significantly lower among

patients who underwent surgery after their 6-week course of aspirin and clopidogrel were completed.

In 2001, drug-eluting stents (DES) were introduced as a strategy to minimize restenosis and requirement for reintervention. The currently available polymer-coated stents contain antiproliferative agents which elute locally in the implanted coronary artery to prevent neointimal hyperplasia. Initial animal studies demonstrated a clear benefit over BMS (4-6% restenosis versus 20-30%), and early clinical trials further supported this.<sup>2,8</sup> In addition, at 2-year follow-up using both angiography and ultrasound, the clinical safety of DES was further established with minimal late lumen loss observed.<sup>9</sup> A recent pooled analysis demonstrated a 74% reduction in the risk of target lesion revascularization for both sirolimus-eluting stents (SES) and paclitaxel-eluting stents (PES) compared to BMS.<sup>10</sup> At present, 90% of all stents placed in the United States and Europe are DES.

Despite the enthusiasm that resulted with the advent of DES, incomplete endothelialization and stent thrombosis continue to plague these devices. Initial animal studies demonstrated complete endothelialization with BMS at 28 days, whereas **DES uniformly showed incomplete healing at 180 days.**<sup>11</sup> Based on early observations in both animal and human studies, it was recommended that patients with DES receive dual anti-platelet therapy with aspirin and clopidogrel for at least 3-12 months, followed by life-long aspirin therapy, depending on the stent placed and the pre-existing comorbidities which further increase the risk of stent thrombosis.<sup>12,13</sup> Despite this regimen, late stent thrombosis (LST)—defined as occurring >30 days post-stent insertion—remains a significant complication in patients with DES. Late stent thrombosis carries a 45% mortality rate.<sup>14,15</sup> It presents as an ST-segment elevation myocardial infarction (STEMI) or sudden death. Late stent thrombosis has been documented in both clinical and autopsy studies in

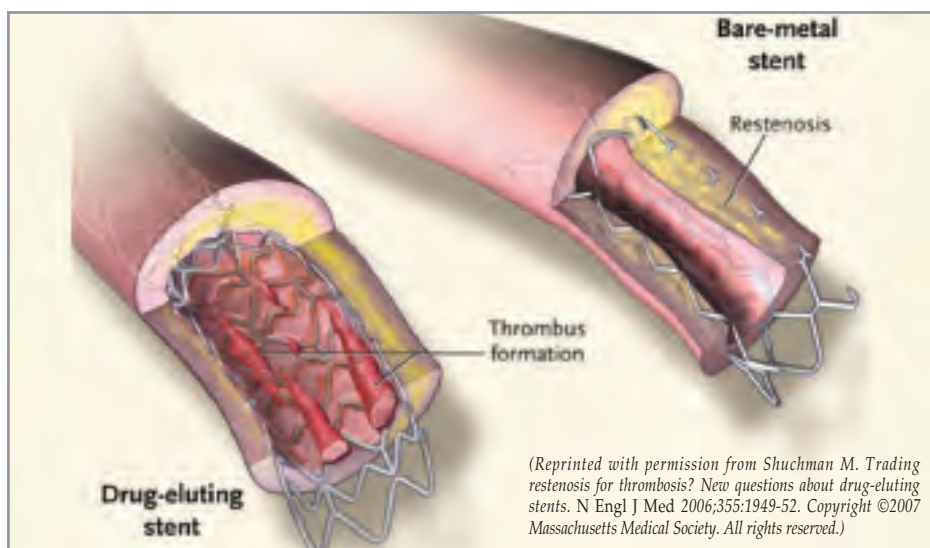
patients as far as 4 years after stent insertion.<sup>14-16</sup> Further, LST is associated with the 1) discontinuation of clopidogrel ± aspirin, 2) stable aspirin monotherapy, or 3) a hypersensitivity reaction to the stent polymer, or to the antiproliferative agent (sirolimus vs. paclitaxel).<sup>10-15</sup> A recently published study reported that patients with DES implanted had significantly increased rates of death when clopidogrel was discontinued at 6-, 12-, and 24-months when compared to patients who remained on this therapy at the same time intervals.<sup>16</sup>

