

APSF Workshop: Cerebral Perfusion Experts Share Views on Management of Head-Up Cases

by Lorri Lee, MD and Robert Caplan, MD

The APSF held their annual Board of Directors Workshop in New Orleans, LA, on the topic of cerebral perfusion pressure (CPP) in the beach chair position. This conference followed a series of articles over the last year in the *APSF Newsletter* describing several cases of severe brain and spinal cord injury following the use of deliberate hypotension in the beach chair position for shoulder surgery. Dr. Robert K. Stoelting, president of the APSF, opened the workshop by introducing the APSF's position statement: "The APSF believes that reports of global ischemic brain damage following surgical procedures in the semi-sitting ("beach chair") position may reflect unrecognized cerebral hypoperfusion. Patient safety may benefit from a discussion of acceptable cerebral perfusion pressures and methods to monitor the adequacy of cerebral blood flow." He noted the 4 goals of the workshop were "to understand how experts currently identify 1) the lower limit of acceptable blood pressure during anesthesia, 2) the effects of patient position on the lower limit of acceptable blood pressure, 3) patients who are appropriate candidates for deliberate hypotension and/or beach chair position, and 4) how we can improve safety in the presence of deliberate hypotension and/or the beach chair position."

Dr. Robert C. Caplan, member of the APSF Executive Committee and of the ASA Closed Claims Group, and staff anesthesiologist at Virginia Mason Hospital in Seattle, WA, moderated the workshop which included a list of speakers nationally and internationally recognized for their expertise in neuroanesthesia, outcomes research, and research on the use

of deliberate hypotension. Dr. David Cullen, previous chair in the Department of Anesthesiology at Tufts Medical Center, reviewed his case series of 4 patients who developed severe and permanent brain or spinal cord infarcts after having anesthesia with deliberate hypotension in the beach chair position. He reported that he was aware of an additional 11 cases in which patients suffered severe brain damage under similar circumstances. Dr. Cullen believes that anesthesia care providers need to maintain blood pressure at or near baseline levels in the sitting position. He provided the following recommendations to avoid hypotension in the sitting position: 1) titration of anesthetics to avoid excessive depth of anesthesia; 2) minimizing sudden changes in position; 3) administration of intravenous fluids to offset the effects of NPO status and the sitting position on venous return; 4) use of vasopressors to maintain blood pressure, as needed; and 5) correction of blood pressure for the difference in height between the site of measurement and the brain (1 cm height = 0.77 mmHg or 1 mmHg = 1.25 cm height).

Dr. Daniel I. Sessler, chair of the Department of Outcomes Research at the Cleveland Clinic presented preliminary data from a retrospective study of 24,000 patients undergoing volatile anesthesia with Bispectral Index (BIS) monitoring. Dr. Sessler's group examined combinations of mean arterial pressure ≤ 75 mmHg, BIS < 45 , and minimum alveolar concentration (MAC) < 0.7 (each averaged over case duration). Thirty-day mortality was similar in patients in whom only a single average was low and in those with no low averages. However, 30-day mortality was doubled when 2 were low averages, and tripled when all 3 were low. A Triple Low of MAP, MAC, and BIS is

thus an ominous predictor of postoperative mortality. Dr. Sessler described additional preliminary and unadjusted data demonstrating that 20 or more minutes of a Triple Low was associated with prolonged hospitalization and a 3-fold increase in mortality. The team also found that mortality was no higher than normal when patients were given a vasopressor within 5 minutes of entering a Triple Low. Dr. Sessler cautioned that these results are based on retrospective data and preliminary analyses, and that prospective study would be required to validate these findings. The study was supported by Aspect Medical and some coinvestigators are Aspect employees.

Dr. Nigel E. Sharrock, staff anesthesiologist from the Hospital for Special Surgery in New York, reviewed his experience with the use of deliberate hypotension in elderly patients undergoing

See "Workshop," Page 47



Dr. Stoelting convenes Board of Directors Workshop.

Inside:

President's Report.....	Page 46
Grant Recipients.....	Page 49
Dear SIRS—Fabius Leak Test	Page 52
Q&A—Cleaning Fiberoptic Scopes	Page 55
Scientific Papers at 2009 ASA.....	Page 58
ASA Safety-Related Exhibits.....	Page 60
Grant Guidelines	Page 64

President Reviews 2009—Prepares for 2010

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 that 2009 has been an active and productive year as the APSF continues to pursue patient safety initiatives intended to further our vision that "no patient shall be harmed by anesthesia."

As an advocacy group the APSF does not write standards. Recommendations developed and promulgated by the APSF are intended to assist professionals who are responsible for making health care decisions. The APSF's recommendations focus on minimizing the risk to individual patients for rare adverse events rather than necessarily on practices that balance all aspects of population health quality and cost. The APSF does not intend for these recommendations to be standards, guidelines, practice parameters, or clinical requirements nor does application of these recommendations guarantee any specific outcome. Furthermore, these recommendations may be adopted, modified, or rejected according to clinical needs and restraints. The APSF recognizes that these recommendations are subject to revision as warranted by the evolution of medical knowledge, technology, and practice.

Research

The APSF Committee on Scientific Evaluation chaired by Sorin J. Brull, MD, received 32 grant applications in 2009 for awards to begin in January 2010. In October 2009, the committee recommended funding 5 research awards for a total of \$668,484. Among the named grants were the APSF/American Society of Anesthesiologists (ASA) Endowed Research Award, APSF/ASA President's Research Award, APSF/Covidien Research Award, and the APSF/Eisai Research Award. The APSF/ASA research award utilizes funds from the APSF endowment fund that were made possible by contributions from the ASA to the APSF over the past 2 decades.

The APSF is the largest private funding source for anesthesia patient safety research in the world. Since the inception of the APSF grant program more than 430 grant applications have been received by the APSF. When the first grants were funded in 1987, funding for anesthesia patient safety was virtually unknown. Since 1987, the APSF has awarded 88 grants for a total of more than \$5.96 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.

APSF Newsletter

The *APSF Newsletter* continues its role as a vehicle for rapid dissemination of anesthesia patient safety information with Robert C. Morell, MD, and Lorri A. Lee, MD, acting as co-editors. The circulation of the *APSF Newsletter* exceeds 84,000 recipients and is sent as a member benefit by the ASA, American Association of Nurse Anesthetists (AANA), American Association of Anesthesiologists Assistants (AAAA), and the American Society of Anesthesia Technologists and Technicians (ASATT) to all of their members. This Winter 2009-2010 issue of the *APSF Newsletter* represents the last "routine" hardcopy publication, as the newsletter is converting to an electronic format with the Spring 2010 issue (Volume 25, No 1). The *APSF Newsletter* will continue to be available online (www.apsf.org), and individual subscriptions to the hardcopy of the newsletter will be available for \$100 annually.

Important issues presented in recent editions of the *APSF Newsletter* include the special edition of the Spring 2009 issue on cerebral perfusion pressure. The topic was introduced by an editorial, "Cerebral Perfusion: Err on the Side of Caution," authored by William L. Lanier, MD. The APSF believes that reports of global ischemic brain damage following surgical procedures in the semi-sitting ("beach chair") position may reflect unrecognized cerebral hypoperfusion.

See "President's Report" Page 56



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Numerous Experts Share Experience and Perspective

“Workshop,” From Page 45

hip surgery. He and his colleagues have published multiple papers on the use of this technique for minimizing blood loss, and its safety in elderly patients. Their anesthetic technique includes lowering the MAP to 45 to 55 mmHg, epidural anesthesia, and an epinephrine infusion to augment the cardiac output. He noted that when his center initially started using deliberate hypotension to a MAP of 50 mmHg with epidural anesthesia (without epinephrine) for hip surgery to decrease blood loss, patients would complain of feeling light-headed. A variety of vasoactive agents were used to augment the cardiac output, and epinephrine proved most effective for eliminating the presyncopal symptoms. Dr. Sharrock's studies have shown that the epinephrine infusion significantly raises the cardiac output under these conditions. He believes that is why these patients did not have any significant increase in complications compared with control patients who had their MAP maintained between 60 to 70 mmHg. Complications that were examined included stroke, myocardial infarction, and postoperative cognitive dysfunction. Dr. Sharrock has examined small subsets of patients including those with hypertension ($n = 31$) chronic renal dysfunction ($n = 54$), moderate to severe aortic stenosis ($n = 22$), or low ejection fraction ($n = 29$). He has found no significant increase in complications in any group utilizing deliberate hypotension compared to patients kept normotensive. He has also studied postoperative cognitive dysfunction (POCD) in patients receiving hypotensive anesthesia compared to those in a normotensive group. At 7 days and 4 months postoperatively, there was no significant increase in POCD in the hypotensive group compared to the normotensive group. It was noted that hip surgery is performed in the lateral decubitus or supine position where the heart is relatively equal with the head level and the lower body. In contrast, the beach chair position places the lower body dependent to the heart, thereby decreasing venous return and cardiac output. The satisfactory outcomes in Sharrock's studies may be partially attributed to good venous return and augmented cardiac output associated with the use of low dose epinephrine.