## Coronary Stents and Surgery

Patients with DES pose a particular dilemma in the perioperative period. Current recommendations include delaying noncardiac surgery until the course of dual anti-platelet therapy is complete. Based on current clinical and autopsy findings, it is unclear how long dual anti-platelet therapy must continue to prevent LST.<sup>13-18</sup> It is clear, though, that patients must remain on aspirin forever. This scenario is particularly challenging to us as anesthesia providers, as there are no guidelines currently to manage these patients perioperatively. The perioperative period is especially problematic because 1) surgery induces a hypercoagulable state; 2) surgeons often stop aspirin ± clopidogrel preoperatively to minimize the risk of surgical bleeding, but without consulting their patients' cardiologists; and 3) there is a high likelihood that the DES are not yet endothelialized. Thus, each DES patient, if stent thrombosis occurs, has a 45% chance of dying perioperatively. There are 3 points to consider: 1) transition of dual anti-platelet therapy in the perioperative period; 2) returning patients to their regimen as soon as possible postoperatively; 3) maintaining these patients on aspirin throughout the entire perioperative period, since perioperative STEMI and death have been associated with the discontinuation of aspirin in these patients.<sup>10</sup>

## Our Current Approach to Perioperative Patients With Stents

We collaborated with the interventional cardiologists at Wake Forest University Health Sciences to develop a strategy to best manage these patients. Our protocol includes utilizing both eptifibatide (Integrilin, a GP IIb/IIIa inhibitor) and heparin as "bridging therapy" to prevent stent thrombosis in the perioperative period. Both medications are necessary in order to 1) prevent platelet activation and adhesion (eptifibatide) and 2) prevent thrombin formation (heparin), which again causes platelet activation and clot formation. Both eptifibatide and heparin have short half-lives, necessitating these drugs to be given as intravenous infusions. Further, both drugs can be stopped 6 hours prior to surgery with complete return of platelet function and coagulation. Cooperation between anesthesiology, cardiology, and surgery are of the utmost importance. The surgeon may elect to proceed with surgery



Drawing of intraluminal view of bare-metal stent compared to drug-eluting stent.

See "Stents," Next Page

# Late Thrombosis is Risk With Drug-Eluting Stents

## “Stents,” From Preceding Page

while the patient remains on clopidogrel and aspirin. Alternatively, if the surgeon feels that perioperative clopidogrel will be deleterious in terms of increased surgical bleeding, then the following protocol will be instituted:

- The following information must be obtained from the patient’s cardiologist:
  - Type(s) of DES placed and date of procedure
  - any complexities associated with stent placement (bifurcations, coronary vessel diameter, total stent length)
  - comorbidities: renal failure, diabetes, depressed ejection fraction.
- Clopidogrel is discontinued 5 days prior to surgery (a cardiology consult should be obtained prior to discontinuation of clopidogrel).
- Aspirin must be continued throughout the perioperative period.
- The patient will be admitted to the appropriate surgical service 2 days prior to surgery to receive bridging therapy (eptifibatide and heparin) and prevent stent thrombosis.
- The bridging therapy will be initiated according to the paradigm shown in Table 1.
- IV eptifibatide and heparin infusions will be discontinued 6 hours prior to surgery to 1) facilitate normal intraoperative platelet function and coagulation, and 2) allow for regional anesthetic techniques to be performed preoperatively.
- Upon agreement between cardiology and surgery, clopidogrel/eptifibatide will be readministered as soon as possible postoperatively (preferably, the postoperative night):
  - clopidogrel loading dose: 600 mg p.o.
  - clopidogrel maintenance dose: 75 mg p.o. daily
  - eptifibatide infusion will be restarted according to the above paradigm if clopidogrel cannot be reintiated.

In conclusion, DES represents the most current therapy in interventional cardiology. However, late stent thrombosis is a major problem with these devices. In fact, the FDA has recently reviewed the safety of these devices, and new recommendations regarding dual anti-platelet therapy may be forthcoming. By utilizing a combination of eptifibatide, heparin, and aspirin, the risk of stent thrombosis will be markedly reduced in the perioperative period. However, we will continue to address and modify our therapeutic approach as the dynamic nature of this subject continues to evolve. This is an important patient safety issue because of the high mortality rate if stent thrombosis occurs.

**Editor’s Note:** While this issue of the APSF Newsletter was in production, a pre-publication scientific advisory from the American Heart Association was released electronically. This advisory addresses the issue of premature discontinuation of antiplatelet drugs in patients with drug-eluting stents, including patients presenting for non-cardiac surgery. The Advisory will be published in the February 13, 2007 issue of Circulation.

Table 1: Eptifibatide Dosing Chart


Eptifibatide (Integrilin) Dosing	Loading Dose	Infusion Rate
Patients with Normal Renal Function	180 mcg/kg IV	2.0 mcg/kg/min IV
Patients with serum creatinine >2.0 mg/dl or creatinine clearance <50 ml/min	180 mcg/kg IV	1.0 mcg/kg/min IV


Intravenous heparin infusion will be initiated to maintain a PTT of 70-90 seconds

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Dr. Royster is Professor and Executive Vice Chair, Department of Anesthesiology, Dr. Newsome is Assistant Professor of Anesthesiology, Dr. Gandhi is Assistant Professor of Cardiology, and Dr. Kutcher is Associate Professor of Cardiology—all are faculty at Wake Forest University Health Sciences, in Winston-Salem, NC. Dr. Prielipp is the J.J. Buckley Professor and Chair, Department of Anesthesiology at the University of Minnesota in Minneapolis, MN and Chair of the APSF Committee on Education.





**SECTION EDITOR, PATIENT SAFETY**



The Anesthesia Patient Safety Foundation (APSF) is pleased to accept applications for Section Editor, Patient Safety, of our organization’s new official scientific journal, *Anesthesia & Analgesia*. Candidates should be leaders in anesthesiology, with specific expertise and experience in patient safety, including a national and/or international reputation for research and contributions to patient safety within anesthesiology. Candidates should also have experience in medical editing, and proven administrative and organizational skills.

The duties of the Section Editor for Patient Safety include (1) handling of approximately 50 manuscripts per year, (2) providing an annual report, (3) attending at least one APSF Board of Directors meeting per year, (4) attending the *Anesthesia & Analgesia* Editorial Board meeting, and (5) commissioning review articles, updates, annual meeting reports, and other articles related to patient safety in *Anesthesia & Analgesia*.

*Anesthesia & Analgesia*, the first scientific publication in the field of anesthesiology, is the journal of the Anesthesia Patient Safety Foundation, the International Anesthesia Research Society, the Society of Cardiovascular Anesthesiologists, the Society for Pediatric Anesthesia, the International Society for Anaesthetic Pharmacology, and the Society for Technology in Anesthesia.

Interested candidates should electronically submit their curriculum vitae to

Robert K. Stoelting, MD  
Stoelting@apsf.org

## Letter to the Editor

# Oxygen Gradient Hypothetical Means to Detect Malignant Hyperthermia

## To the Editor:

Dr. Rosenberg and Mr. Rothstein should be commended for their sensitive and in-depth report on the unfortunate circumstances surrounding the death of a healthy, young man from malignant hyperthermia (MH).<sup>1</sup> The authors summarize 3 main factors as being responsible for the decline in mortality from MH over the past several years: education of the anesthesia community, the routine measurement of exhaled carbon dioxide and body temperature, and the US FDA approval of dantrolene sodium IV for the treatment of MH in 1979. Despite these advances, MH remains a potentially lethal, ever-present danger during general anesthesia as shown by this case report.

We would like to draw attention to another potentially sensitive monitoring parameter that could aid in the earlier detection of an impending MH crisis.

Inspired oxygen concentration (FiO<sub>2</sub>) is routinely monitored during general anesthesia. In addition, during the last decade, end-tidal oxygen concentration (FeO<sub>2</sub> monitoring) has also become available. With the fast response paramagnetic oxygen sensors that are now integrated into most anesthesia gas monitoring systems (such as the Phillips M1026B AGM), we can analyze breath-by-breath end-tidal oxygen concentrations. The "oxygen difference" calculated as the F (inspired - end-tidal) O<sub>2</sub> is a very sensitive measure of metabolism and ventilation.<sup>2,3</sup> This oxygen difference reflects the overall balance between alveolar oxygen consumption and oxygen delivery. Metabolism influences oxygen removal from the alveoli and ventilation influences oxygen entry into the alveoli. The measurement of adequate ventilation in relation to oxygen consumption or the VO<sub>2</sub>/VA ratio shows good correlation with the oxygen difference.<sup>4</sup>