Dr. Joseph A. Bosco, vice chairman of orthopedic surgery from New York University Hospital for Joint Diseases, described the surgical rationale for the use of deliberate hypotension for shoulder surgery. He explained that the surgeon may find it difficult to visualize the operative field through the arthroscope if there is significant bleeding, and that injured tissue can be hyperemic and prone to bleeding. Raising the pressure of the irrigant can be problematic because it may lead to swelling and compartment syndrome in the shoulder. Dr. Bosco noted the beach chair position facilitates the arthroscopic access to joint structures, and presents these structures in a manner that is anatomically straightforward. He noted, however, that younger surgeons are now being trained to perform arthroscopic shoulder surgery in the lateral decubitus position.

Dr. James R. Munis, head of the Division of Neuroanesthesia at the Mayo Clinic, provided a brief physiologic review of the differences in cerebral perfusion pressure in a “siphon” or closed vascular system compared to a “waterfall” or open system. He believes that cerebral perfusion pressure should be maintained at or near awake levels by keeping the blood pressure (measured in the upper arm) at the baseline awake level. He does not believe that it is necessary to correct for the difference in height between the head and heart level. Dr. Munis believes that correcting for the height difference and maintaining awake MAP values at the head level would essentially make the patient hypertensive.

Dr. Michael J. Souter, a neurointensivist and acting chief of Neuroanesthesia at Harborview Medical Center in Seattle, WA, discussed the ideal way to monitor for adequate cerebral perfusion. He noted that the goal is to avoid cerebral ischemia. In the absence of proven modalities, he highlighted monitoring techniques explored by Moritz and colleagues (*Anesthesiology* 2007) in awake patients undergoing carotid endarterectomy with regional anesthesia. They found that using the percent change in transcranial Doppler flow velocity and in near infrared spectroscopy (NIRS) proved the most valuable tools for assessing adequacy of cerebral perfusion in relation to ischemic symptoms. Neither stump pressure nor somatosensory evoked potentials were as useful. Dr. Souter noted that 2 of 4 patients reported by Pohl and Cullen had posterior infarcts, so the ideal approach to monitoring should include the ability to assess multiple areas (e.g., anterior and posterior) of the brain. He reminded the audience that McCullough's data showed an intact or “classic” Circle of Willis in only 34.5% of 1,413 brains.

Dr. John C. Drummond, professor and former chair of the Department of Anesthesiology at the University of California at San Diego, started his lecture by showing erroneous representations of the lower limit of autoregulation in neuroanesthesia chapters in textbooks of anesthesia—some of which he

admittedly authored. He presented an overview of studies of autoregulation and showed the wide range in reported lower limits of autoregulation (30-110 mmHg, *Anesthesiology* 1997). Dr. Drummond believes that the available evidence favors a lower limit of 70 mmHg in the healthy and normotensive adult in the supine position, rather than the conventional or classic limit of 50 mmHg. Dr. Drummond commented that his most recent chapter in Miller has been modified to reflect this change in interpretation of available studies. He also emphasized that over 45% of the population has an incomplete circle of Willis, which may decrease the autoregulatory capacity.

Dr. William L. Lanier, professor of Anesthesiology at the Mayo Clinic in Rochester, MN, and editor of the Mayo Clinic Proceedings offered closing comments. He stated that we currently lack any reasonable outcome studies because the incidence of severe and dramatic injuries is low. Dr. Lanier called for research studies that prospectively test for changes in postoperative cognitive function in patients undergoing anesthesia in the beach chair position, with specific emphasis on the relationship between blood pressure and cognitive function. This may be the most “sensitive” way to detect a critical threshold. He noted that it may be difficult to identify all high risk patients, which increases the need for sensitive and specific methods for intraoperative monitoring. He concurred with other speakers that we need a monitor to assess cerebral function in multiple regions of the brain. Dr. Lanier remarked that NASA already uses much more advanced monitoring technology in space and aviation medicine, so there may be a way to improve our care with better technology. He noted that general anesthesia and deep sedation may adversely affect cerebral blood flow distribution by blunting the sympathetic response to blood pressure homeostasis. He also noted that anesthesia may also prevent or inhibit behavioral activities that prevent ischemia, such as limiting one's degree of head rotation in the presence of spinal

See “Workshop,” Next Page



Dr. Caplan moderates as workshop expert panels field questions from participants.

Workshop Groups Offer Recommendations

“Workshop,” From Page 27



Left to Right: Sorin Brull, MD; Roger Moore, MD; and William Lanier, MD, confer prior to the start of the workshop.

stenosis. He believes that we should err on the side of caution in using deliberate hypotension in the beach chair position until we have better information.

After the presentations, the audience and speakers participated in a “question and answer” session. Dr. David Cullen reiterated his belief that the risk of cerebral injury in the beach chair position could be viewed at a “macro” level by focusing on an acceptable lower limit for blood pressure. Dr. Richard Prielipp questioned whether or not positive pressure versus spontaneous ventilation affected cerebral perfusion, and whether a low PaCO₂ might contribute to low cerebral blood flow as well. Dr. Steven Rupp thought that determining the incidence of severe neurologic injury is essential as the ASA Closed Claims data are not revealing.

APSF BOD Workshop Groups Offer Recommendations

Group 1 was charged with the question of “What further research needs to be done?” As a starting point, the group suggested that the APSF conduct a poll to determine the range of anesthetic practice for shoulder surgery in the beach chair position and whether practitioners know of any cases of severe brain or spinal cord damage after shoulder surgery in the beach chair position. The group also suggested a study of national databases to identify any association between shoulder surgery in the sitting position and postoperative cerebral injury. Many felt that a

registry of these catastrophic outcomes, similar to the ASA Postoperative Visual Loss Registry, would be useful in light of the low incidence of this complication. Prospective studies using a subtle and sensitive marker of cerebral ischemia, such as postoperative cognitive dysfunction, were recommended. Similarly, the group thought that prospectively utilizing surrogate markers of cerebral ischemia or flow such as PET scans, transcranial Doppler, BIS, NIRS, and EEG could be used to examine the effects of changes in position and blood pressure. The effects of vasoactive agents and fluid administration, head rotation, and other factors could also be examined. Lastly, the group thought that surgical studies examining outcomes in the sitting versus lateral positions were essential if we are to continue this practice.

Group 2 addressed the question “What can companies do to make a difference?” This group pointed out that the role of companies cannot be fully understood until we have a basic understanding and consensus about causes, risk factors, and effective preventive strategies. However, several technologies were identified as promising. The first recommendation was continuous, non-invasive blood pressure monitoring. This capability would allow tighter control of blood pressure. The second recommendation was a “smart alarm” that would operate in conjunction with automated anesthesia records. This smart alarm could signal the anesthesia team that a critical threshold—defined by factors such as blood pressure, table inclination, and duration of blood pressure change—had been exceeded. A system with a smart alarm could also supply data to a national registry, and this registry could strengthen our understanding of the relationship between critical thresholds, interventions, and outcomes. They recommended standardizing the degree of incline used in these procedures, which could be facilitated with the use of photographs. Group 2 emphasized 2 critical characteristics for cerebral function monitors—user-friendly function and non-invasive technology. The group also wondered if companies could design devices to regulate blood flow locally—within the shoulder joint—while leaving pressure and flow unchanged in the rest of the body. Lastly, they noted that surgeons should be educated on the potential risks associated with the use of deliberate hypotension in the beach chair position.