Pathophysiologically, MH is a skeletal muscle hypermetabolic syndrome that is associated with increasing O<sub>2</sub> consumption and CO<sub>2</sub> production. Clinically, a rise in exhaled CO<sub>2</sub> is typically seen in the early stages of MH. However, we know that tissue stores of CO<sub>2</sub> far exceed those of O<sub>2</sub>.<sup>5</sup> In addition, the body has tremendous ability to buffer CO<sub>2</sub> but lacks O<sub>2</sub> buffering systems. Therefore, the rise in the alveolar CO<sub>2</sub> concentration with MH will be slower than the fall in alveolar O<sub>2</sub> concentration.<sup>3</sup> So, when CO<sub>2</sub> production and O<sub>2</sub> consumption abruptly increase in MH, the increase in the removal of oxygen from the alveoli should effectively widen the F (inspired - end-tidal) O<sub>2</sub> differ-

ence quickly. We believe that such an increasing oxygen difference under general anesthesia could be an earlier marker for MH. Further, we believe that this oxygen difference will change faster and more (as a percentage change from its initial value) than the changes in end-tidal CO<sub>2</sub>. Finally, as the alveolar CO<sub>2</sub> levels start to rise while maintaining the same minute ventilation (i.e., a state of relative hypoventilation), the oxygen difference should increase even more. The following equation will help explain our assertions: VO<sub>2</sub> = VA \* F (inspired - end-tidal) O<sub>2</sub>.<sup>2</sup>

In MH, the increase in VO<sub>2</sub> and relative decrease in VA will result in an increasing oxygen difference. While the FiO<sub>2</sub> will influence FeO<sub>2</sub> measurements, the oxygen difference should be usable at any given FiO<sub>2</sub>. At the FiO<sub>2</sub> settings used during most general anesthetics (i.e., 30-60%), this oxygen difference parameter will be within the sensitive range of the paramagnetic oxygen sensors. In addition, the oxygen difference may be influenced by changes in cardiac output, hemoglobin concentration, arterial oxygen saturation, and changes in anesthetic state. These parameters will need to be considered while interpreting changes in the oxygen difference.

In conclusion, we suggest that our hypothesis be tested in an experiment. This experiment could be designed to evaluate whether changes in oxygen difference occur earlier than changes in end-tidal CO<sub>2</sub> during an MH episode. Use of an animal model for MH such as the pig model would be ideal. Simultaneous measurements of FiO<sub>2</sub>, FeO<sub>2</sub>, FeCO<sub>2</sub>, invasive monitoring of arterial pressures and blood gases, and cardiac output should be carried out and the effects of MH on these measures can then be studied. We appeal to the larger university hospitals/MH research laboratories to consider such a study. If we find that empirical observations confirm our hypothesis, we will be able to use a currently available monitoring parameter to detect or suspect MH at an earlier stage. This will move us closer to the goal of safer anesthesia for all patients.

Karthik Raghunathan, MD, MPH  
Gary Kanter, MD  
Sajid Shahul, MD  
Springfield, MA

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## In Reply:

I appreciate the comments concerning measurement of oxygen consumption during anesthesia as a marker for the hypermetabolic response that is the hallmark of malignant hyperthermia (MH).

The suggestion that the difference between inspired and end-tidal oxygen would indicate an increase in oxygen consumption provided that minute ventilation is kept constant is quite reasonable in the same way that measurement of end-tidal carbon dioxide is used as an indicator of metabolic rate.

For more accurate measurement of oxygen consumption, mixed expired oxygen tension measurement would be needed. I do not believe that current anesthesia monitors have a built-in mixing chamber in order to obtain mixed expired values.

For that reason the proposed experiment is reasonable and should include mixed expired oxygen measurement as well.

Henry Rosenberg, MD, CPE  
Mount Sinai School of Medicine

**New Website Feature**

## APSF Question of the Month

[www.apsf.org](http://www.apsf.org)

Take our Safety Poll and  
answer the safety question  
of the month.

Register your answer and  
view results of the poll online.

# Anesthesia Patient Safety Foundation (APSF) 2007 GRANT PROGRAM

## Guidelines for Grant Applications Scheduled to Start January 1, 2008

The **Anesthesia Patient Safety Foundation (APSF) Grant Program** supports research directed toward enhancing anesthesia patient safety. Its major objective is to stimulate studies leading to prevention of mortality and morbidity resulting from anesthesia mishaps.

**NOTE: The grant award limit has increased to \$150,000 per project (including up to 15% institutional overhead). Additionally, there have been changes in areas of designated priority, in requirements for materials, and specific areas of research. For the current funding cycle, APSF is placing a specific emphasis on PATIENT SAFETY EDUCATION and MEDICATION ERRORS.**

To recognize the patriarch of what has become a model patient safety culture in the United States and internationally, the APSF inaugurated in 2002 the **Ellison C. Pierce, Jr., MD, Research Award**. The APSF Scientific Evaluation Committee will designate one of the funded proposals as the recipient of this nomination that carries with it an additional, unrestricted award of \$5,000.

APSF is also proud to announce the availability of two named awards, **made possible by generous, unrestricted grants of \$150,000 each:**

- **Anesthesia Healthcare Partners (AHP) Research Award**
- **Cardinal Health Foundation Award.**

### PRIORITIES

The APSF accepts applications in one of two categories of identified need: **CLINICAL RESEARCH and EDUCATION AND TRAINING.**

Highest priority is given to

- Studies that address peri-anesthetic problems for relatively healthy patients; or
- Studies that are broadly applicable AND that promise improved methods of patient safety with a defined and direct path to implementation into clinical care; or
- Innovative methods of education and training to improve patient safety; or
- Innovative methods of studying processes that lead to medication errors.

### AREAS OF RESEARCH

Areas of research interest include, but are not limited to

- New clinical methods for prevention and/or early diagnosis of mishaps including medication errors;
- Evaluation of new and/or re-evaluation of old technologies for prevention and diagnosis of mishaps;
- Identification of predictors of negative patient outcomes and/or anesthesiologist/anesthesiologist assistant/anesthetist clinical errors;
- Development of innovative methods for the study of low-frequency events;
- Measurement of the cost effectiveness of techniques designed to increase patient safety;
- Development or testing of educational content to measure, develop, and improve safe delivery of anesthetic care during the perioperative period; and
- Development, implementation, and validation of educational content or methods of relevance to patient safety (NOTE: both patient and care provider educational projects qualify).

### REVIEW PROCESS

Applications will be accepted electronically ONLY (see below). All completed applications will

be distributed to members of the Scientific Evaluation Committee (SEC) who will score applications on a priority scale (1 – highest priority; 5 – lowest priority). Applications that do not meet APSF criteria will be disallowed and given a score of 8. Applications that attain sufficient priority will then be selected for full-committee presentation and scoring. This second round of reviews takes place at the full Scientific Evaluation Committee meeting, which occurs in conjunction with the ASA Annual Meeting. Winners are announced at the APSF Board of Directors Meeting that is held on the Saturday of the ASA Annual Meeting.

### SCORING

Studies will be scored on

- Soundness and technical merit of proposed research with a clear hypothesis and research plan;
- Adequacy of assurances detailing the safeguarding of human or animal subjects;
- Uniqueness of scientific, educational, or technological approach of proposed research;
- Applicability of the proposed research and potential for broad health care adoption;
- Clinical significance of the area of research and likelihood of the studies to produce quantifiable improvements in patient outcome such as increased life-span, physical functionality, or ability to function independently, potential for reductions in procedural risks such as mortality or morbidity, or significant improvements in recovery time;
- Ability of research proposals to maximize benefits while minimizing risks to individual human research participants. Each proposal should prospectively enunciate the criteria for instituting rescue therapy whenever there is the remotest possibility of an untoward adverse event to a human research volunteer. In some instances, the rescue therapy may be triggered by more than one variable (e.g., duration of apnea [in seconds], oxygen saturation <90 %, etc.). Additionally, the protocol should specify the nature of the rescue procedure(s), including the rescue therapy and dosages, and the responsible personnel. If other departments are involved in the rescue process, the

application should specify if such departments are to be informed when a new volunteer is participating in the trial.

- Priority will be given to topics that do not have other available sources for funding.
- Proposals to create patient safety education content or methods that do not include a rigorous evaluation of content validity and/or benefit will be unlikely to attain sufficient priority for funding.

**NOTE:** Innovative ideas and creativity are strongly encouraged. New applicants are advised to seek guidance from an advisor/mentor skilled in experimental design and preparation of grant applications. Poorly conceived ideas, failure to have a clear hypothesis or research plan, or failure to demonstrate clearly the relationship of the work to patient safety are the most frequent reasons for applications being disapproved or receiving a low priority score.

### BUDGET

The budget request must not exceed \$150,000 (including a maximum of 15% institutional overhead). Projects may be for 2 years in duration, although shorter anticipated time to completion is encouraged.