Group 3 dealt with the question “What are the current best practices for blood pressure management?” The group began by pointing out that we do not have a generally accepted or validated method for defining a patient’s normal or baseline blood pressure. Similarly, we do not have a user friendly, noninvasive method for defining the lower limit of acceptable blood pressure for any given patient. As a general principle, Group 3 believed that blood pressure in the beach chair position should be adjusted to account for a hydrostatic gradient, and that deliberate hypotension should be avoided in the beach chair position. Most of the participants in the group believed that the maximum

reduction from baseline pressure should be 30% with adjustment for any hydrostatic gradient in the sitting position. There was no consensus regarding how to raise the blood pressure with respect to fluid versus vasopressor administration. The group did not reach full agreement on whether non-invasive blood pressure monitoring was appropriate for all patients, but the group did agree that non-invasive measurements should be taken in the arm and not in the leg. Finally, Group 3 emphasized that the surgery and anesthesia teams must share decision-making and consent as it relates to blood pressure management in the beach chair position.

Group 4 participants addressed the question “What should the APSF recommend as the next best steps?” Multiple suggestions were offered including: 1) Have the APSF fund a Request for Proposal (RFP) for a large (possibly multicenter) study with neurocognitive testing before and after surgery in the beach chair position with deliberate hypotension; 2) Increase awareness to a) the presence of a hydrostatic gradient between blood pressure at the arm and blood pressure in the head, b) keep blood pressure relatively normal, and c) keep head position relatively normal; 3) Have Dr. Stoelting contact orthopedic and surgical journals to provide commentary from the APSF regarding potential risks of deliberate hypotension; 4) Increase focus on informed consent and shared responsibility with the surgeon (also suggested by Group 3).

The meeting was adjourned by Dr. Stoelting with general agreement from the audience and participants that significant research will be required to define safe hemodynamic management practices for surgery in the beach chair position.

Lorri Lee is co-editor of the APSF Newsletter and Associate Professor of Anesthesiology at the University of Washington in Seattle, WA. Robert Caplan is member of the APSF Executive Committee and ASA Closed Claims Project as well as staff anesthesiologist at Virginia Mason Medical Center in Seattle, WA.

Beach Chair Survey

How Do YOU Manage the Blood Pressure?



Click on the link below to participate in the APSF survey on anesthetic practice trends for shoulder surgery in the beach chair position.

<https://catalysttools.washington.edu/webq/survey/rbruchas/91739>

Five Grant Recipients Selected for 2010

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 newly redesigned APSF website (www.APSF.org), a process that facilitates the application review by members of the Scientific Evaluation Committee, improves the timeliness of responses to queries, 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 the total amount of funding that the APSF continues to award; this year, the APSF is committing a total of \$668,484 to support research and educational projects dedicated to patient safety.

The second development is the continued funding of named awards, including the **APSF/American Society of Anesthesiologists (ASA) President's Endowed Research Award**, utilizing funds from the APSF endowment account that was made possible by the generous financial support from ASA over the past 20+ years; the **APSF/Covidien Research Award**, supported by a generous partial (\$100,000) grant from Covidien; the **APSF/American Society of Anesthesiologists (ASA) Endowed Research Award** (\$150,000); the **APSF/Eisai, Inc. Research Award**, made possible by a \$150,000 unrestricted grant from Eisai, Inc.; and the **APSF/Research Award**, sponsored entirely by a grant from the APSF.

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 selected nomination carries with it an additional, unrestricted award of \$5,000.

The APSF also has awarded **The Doctors Company Foundation Ann S. Lofsky, MD, Research Award**. This award is made possible by a \$5,000 grant from The Doctors Company Foundation that will be awarded annually for a total of 5 years to a research

project deemed worthy of the ideals and dedication exemplified by Dr. Ann S. Lofsky. Dr. Lofsky was a regular contributor to the *APSF Newsletter*, a special consultant to the APSF Executive Committee, and a member of the APSF Board of Directors. Her untimely passing cut short a much-valued and meaningful career as an anesthesiologist and as a dedicated contributor to anesthesia patient safety. It is the hope of the APSF that this award will inspire others toward her ideals and honor her memory.

For the year 2010 (projects to be funded starting January 1, 2010), 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 a total of 32 applications in the first round, 12 of which were selected for final review at the American Society of Anesthesiologists (ASA) Annual Meeting in New Orleans, LA. As in previous years, the grant submissions addressed areas of high priority in clinical anesthesia. The major goal of the APSF funding is to stimulate the performance of studies that lead to prevention of mortality and morbidity due to 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 convened during the ASA Annual Meeting on October 17, 2009, in New Orleans for final evaluation and selection of the proposals. Of the 12 finalists, the members of the APSF Scientific Evaluation Committee selected the following 5 applications:

Richard H. Blum, MD



Senior Associate in Anesthesia, Boston Children's Hospital; Assistant Professor of Anesthesia, Harvard Medical School, Boston, MA.

Dr. Blum's Education and Training submission is entitled *"Assessing Performance of First Year Anesthesia Residents to Ensure Minimum Competence."*

Background: Evaluation of anesthesia resident performance is a common challenge for academic anesthesia programs; there is frequent concern that some trainees graduate from programs not having attained what is perceived to be minimum anesthesia competency. Although patient safety is primarily a problem of flawed systems, there are some physicians who are the primary cause of adverse events due to a lack of sufficient skills within their specialty; this shortcoming in education and training must be addressed in order to gain the trust of patients and the public.

Aims: This study plans to improve patient safety by building on an ongoing pilot research study to develop an effective, credible, ongoing, simulation-enabled assessment to more reliably identify anesthesia residents at an early stage of training who may not have attained sufficient skills. Early intervention is more likely to have a positive impact on attaining proficiency or directing residents toward another specialty with the goal of ensuring that no underperforming resident graduates from a residency program. Pilot data have identified critical cognitive and behavioral competencies (as opposed to basic anesthesia skills and tasks) via a modified Delphi study of an expert consensus panel; a simulation-based assessment has been developed to evaluate these competencies within a wide spectrum of anesthesia settings targeted to inexperienced CA-1 residents. This study plans to build on data and experience from the pilot study to improve psychometric variables including reliability and validity of the simulation-based assessment tool. The main psychometric outcome variable will be to demonstrate construct validity by showing a statistically significant difference in assessment scores between an inexperienced CA-1 cohort and an experienced CA-3 cohort. The key to success will be the ability to reliably and reproducibly transfer the assessment process to 2 hospital-based simulation programs. Extension to these hospital simulation programs is critical to the feasibility of increasing subjects and moving toward a multi-hospital based summative assessment program that is ongoing and sustainable. Carefully trained anesthesia faculty will confidentially and systematically rate assessment data. Use of an on-line audio video database system will allow safe storage of confidential data and provide the ability to do on-line asynchronous ratings.

Implications: The investigators foresee this work potentially leading to standards and criteria that can be adapted at other academic anesthesia training programs as well as different medical specialties, having significant potential to enhance patient safety on a large scale.

See "Grant Awardees," Next Page

Blum Receives E.C. Pierce, Jr., MD, Research Award

"Awardees," From Preceding Page

In addition to receiving the requested funding of \$150,000 for his project, Dr. Blum's application was designated as the **APSF/American Society of Anesthesiologists (ASA) President's Endowed Research Award**. Dr. Blum is also the recipient of the **Ellison C. Pierce, Jr., MD, Research Award**, which consists of an additional, unrestricted award of \$5,000.

Ashraf S. Habib, MB, BCh



Associate Professor, Department of Anesthesia, Duke University Medical Center, Durham, NC.

Dr. Habib's Clinical Research project is entitled *"Computerized Surveillance of Opioid-Related Adverse Drug Events in the Perioperative Period."*

Background: Opioid-induced respiratory depression can cause morbidity and mortality in surgical patients. While some risk factors are identified, there remains a subset of healthy patients who experience unpredictable life-threatening opioid-induced events. This indicates that there are other risk factors not yet identified that might include unrecognized patient factors, interactions with sedative agents, or genetic factors that increase the risk of adverse events. Recognition of patients at increased risk for respiratory depression could significantly improve patient safety by allowing health care providers to tailor the anesthetic plan, postoperative analgesia regimen, and discharge location to account for an increased risk for opioid induced respiratory depression.

Aims: To identify those risk factors, the investigators plan to perform a matched case control study. Patients who have received naloxone will be identified using a computerized surveillance system. This system delivers an electronic, daily report on all triggers activated, which are then evaluated the following day for causality and severity. If an episode of opioid-induced respiratory depression is confirmed, the patient will be consented to participate in the study involving collection of information about comorbidities and medications used, as well as

collection of blood samples for analysis of known genetic polymorphisms involving the opioid mu receptor and the CYP2D6 enzyme. Controls matched by age, gender, ethnicity and type of surgery will be prospectively enrolled in a 2:1 ratio.

Implications: With approximately 19,000 surgeries and 127 events of opioid-induced respiratory depression per year, this research will very likely lead to recognition of important risk factors that can significantly improve the safety of patients in the perioperative period.

In addition to receiving the requested funding of \$149,999 for his project, Dr. Habib's application was designated as the **APSF/Covidien Research Award**, made possible by an unrestricted, partial \$100,000 grant from Covidien.

Guy L. Weinberg, MD



Professor and Vice-Head for Research, Department of Anesthesia, University of Illinois College of Medicine, Chicago, IL.

Dr. Weinberg's Education and Training project is entitled *"Developing an Educational Tool for Managing Local Anesthetic Systemic Toxicity."*

Background: Local anesthetics are exceedingly useful for providing perioperative anesthesia and analgesia. However, this utility is limited by their potential for causing severe neurological or cardiac toxicity following systemic absorption or unintended intravascular injection. Local anesthetic systemic toxicity (LAST), a much-feared and potentially fatal complication of regional anesthesia, is nonetheless reversible with appropriate treatment.

Aims: The investigators propose to create an instructional training module to improve physician understanding of LAST, focusing on its prevention, diagnosis and treatment. The investigators will develop the educational content in collaboration with experts in LAST and representatives of the American Society of Regional Anesthesia and Pain Medicine (ASRA). The educational design and assessment tools will be developed in collaboration with experts in

medical education at the University of Illinois at Chicago, Department of Medical Education. The educational module will be piloted and assessed with anesthesiology residents and staff at the University of Illinois at Chicago Medical Center. After review of the pilot outcomes and addressing of any final revisions recommended by the LAST advisory committee, the definitive educational toolkit for the training module will be distributed to all anesthesia departments in both academic and non-academic anesthesia programs throughout the country. The toolkit will also contain a faculty development component for workshop facilitators that will make implementation of the LAST prevention and treatment workshop simple and easy to use within their own anesthesia departments. The investigators will also provide a faculty development workshop and distribute toolkits to participants at the 2011 ASA and ASRA annual meetings.

Implications: This educational tool intends to improve patient safety by helping anesthesiology program directors implement the LAST training module that will reduce the incidence, morbidity, and mortality of local anesthetic systemic toxicity.

In addition to receiving the requested funding of \$150,000 for the project, Dr. Weinberg's application was designated as the **APSF/American Society of Anesthesiologists (ASA) Endowed Research Award**, made possible by an unrestricted, \$150,000 grant from the American Society of Anesthesiologists. Dr. Weinberg is also the recipient of **The Doctor's Company Foundation Ann S. Lofsky, MD, Research Award**, which consists of an additional, unrestricted grant of \$5,000.

Marcin Wasowicz, MD



Assistant Professor, Department of Anesthesia, University of Toronto, Toronto General Hospital, Toronto, ON, Canada.

See "Grant Awardees," Next Page

Grant Topics Innovative and Diverse

"Awardees," From Preceding Page

Dr. Wasowicz's Clinical Research project is entitled *"The Association Between Platelet Inhibition and Perioperative Major Adverse Cardiac Events in Post-Percutaneous Coronary Intervention Patients Undergoing Non-Cardiac Surgery."*

Background: In post-coronary intervention patients undergoing non-cardiac surgery (NCS), inadequate platelet inhibition is an independent predictor of major adverse cardiac events (MACE). Long-term anti-platelet treatment is required after a successful percutaneous coronary intervention (PCI). About 5% of patients will undergo NCS within 1 year after intracoronary stenting. Physicians are increasingly confronted with the challenge of appropriate perioperative management of patients who underwent PCI with stent implantation, and are scheduled for NCS. The dilemma of handling the anti-platelet therapy during the perioperative period involves balancing the risk of increased blood loss when anti-platelet agents are continued during the perioperative period, with the risk of MACE due to stent thrombosis if anti-platelet therapy is stopped prior to the surgery. The average perioperative complication rate of these patients is as high as 45%, and the mortality rate is 20-83%. Strong supporting evidence is lacking for the preferred perioperative anti-platelet therapy for patients who previously had stent implantation. Recently published recommendations were based mainly on the cardiology literature and expert opinions.

Aims: The study will investigate the independent relationship between platelet function and MACE during the perioperative period. This will be accomplished by measuring platelet inhibition during the perioperative period (before and after surgery) in post-PCI patients undergoing NCS who are taking anti-platelet medications. The investigation is designed as a prospective, multi-center observational study. Recruitment will involve patients who underwent PCI, receive anti-platelet therapy, and are scheduled for NCS. Patients will be assessed for the presence of MACE during their hospital stay. Thromboelastography (TEG) and Platelet Mapping Assay (PMA) will be used to measure platelet inhibition before and after surgery. These methods are validated point-of-care (POC) measurements. In addition to platelet inhibition, 4 covariates will be included in the model: type of stent, time between PCI and NCS, mono- or dual-therapy (aspirin or aspirin plus Plavix), and urgent surgery.

Implications: The incidence of MACE in post-PCI patients undergoing NCS is very high, while current perioperative management is based on experts' opinions and recommendations. The results of this study will help us understand the pathophysiology of MACE and guide anti-platelet therapy to decrease the incidence of MACE in the studied group of

patients. If inadequate platelet inhibition is an independent predictor of MACE, then it is highly likely that identifying and enhancing anti-platelet therapy in this high-risk group will lead to improved outcomes.

In addition to receiving the requested funding of \$147,835 for his project, Dr. Wasowicz's application was designated as the **APSF / Eisai, Inc. Research Award**, made possible by an unrestricted, \$150,000 grant from Eisai, Inc.

Stuart McCluskey, MD



Assistant Professor, Department of Anesthesia, University of Toronto, Toronto General Hospital, Toronto, ON, Canada.

Dr. McCluskey's Education and Training proposal is entitled *"Virtual Anesthesia: An Online Simulation of Intraoperative Hemodynamic Management in Major Surgical Procedures."*

Background: The use of simulation as an adjunct to the training of anesthesiologists has a long history, beginning in 1969. This tool for training and evaluation of skills in anesthesia can broadly be divided into the use of mannequin-based simulations that employ a dummy in a realistic replication of the operating room (OR) environment, and screen-based simulations that rely only on a personal computer. The key advantage of mannequin-based systems is the ability to simulate complex interactions and communication between the members of the OR team during adverse events, which has been termed Crisis Resource Management (CRM). However, high-fidelity simulators are not without drawbacks. They are expensive to acquire, and require an extensive infrastructure of space and personnel to operate them. This limits the number of simulators an institution can provide, which in turn restricts the availability of simulators for students to engage in "deliberate practice." Facilitators also must also be trained for the complex debriefing that is an essential part of the simulation exercise.

Aim: The objective of this project is to create a new web-based simulation of patients undergoing surgery (Virtual Anesthesia) to provide an opportunity for trainees in anesthesia to exercise their skills in the intraoperative hemodynamic management of surgical patients. This will provide a safe environment to practice diagnosing and treating problems that the trainees will encounter in managing real future surgical cases. Feedback will be provided at the end of each case, with an overall score reflecting the trainees' success in managing the case, and a debriefing describing the items used in calculating the score. Practice in a simulated environment will improve trainees' comfort level and reduce the initial stress when they encounter these problems in the OR. The simulation will be evaluated by assessing the face and content validity, the usability and the construct validity. Construct validity will be determined by measuring the scores obtained by novice, intermediate, and expert users, and by measuring the improvement in scores with repeated practice in managing simulated cases. Virtual Anesthesia will use a mathematical model of the circulation, which simulates some of the cardiovascular complications that can arise during surgery, including depressed myocardial contractility, myocardial infarction, arrhythmias, hypothermia, fever, hypo- and hypertension, hypervolemia, bleeding and hypovolemia, as well as abnormalities in hematocrit and serum electrolytes.