### ELIGIBILITY

Awards are made to a sponsoring institution, not to individuals or to departments. Any qualified member of a sponsoring institution in the United States or Canada may apply. Only one person may be listed as the principal investigator. All co-investigators, collaborators, and consultants should be listed. Applications will not be accepted from a principal investigator currently funded by the APSF. Re-applications from investigators who were funded by APSF in previous years, however, will be accepted without prejudice.

Previous applicants are strongly encouraged to respond to the reviewers' comments in a letter indicating point-by-point how the comments and suggestions were addressed.

Applications that fail to meet these basic criteria will be eliminated from detailed review and returned with only minimal comment. A summary

See "Application," Next Page



# Grant Application Submission Date—June 18, 2007

## “Application,” From Preceding Page

of reviewers’ comments and recommendations will be provided to applicants only if requested from the Scientific Evaluation Committee Vice-Chair.

## AWARDS

Awards for projects to begin January 1, 2008, will be announced at the meeting of the APSF Board of Directors on Saturday, October 13, 2007 (2007 ASA Annual Meeting, San Francisco, CA).

**NOTE:** No award will be made unless the statement of institutional human or animal studies' committee approval is received by the committee prior to October 1, 2007.

## PAPERLESS APPLICATIONS

All applications and accompanying documents MUST INCLUDE

- application
- applicant's curriculum vitae
- applicant's acceptance form
- departmental chair letter of support
- budget justification; and
- Institutional Review Board approval or submission letter.

These documents will be accepted in **ELECTRONIC** Adobe PDF format only. Electronic files in PDF format are acceptable for all text, charts, and graphics, and must be uploaded to the APSF website:

<http://apsf.org/grants/application/applicant/>

Please follow the Application Format instructions carefully; applications not conforming to the requirements may be disallowed.

## APPLICATION FORMAT

### I. Cover Page

- A. Title of research project
- B. Designation of proposal as “Clinical Research” or “Education and Training”
- C. Name of applicant with academic degrees, office address, phone number, fax number, and e-mail address
- D. Name, office address, and phone number of departmental chairperson
- E. Sponsoring institution and name, office address, phone number, and e-mail address of the responsible institutional financial officer
- F. Amount of funding requested
- G. Start and end dates of proposed project.

II. **Research Summary**—a 1-paragraph description of the project.

III. **Research Plan** (limited to 10 pages, typed, double-spaced, excluding references; appendices are discouraged):

#### A. Introduction

1. Objectives of the proposed clinical research or education and training project.

2. Background: reference work of other authors leading to this proposal and the rationale of the proposed investigation or project. Describe the relationship to the priorities highlighted in the first paragraph of the APSF guidelines. Include copies of in-press manuscripts containing pilot data, if available.

3. Specific aims: what questions will be answered by the investigation? If applicable, what hypothesis will be tested? For an educational project, what are the specific learning objectives or objectives of the methodology being developed?

4. Significance and applicability: briefly describe the historical prevalence and severity of the morbidity and mortality of the studied anesthesia mishaps. Quantify the potential improvements in patient outcome or recovery time and identify how the proposed work can be broadly applied to reduce procedural risks in health care.

5. If the application is a resubmission, describe changes from the prior application, and specifically address the reviewers' comments point-by-point.

### B. Methods to be employed

1. Describe data collection procedure, specific techniques, and number of observations or experiments. For educational projects, describe how the effects of the intervention program will be assessed. Qualitative methodologies are acceptable.

2. Describe types of data to be obtained and their treatment, including statistical and/or power analyses, if indicated.

3. Point out and discuss potential problems and limitations of the project.

4. If appropriate, include a statement of approval of this proposal by the institutional committee reviewing human or animal investigations, or a statement that approval has been requested.

IV. **Budget**—include all proposed expenditures. Indicate under each category the amount requested or provided from other sources.

- A. Personnel (limit salaries of individuals to NIH Guidelines)
- B. Consultant costs
- C. Equipment
- D. Supplies
- E. Patient costs
- F. Other costs

- G. Total funds requested (including a maximum of 15% institutional overhead)

- H. Budget justification—CLEARLY and completely justify each item, including the role of each person involved in the project. If computer equipment is requested, explain why such

resources are not already available from the sponsoring department/institution. NOTE: Failure to adequately justify any item may lead to reduction in an approved budget.