Implications: Once developed, the Virtual Anesthesia will be provided as a free educational resource for teaching hospitals around the world, encouraging trainees to engage in a virtual practice with a variety of problems and degrees of difficulty. Virtual Anesthesia can also be used by medical educators as a focus for group discussions, or as a teaching aid in the classroom.

In addition to receiving the requested funding of \$70,650 for his project, Dr. McCluskey's application was designated as the **APSF Research Award**, made possible by an unrestricted grant from 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, the significant amount of resources offered by the APSF, 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.

Dr. Brull is the Chair of the APSF Scientific Evaluation Committee.

Dear SIRS

Dräger Fabius Leak Test Questioned

SAFETY INFORMATION RESPONSE SYSTEM

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, former chair of the Committee on Technology, and Robert Morell, co-editor of this newsletter. A. William Paulsen is currently overseeing the column and coordinating the readers' inquiries and the responses from industry. **Dear SIRS** made its debut in the Spring 2004 issue.

The information provided is for safety-related educational purposes only, and does not constitute medical or legal advice. Individual or group responses are only commentary, provided for purposes of education or discussion, and are neither statements of advice nor the opinions of APSF. It is not the intention of APSF to provide specific medical or legal advice or to endorse any specific views or recommendations in response to the inquiries posted. In no event shall APSF be responsible or liable, directly or indirectly, for any damage or loss caused or alleged to be caused by or in connection with the reliance on any such information.

Dear SIRS,

We have discovered what we believe to be a flaw in the Dräger Fabius Tiro[®] anesthetic machines, which we use in our same day surgery operating rooms. We have observed a problem with the leak test, which does not detect a cracked, broken, or absent carbon dioxide absorbent canister. We discovered this problem a few weeks ago when the Fabius Tiro[®] machine passed all the checks in the morning, but shortly after beginning our first case we realized that the carbon dioxide absorbent was missing from the circuit. By the time a canister was placed, the patient's inspired $p\text{CO}_2$ was 30 mmHg. Fortunately the patient experienced no lasting sequelae from this event.

After investigating the incident, we discovered that the Dräger Fabius Tiro[®] leak test uses positive pressure, which closes the valve to the carbon dioxide absorbent, sealing off any leaks caused by abnormalities in the carbon dioxide absorbent canister. Furthermore, there is no prompt to remind clinicians to check the carbon dioxide absorbent during the

machine checkout. This is a particularly dangerous situation as many clinicians at our institution are under the impression that the absence of a carbon dioxide absorbent canister would cause an alert during the leak test. We would like to advise others of this potential error and suggest that Dräger incorporate the carbon dioxide absorbent canister into the Fabius Tiro[®] machine's leak test.

Karen C. Nanji, MD, MPH
Edward A. Bittner, MD, PhD
Boston, MA

In Response:

The leak test performed by the Dräger Fabius Tiro (also applies to Fabius GS) does not detect the absence of a CO_2 absorbent canister when using the CLIC adapter. That adapter is designed to allow for the canister to be removed and changed during patient care by closing a valve and preventing any leaks from the patient circuit when the canister is removed. Since the

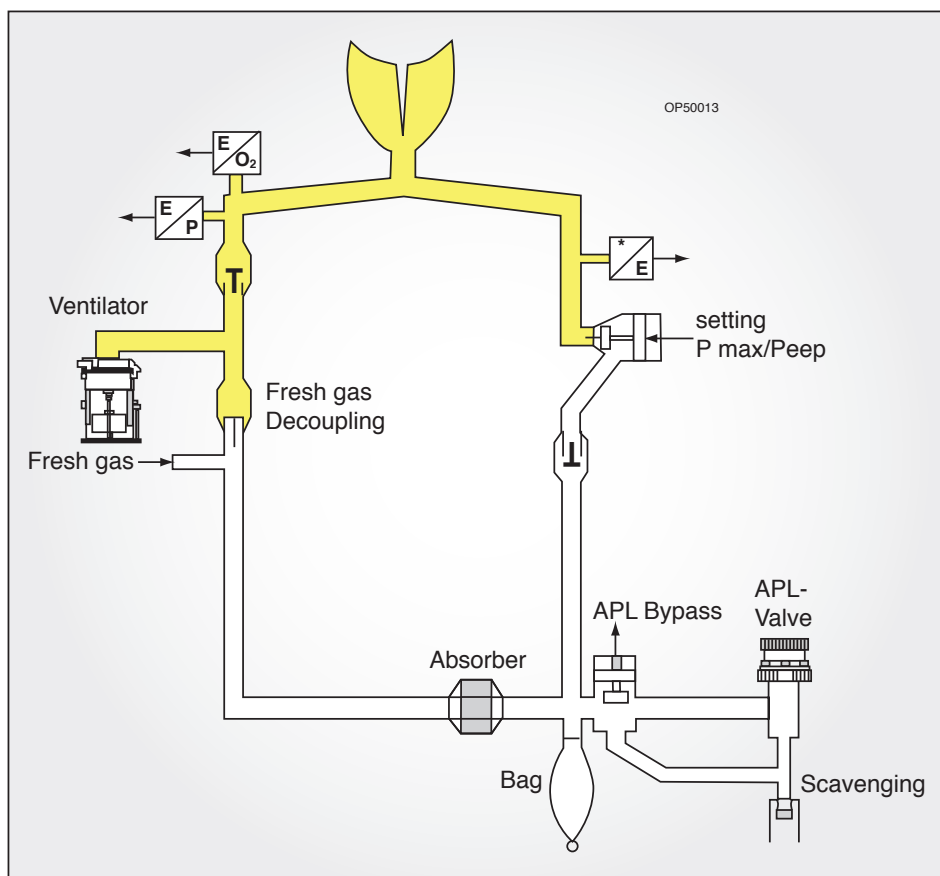


Figure 1. Fabius Tiro / Fabius GS Ventilator leak test.

See "Dear SIRS," Next Page

Manufacturer and C.O.T. Provide Clarification

“Dear SIRS,” From Preceding Page

leak test was performed without a CO₂ absorbent canister in place, no leak was detected.

The supposition that the machine leak test does not identify leaks in the absorbent canister is not correct. The Fabius Tiro and GS incorporate a semi-automatic leak and compliance test as part of the recommended pre-use check. The test is divided into 2 parts to assist the user with troubleshooting, one for the patient circuit during mechanical ventilation, and one for the complete system back to the flow control valves (Figures 1 and 2). The complete system test includes the CO₂ absorbent canister, and will identify leaks in the canister assuming the canister is properly placed and the CLIC adapter closed.

The recommended checkout procedure in the Tiro and Fabius manuals includes a step for “Checking the Condition of the CO₂ Absorbent.” This is a visual inspection intended to identify that the absorbent is present and the amount of indicator is not excessive. If this visual step is performed and a CO₂ canister properly placed, the leak test will identify a leak if the integrity of the CO₂ absorbent canister is compromised.

The Fabius Tiro and GS anesthesia delivery systems are also available with a loose fill CO₂ absorbent canister option instead of the CLIC absorber. The loose fill canister must be in place and secured during the leak test; otherwise, a leak will be detected.

The concerns expressed above underscore the challenge of automating pre-anesthesia checkout procedures. No anesthesia system on the market has completely automated all aspects of the checkout procedures and eliminated the need for manual checkout. The current Pre-Anesthesia Checkout Guidelines published by the American Society of Anesthesiologists recognizes the need for both automated and manual procedures as well as the differences between anesthesia delivery systems. These guidelines are a useful resource for evaluating checkout procedures used for individual delivery systems (see <http://www.asahq.org/clinical/fda.htm>).