- I. List all current or pending research support (federal, foundation, industrial, departmental) available for the proposed project to the principal investigator, his collaborators, or his mentor. List all other research support for the principal investigator, stating percentage of effort devoted to current projects, and percentage of effort expected for pending projects .

- J. List the facilities, equipment, supplies, and services essential for this project and indicate their availability.

V. **Abbreviated CV** (maximum of 3 pages) of the principal investigator only.

VI. **Letter from the departmental chairperson** indicating

- A. The number of working days per week available to the applicant for the proposed research, the degree of involvement of the applicant in other research projects, and the chair's degree of enthusiasm for the proposed project.

- B. The availability of facilities essential to the completion of the proposed research.

- C. An agreement to return unused funds if the applicant fails to complete the project.

VII. **Sign and date** the *Acceptance of Conditions* of the Grant form and upload this form as an Adobe PDF file to the website along with the application.

GUIDELINES FOR PREPARATION OF APPLICATIONS AND ELIGIBILITY REQUIREMENTS CAN BE OBTAINED FROM THE APSF WEB PAGE:

<http://www.apsf.org>

**The original application must be submitted electronically to the website no later than Monday, June 18, 2007. Once the completed application is uploaded, an automatic confirmatory e-mail will be generated and sent to the Chair of the Scientific Evaluation Committee:**

Sorin J. Brull, MD  
 Chair, APSF Scientific Evaluation Committee  
 Professor of Anesthesiology  
 Mayo Clinic College of Medicine  
 4500 San Pablo Road, JAB-4035  
 Jacksonville, FL 32224  
 Telephone: (904) 296-5688  
 Facsimile: (904) 296-3877  
 E-mail: [APSF-SEC@Mayo.edu](mailto:APSF-SEC@Mayo.edu)

Letter to the Editor

# Vial Look-Alikes Pose Risks

To the Editor:

My group does a lot of plastic surgery "office anesthesia." Recently, I came upon these 2 vial "look-alikes" that are used in almost every case, one by us and the other by the surgeon. We use Decadron very liberally as an IV push—about 2-3 mg. The other, epinephrine (1:1000), is used by the surgeons in their various dilute "local/tumescent" solutions, and could be potentially lethal in certain patients in a 2-3 mg push. I grabbed the epinephrine the other day in preparation for giving the Decadron. Fortunately, I checked the label.

*James G. Chapman, MD  
Jacksonville, FL*



# Wisconsin Team Receives Ellison C. Pierce, Jr., MD, 2006 Best Scientific Exhibit Award

Dr. Richard Prielipp (far right), Chair of the APSF Committee on Education and Training, presents the Ellison C. Pierce, Jr., MD, Award for the Best Scientific Exhibit at the 2006 ASA Meeting, in Chicago, IL. Left to right are Timothy N. Harwood, MD (APSF Education Committee) and Tricia A. Meyer, Pharm D (APSF Education Committee), Chad Vandrovec, MD, Neil Farber, MD, PhD, Roger Johnson CBET (from the Children's Hospital of Wisconsin, Milwaukee, WI), and Richard Prielipp, MD, MBA, FCCM (Chair of the APSF Education Committee). Their exhibit highlighted components of the anesthesia machine and how to avoid machine-related mishaps.



*Wisconsin team accepting their award.*

**Check out the Virtual Anesthesia Machine Website and the APSF Anesthesia Machine Workbook at [www.anest.ufl.edu/vam](http://www.anest.ufl.edu/vam)**



## Letters to the Editor

### *Air Embolism During Spine Surgery in the Prone Position*

#### To The Editor:

In 1995 we set up a registry<sup>1</sup> for reporting cases of venous air embolism (VAE) during spine procedures in the prone position. A recent case report also containing a literature review<sup>2</sup> revealed the existence of 20 cases of VAE as well as paradoxical air embolism (PAE) during spine procedures in the prone position in both adults and children. Surprisingly, 11 of the 20 died, with 8 of the deceased being pediatric patients. Our registry noted 9 probable cases of VAE/PAE with 8 deaths in the prone position during spine surgery probably due to VAE and/or PAE.<sup>3</sup> My concern is that we are but seeing the tip of the proverbial iceberg in terms of the incidence of VAE-PAE in the prone position during spine procedures. With this in mind, I would appreciate hearing from anyone who believes he or she might have encountered a clinical problem where VAE/PAE during a spine procedure in the prone position might have been a distinct possibility. My contact e-mail is MALBIN@BHAM.RR.COM.