Users of the Dräger CLIC absorber must be aware of the potential disadvantages of that system. One disadvantage is highlighted in this report and can be

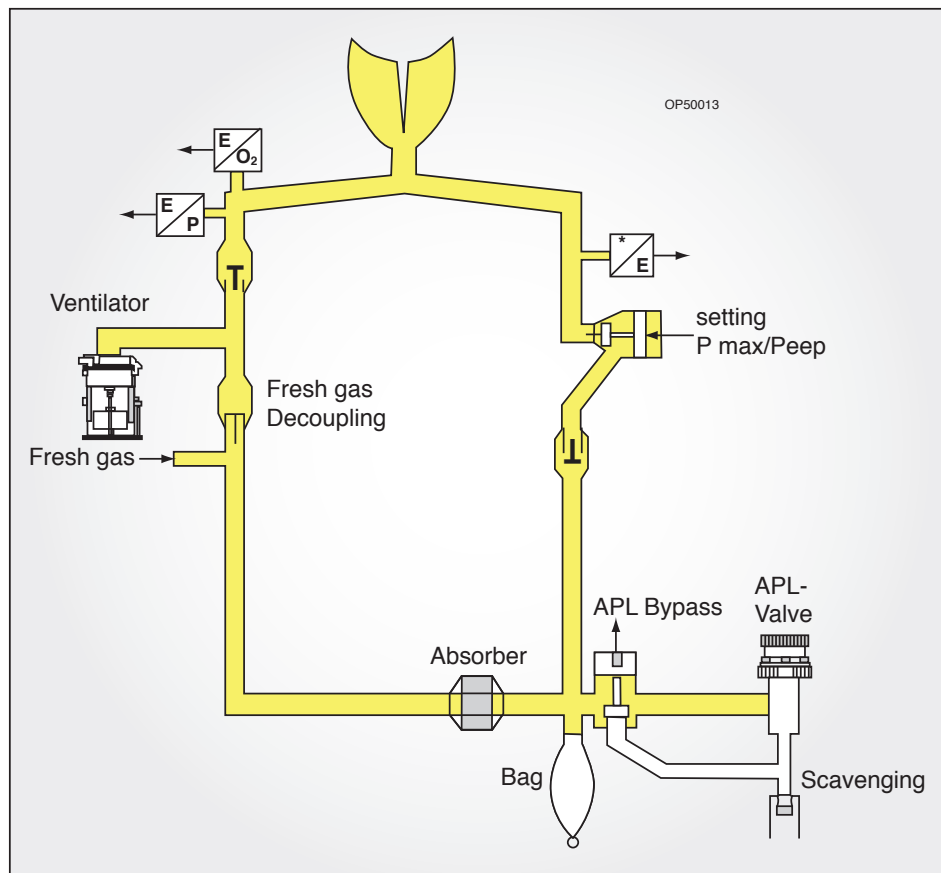


Figure 2 . Fabius Tiro / Fabius GS System leak test includes the absorber (including CLIC disposable if in place).

eliminated by noting the presence of a properly placed absorbent canister before starting the automated leak test. The other disadvantage will be apparent if a cracked or leaking absorbent canister is replaced during patient care. The leak test cannot be performed during patient care without interrupting anesthesia delivery and ventilation. If a leak should become apparent after changing the canister during a case, the integrity of the canister should be suspected as the cause of the leak.

The value of capnography is also highlighted by this report. Increased inspired carbon dioxide concentration resulted from the absence of an absorbent canister and helped to identify the problem. It should be

noted that CO₂ absorbent is present in a circle system to deliver vapor efficiently by allowing rebreathing of exhaled gas, and is not required to prevent hypercarbia. When inspired CO₂ results from absent or exhausted CO₂ absorbent material, inspired CO₂ can be eliminated by increasing fresh gas flow to exceed minute ventilation until the problem can be rectified.

Robert Clark
CareArea™ Director, Perioperative Care
Dräger Medical, Inc.

Jeffrey Feldman, MD, MSE
APSF Committee on Technology

The APSF continues to accept and appreciate contributions.

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Q&A

Cross-Contamination From Anesthesia Equipment

Q Dear Q&A,

Do you have any advice about the most up-to-date guidelines regarding the cleaning and processing of dirty fiberoptic scopes? Specifically, I am curious as to whether there is a national trend for anesthesiology departments to develop a tracking system for each individual fiberoptic scope. This might include the date, medical record number, anesthesia provider, and the anesthesia technician involved with the cleaning.

I have been practicing anesthesiology in Washington, DC, for the past 3 years and have taken a particular interest in difficult airway techniques and equipment. Having evaluated endoscopy inventory and issues involving maintenance, I believe that the implementation of an endoscope tracking log would provide multiple benefits involving issues with infection, maintenance, and accountability.

Thanks for your time.

Sincerely,
Gregory K. Applegate, DO
Washington, DC

A Dear Dr. Applegate,

Thank you very much for your question to the APSF. We have initiated some investigation with experts in this field. Meanwhile, you might also propose your question to the *Newsletter* editor, in the form of an APSF "Poll Question" to determine whether this type of specific tracking is unique to isolated hospitals or widespread.

Committee on Technology

A Dear Dr. Applegate,

The recommendations are that each time a patient is scoped, that you record on a log the scope that was used. That way, if a problem develops, you can easily determine others that may have been exposed. For example, you might recall the recent large hepatitis B exposure in Las Vegas. The cited reference is a good one. Recommendation number 24 is quoted here for a specific answer to your tracking question:

24. Maintain a log for each procedure and record the following: the patient's name and medical record number (if available), the procedure, the date, the endoscopist, the system used to reprocess the endoscope (if more than one system could be used in the reprocessing area), and the serial number or other identifier of the endoscope used. Strongly recommended.¹

Reference

1. Rutala WA, Weber DJ. Reprocessing endoscopes: United States perspective. *J Hosp Infect* 2004;56 (Suppl 2):S27-39.

Sincerely,

Robert J. Sherertz, MD
Section Head, Infectious Diseases
Department of Internal Medicine
Wake Forest University School of Medicine
Winston-Salem, NC

A Dear Dr. Applegate,

The applicable standards and recommended practices are listed below. The Joint Commission establishes standards and not specifics. . . . I believe these areas address the need of

effective endoscope leak testing, cleaning, and reprocessing and its documentation.

The Joint Commission's Comprehensive Accreditation Manual for Hospitals—2009

- EC.02.01.01 The hospital identifies safety and security risks associated with the environment of care. Risks are identified from internal sources such as ongoing monitoring of the environment, results of root cause analyses, results of annual proactive risk assessments of high-risk processes, and from credible external sources such as Sentinel Event Alerts. The problems identified in the VA system this year are considered sentinel events.
- EC.04.01.01 The hospital establishes a process for continually monitoring, internally reporting, and investigating medical equipment management problems, failures, and user errors.
- IC.01.03.01 The hospital prioritizes the identified risks for acquiring and transmitting infections. These prioritized risks are documented.
- IM.01.01.01.01 The hospital plans for managing information. The hospital identifies the internal and external information needed to provide safe, quality care.
- PI.01.01.01 The hospital collects data to monitor its performance. EP.1 The leaders set priorities for data collection. EP.2 The hospital identifies the frequency for data collection. The hospital collects data on: EP.3 performance improvement priorities identified by leaders. EP.4 operative or other procedures that place the patients at risk of disability or death. EP.16 Patient perception

See "Q&A," Page 67

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.

The information provided is for safety-related educational purposes only, and does not constitute medical or legal advice. Individual or group responses are only commentary, provided for purposes of education or discussion, and are neither statements of advice nor the opinions of APSF. It is not the intention of APSF to provide specific medical or legal advice or to endorse any specific views or recommendations in response to the inquiries posted. In no event shall APSF be responsible or liable, directly or indirectly, for any damage or loss caused or alleged to be caused by or in connection with the reliance on any such information.

President Stoelting Comments on State of APSF

"President's Report," From Page 46

Cerebral perfusion and acceptable systemic blood pressure was also the topic of the APSF Board of Directors Workshop in October 2009.

As a response to the recommendations from the speakers and attendees at the workshop, the APSF has issued a Request for Proposal to study the nature and potential etiological factors of unexpected neurocognitive deficits in patients undergoing general anesthesia during surgery in non-supine positions. There have been increasing reports of severe neurological injury in previously healthy patients having surgery in head-above-heart positions (shoulder surgery in the beach chair position) but the incidence and mechanisms are unknown. The APSF believes this is a major patient safety issue that warrants rigorous study. Thus, the APSF will provide up to \$200,000 for a period not to exceed 2 years to study this question. In addition, the APSF is funding the creation of a registry (Neurologic Injury after Non-Supine Surgery Registry, NINS) to collect and analyze adverse neurologic outcomes following shoulder arthroscopy surgery. The NINS will be under the direction of Drs. Domino, Lee, and Posner at the University of Washington in Seattle, WA.