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#### References

1. Albin MS, Ritter RR, Sloan T, et al. Central registry for venous air embolism. *Anesth Analg* 1995;81:658.
2. Wills J, Schwend RM, Paterson A, Albin MS. Intraoperative visible bubbling of air may be the first sign of venous air embolism during posterior surgery for scoliosis. *Spine* 2005;30:E629-35.
3. Personal Communication from Lorri A. Lee, MD, ASA Closed Claims Project, with permission from the ASA Closed Claims Committee to publish these data.

### Some Simpler Approaches to Team Training in Obstetrics

#### To The Editor:

Dr. Pratt's article on medical errors and the attempts of various experts to minimize such errors in obstetric anesthesia was very interesting. There is little question that many of our problems, especially in acute, high-risk cases, arise from a lack of communication between the obstetric and anesthesia staffs. The paradigm of such lack of communication is the scenario in which a high-risk parturient is brought back to the operating room for emergent cesarean section, prepped and draped, and is about to be operated on when someone recognizes that the anesthesia team has not been called. I think it would be rather surprising were we to discover just how often this scenario is played out in real life. Clearly, the failure to notify the anesthesia team early has negative consequences for the patient as it severely restricts the anesthesiologist's options for the provision of surgical anesthesia.

One common factor running through the suggestions of all 3 of the experts is complexity. Dr. Sachs's training program involves major changes to traditional practice. Dr. Birnbach's work at the University of Miami requires the use of a very expensive (more than \$3 million) stimulator system for training, and Dr. Preston's team training program also involves the use of a stimulator and major didactic innovations. While all of these programs are certainly very valuable, they are beyond the reach of many institutions, both academic and private.

We have had the usual number of communication failures in a large teaching hospital and have always utilized a form of "critical event" analysis after a bad outcome. This tends to promote communication for a relatively short period of time following the critical incident. It does not tend to change traditional patterns of behavior.

One change that has been of great help was actually suggested by the division head of maternal-fetal medicine here. He invited us, meaning the anesthesiology attending and resident covering for the day, to regularly attend their morning teaching rounds where all of the obstetric patients are discussed and any questions regarding anesthetic issues can be answered. In addition to the obvious advantage of providing our anesthesia residents with a printed list of all obstetric patients and the obstetric plans for those patients, our participation in obstetric daily teaching rounds effectively makes us a recognized part of the daily management of the patients on labor and delivery. Our presence at rounds symbolically makes us an integral part of the

obstetric team. This is critical for us as we have multiple short (2-week) rotations in obstetric anesthesia for our residents, and, although we have a core of obstetric anesthesiologists, it is not unusual for someone outside that core to cover obstetrics during the day and to routinely cover at night.

We are physically separate from the main obstetric floor with an anesthesia call room and lounge next to the operating room. Without our formal involvement in morning obstetric rounds we tend to resemble a mysterious group, appearing when called, but otherwise forgotten. It is critical that we not be regarded as a merely technical "epidural service" with the unit secretary making calls to our residents like "epidural now in room 4." In order to avoid this, we require the obstetric resident to contact our resident before the placement of an epidural. This maintains the physician-to-physician relationship and tends to lessen the perception that we are simply "needle jockeys" rather than physicians.

Although complex team teaching systems and anesthesia stimulators certainly are effective and have a place, they are not practical for many departments. For those of us who lack the resources to fund such systems, there are very simple, no-cost alternatives, which can increase the communication between obstetrician, and anesthesiologists, and may be critical to the prevention of bad outcomes. Certainly in teaching hospitals the participation of a member of the obstetric anesthesiology team in daily obstetric teaching rounds is very beneficial, as is maintaining the requirement for physician-to-physician consultation prior to labor epidural placement. Although we have not followed outcomes since the above 2 changes were instituted in our practice, we believe that they have improved the quality of care that we are able to deliver and have reduced the number of incidents in which no one calls "anesthesia" until the last moment. These are simple, no-cost changes which can be easily instituted in any teaching hospital. One more item, which we hope to make a monthly event, is a mock emergent cesarean section drill involving the labor and delivery nurses; obstetric, neonatal and anesthesia residents; and attendings. Such drills do not require any significant additional resources and can highlight potential problems before they involve a patient. They also allow each specialty to voice concerns in front of colleagues from other specialties.

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