The Summer 2009 issue of the *APSF Newsletter* included an editorial entitled "Dangers of Postoperative Opioids—Is There a Cure?" authored by Drs. Stoelting and Weinger. This editorial was a follow-up to the October 2006 APSF Board of Directors Workshop on the safety of patient controlled analgesia in the postoperative period. Despite the recommendations of this 2006 workshop for monitoring of oxygenation and ventilation, unexpected and potentially harmful opioid-induced respiratory depression continues to occur. In the Summer 2009 editorial, Drs. Stoelting and Weinger propose that every patient receiving postoperative opioids should be managed based on specific clinical considerations that include: 1) individualizing the dose and infusion rate of opioid, 2) continuous monitoring of oxygenation as the rule rather than the exception, 3) assessment of the need for supplemental oxygen especially if pulse oximetry or intermittent nursing assessment are the only methods of identifying progressive hypoventilation, and 4) consideration of the value of monitoring ventilation with technology capable of detecting progressive hypoventilation. The APSF believes that unrecognized postoperative opioid-induced respiratory depression can be reliably detected only if an understanding of the pathophysiology of the sequence of events and available monitoring technology are considered for all patients.

The "Questions and Answers" and the "Dear Sirs" (Safety Information Response System) columns in the *APSF Newsletter* provide rapid dissemination of safety issues related to anesthesia equipment in response to questions from readers. These columns are coordinated by Drs. Olympio and Morell. Dr. Olympio retired as chair of the APSF Committee on Technology at the conclusion of the annual meeting of the APSF Board of Directors in October 2009.

A. William Paulsen, PhD, has graciously agreed to become the acting chair. The APSF thanks Dr. Olympio for his years of service to the APSF and devotion to patient safety.

A section of the *APSF Newsletter* entitled "Innovative Technology and Pharmacology" is intended to describe innovative technological or pharmaceutical developments that may impact patient safety. It is inevitable that this column may discuss products that are sold or distributed by entities that have or continue to support the APSF financially. The APSF will strive to disclose those relationships as appropriate.

Communication

The APSF website (www.apsf.org) is coordinated by APSF Executive Vice President George A. Schapiro. The APSF website includes a monthly poll question related to anesthesia patient safety issues. This poll question is coordinated by Richard C. Prielipp, MD, chair, APSF Committee on Education and Training. The website also permits online donations to the APSF.

Sorin J. Brull, MD, chair, APSF Committee on Scientific Evaluation continues to serve as the Patient Safety Section Editor for *Anesthesia and Analgesia*.

The APSF sponsored a panel at the 2009 Annual Congress of the International Anesthesia Research Society (IARS) on fire safety in the operating room. This panel was organized and moderated by Dr. Prielipp. A panel on intraoperative blood pressure management to be moderated by Dr. Prielipp is planned for the 2010 IARS Annual Congress. Drs. Weinger and Olympio led APSF-sponsored panels on patient safety education curricula and on teaching technology safety at the 2009 annual meeting of the Society for Education in Anesthesia.

Fire Safety Video

The APSF is pleased to announce that the fire safety video entitled "Prevention and Management of Operating Room Fires" is now available. This video was funded by the APSF and produced in cooperation with ECRI Institute. In addition to the 17-minute video a CME course is available. Information regarding the DVD and CME course is available on the APSF website (www.apsf.org).

Medication Safety in the Operating Room

The APSF has identified medication safety errors in the operating room environment as a patient safety concern that needs to be addressed by multidisciplinary experts. In this regard the APSF sponsored a multidisciplinary conference on January 26, 2010, in Phoenix, AZ. Medication errors in the operating room continue to occur and a new paradigm is needed. This new paradigm, designated as STPC (standardization, technology, pharmacy, culture), was the subject of the

multidisciplinary conference. The recommendations of the conference will be published in a future issue of the *APSF Newsletter*.

Financial Support

Financial support to the APSF from individuals, specialty and components societies, and corporate partners in 2009 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 funding for anesthesia patient safety research. The continued uncertainty related to the world-wide economic recovery will require careful attention and analysis of the APSF's budgetary plans for 2010. The level of research support is particularly dependent on the level of financial support received.

Online Donations

The APSF website permits "online" credit card contributions to APSF. Go to "make a donation" on the APSF home page and follow the prompts.

25th Anniversary

The year 2010 represents the 25th anniversary of the formation of the APSF. The APSF was officially incorporated in September 1985 and the first *APSF Newsletter* was published in the spring of 1986. In honor of this milestone the APSF Executive Committee will be planning a special recognition of the 25th anniversary during the annual meeting of the ASA in San Diego, CA.

Concluding Thoughts

The APSF regrets the passing of Joachim S. (Nik) Gravenstein, MD, on January 16, 2009. Dr. Gravenstein was instrumental in the initial organization of the APSF, serving as one of the 7 original members of the APSF Executive Committee and as the first chair of the Committee on Education and Training. He was a life-long advocate of patient safety and his contributions are a lasting memory to his genius and compassion for his fellow man.

The APSF is pleased to welcome Patricia A. Kapur, MD, to the APSF Board of Directors and as an at-large member of the Executive Committee. The APSF is also pleased to welcome Maria Magro, CRNA, as a consultant to the Executive Committee.

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 the 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 year 2010.

Robert K. Stoelting, MD
President

Anesthesia Patient Safety Foundation Officers, Directors, and Committees, 2010

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Scientific Papers Focus on Patient Safety at the 2009 ASA Annual Meeting

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

Over 1,600 abstracts were presented at the 2009 American Society of Anesthesiologists Annual Meeting in New Orleans, Louisiana. As in previous years, a number of these abstracts examined issues directly related to patient safety. This brief review will highlight a few of the important abstracts discussed at the meeting.

Perioperative Medications and Morbidity & Mortality

There continues to be an interest in perioperative therapies that may contribute to improved postoperative patient outcomes. Investigators from Johns Hopkins performed a prospective study to examine the effect of preoperative aspirin, beta blockers, ACE inhibitors, and diuretics on mortality after cardiac surgery (A2). Data were prospectively collected on 9,129 patients from a single center over a 4-year period. Thirty-day mortality was significantly less in patients receiving preoperative aspirin (OR=0.73), beta blockers (OR=0.78), and ACE inhibitors (OR=0.72). The preoperative use of diuretics was associated with an increase in mortality (OR=1.56). Another large database study (20,000 patients undergoing 40,000 surgical procedures were analyzed over a 12-year period) from the San Francisco VA Medical Center (A705) examined the association between perioperative beta blockade and postoperative outcomes. A standard protocol guiding the administration of beta blockers in at-risk patients was used. The addition of beta blockers resulted in a significant reduction in 30- and 365-day mortality (OR=0.59 & OR=0.83, respectively). Withdrawal of beta blockers was associated with an increased risk of death at 30 and 365 days (OR=3.24 & OR=1.83, respectively).

The influence of perioperative statin therapy on patient outcomes was examined in several abstracts. Pan et al. performed a retrospective cohort study (A1) involving patients undergoing CABG surgery with cardiopulmonary bypass. Patients receiving preoperative statin therapy (N=2385) were compared to patients not receiving statin therapy (N=1609). Multivariate logistic regression revealed that preoperative statin therapy was independently associated with a significant reduction in hospital mortality ($p<0.05$), reduced hospital length of stay ($p<0.05$), reduced postoperative renal insufficiency ($p<0.05$), and reduced postoperative IABP support ($p<0.01$). Long-term survival was also significantly improved with statin therapy. Another investigation (A1583) assessed the relationship between preoperative and early postoperative use of statins and the incidence of acute kidney injury (AKI) in elective cardiac surgical patients. Twenty-one percent of 324 patients studied

developed AKI. These patients stayed in the hospital longer and were more likely to develop pneumonia or die. Early postoperative statin use was associated with a lower incidence of AKI ($p=0.03$), while no association between preoperative statin use and AKI was noted. Further analyses such as the ones above may allow for the development of protocols that incorporate such therapies to reduce morbidity and mortality rates.

Acknowledgment and Reduction of Medical Errors

Medical errors harm thousands of patients in hospitals each year. Cooper et al. (A614) attempted to identify human factors contributing to medication errors by anesthesia care providers. A medication error rate of 1:150-200 anesthetics was observed in 10,574 anesthetics. The 3 most common factors that were associated with medication errors were distraction, haste/pressure to proceed, and misread or look-alike vials/labels. New technology for labeling medications may reduce medication errors. Levine et al. (A612) compared the "Smart Label" system (a bar code-assisted syringe labeling technology) with conventional labeling measures. The use of conventional methods revealed a 10.4% error rate (either labeling the drug with the wrong date/time or incorrect drug concentration), while the use of the "Smart Label" system was associated with a 0% error rate. Eight-six percent of the 64 subjects using the new technology reported it to be faster than conventional methods, and 98% of the subjects thought it improved safety by reducing drug labeling errors.

A retrospective study (A1061) identified possible risk factors for retained instruments and sponges after surgery. Patients with retained sponges or instruments ($n=89$) were more likely to have a higher BMI and had counts of sponges and instruments performed at the end of the procedure. Risk of retention of foreign bodies occurred most frequently in non-emergent cases and with unplanned changes to procedures.

Other abstracts addressed patient care "handoffs" as a source of iatrogenic errors. One study (A1164) analyzed the quality of PACU handoffs using 4 criteria: content of handover, patient condition, professional behavior, and outcome assessment. Quality handovers were achieved 90% of the time. Unsatisfactory handovers were more frequent after 5:00 pm and when the anesthesia provider changed during the operation. Poor quality handovers were associated with a 61-minute increase in PACU readiness time. Another investigation (A1179) evaluated results from a survey distributed to assess operating room handoff adequacy, location for best handoff, method of best handoff, and need for inclusion of the electronic medical record in handoff communication.

Of the 70 surveys completed, 34% found the current handoff practice to be inadequate. Most of the surveys revealed that handoffs should occur in the OR and in person. In addition, most surveys reported an interest in incorporating handoff communication into the electronic medical record.

Nosocomial Infections and Prevention

Central venous catheter (CVC) bloodstream and surgical site infections account for a substantial proportion of in-hospital morbidity. A study from Massachusetts General Hospital (A1167) attempted to define the incidence of catheter-related bloodstream infections (CRBSIs) attributable to central lines placed by anesthesiologists in the OR. Thirty-three CRBSIs were identified (out of 3948 catheters placed) over a 9-month period. Only one of the catheters that resulted in a CRBSI was placed in the OR by an anesthesiologist, while 32 catheters were placed by other providers in other locations in the hospital. The authors provide reasons for the low rates of CRBSI in the OR which include provider experience, degree of supervision of trainees, familiarity with sterile technique, placement environment, patients' underlying comorbidities, and the time to CVC removal. Another abstract (A1166) examined staff education and physician simulation training on CRBSI-related costs over a 4-year period. The mandatory steps included an intranet module on infection prevention, a procedure checklist, and a 4-hour skills training course. With the above measures, a 53% total cost reduction (mean cost savings of \$211,968) occurred between the pre-training era (2005-2006) and the post-training era (2007-2008). This cost savings may be attributed to the reduction in CRBSIs during the same time period.

The lack of hand hygiene can contribute to nosocomial infections including CRBSI. An investigation from the Netherlands (A1174) examined the frequency of hand hygiene in an OR among perioperative staff members who did not perform a surgical scrub. Among 28 operations (60 hours) that were observed, only 2% of staff members performed hand hygiene practices upon entering the OR and 8.4% of staff performed hand hygiene upon leaving the OR. In addition, when performing radial arterial catheter placement, 0% of staff members wore gloves. Another study (A1170) surveyed health care providers regarding hand hygiene compliance. All of the 107 providers surveyed agreed that they should maintain hand hygiene, and most respondents believed that their own compliance was high. The author suggests that the low compliance problem associated with hand hygiene worldwide is a behavioral one among health care providers that requires acknowledgement and change.

See "Papers," Next Page

Scientific Papers Presented at the ASA 2009 Annual Meeting

"Papers," From Preceding Page

Potential Complications of the Prone and Sitting Position

Several abstracts reviewed possible deleterious effects associated with intraoperative prone and sitting positioning. An abstract (A1013) examined a database of 43,410 spinal fusion operations among 17 academic centers. This study reported on 100 control patients randomly selected from the 320 controls without postoperative visual loss (POVL). Results revealed that intraoperative blood pressure and hematocrit for prone spinal fusion surgery in control patients without POVL varied substantially. Fifty-four percent of these subjects had mean arterial pressures $\geq 30\%$ below baseline values for at least 15 minutes.

Two investigators examined the effect of prone positioning and general anesthesia on ocular physiology. Grant et al. recruited 10 healthy volunteers to lie prone for 2 separate 5-hour sessions on a Jackson table (A1014). During the study period, intraocular pressure, choroidal thickness, optic nerve diameter and MAP were all significantly increased. The reverse Trendelenberg position had no effect on these changes. An abstract from Nara Medical University (A1016) measured intraoperative changes in intraocular pressure (IOP) under sevoflurane and propofol anesthesia during spine surgery in the prone position. IOP increased from baseline values (8-11mmHg), and continued to be elevated 5 minutes after postural change to the supine position. The increase in IOP was comparable in patients exposed to either sevoflurane or propofol anesthesia. By further studying the physiologic changes and better identifying risk factors for postoperative visual loss, health care providers may eventually be able to mitigate the incidence of this devastating complication.

Several studies assessed cerebral physiologic changes during sitting position operations. Haas et al. (A1009) presented preliminary results of an ongoing case series investigating which level of hypotension is safe for patients undergoing shoulder surgery in the sitting position. In 28 subjects, systolic blood pressure (SBP) was lowered to the range of 90-100mmHg. All of the baseline normotensive patients and 9 out of 10 of the baseline hypertensive patients had unchanged EEGs throughout the procedures. However, significant EEG changes (burst suppression/electrical silence) were observed in one of the chronic hypertensive patients when the SBP was lowered to approximately 90mmHg. The EEG returned to baseline within minutes when the SBP was raised to 120mmHg. The author concluded that most chronically hypertensive patients can safely tolerate significant hypotension in the sitting position during general anesthesia. An abstract from NorthShore University HealthSystem (A620) compared regional cerebral oxygen saturation (rSO₂) values in 110

consecutive patients presenting for elective shoulder surgery in the beach chair position versus the lateral decubitus position. More than 75% of patients in the beach chair group had at least one cerebral desaturation event (defined as a $\geq 20\%$ decrease in rSO₂ values from baseline). No episodes of critical desaturation events were observed in the lateral decubitus position during the entire intraoperative measurement period. Similarly, Lathouwers et al. (A1288) reported changes in cerebral oximeter (StO₂) measurements in patients undergoing shoulder surgery either in the sitting position or side position. Thirty-eight out of 45 patients in the sitting position had StO₂ values of $\leq 55\%$ (critical cerebral desaturation threshold), while no patients in the side position group had critical desaturation events. Lastly, Tange et al. (A522) examined whether the sitting position during general anesthesia promotes changes in cerebral oxygen metabolism in surgical patients. Thirty patients were assigned to either a control group (n=8) versus a cardiovascular risk factor group (n=22) (patients with hypertension, diabetes mellitus, or hypercholesterolemia). Heart rate and blood pressure declined under general anesthesia, but the tissue oxygen index values remained normal in both groups. In contrast to the previous abstracts (A620, A1288), cerebral oxygenation was not significantly altered when MAP was maintained > 60 mmHg (and measured at the patients' upper limb). Additional studies are needed to validate the above findings and further investigate the changes in physiology that occur during the sitting position.

Miscellaneous "Triple Low"

Three notable abstracts examined an association between the combination of low BIS levels, low blood pressure levels, low anesthetic levels, and postoperative morbidity and mortality. An abstract (A6) from the Cleveland Clinic investigated the interaction of the above factors and hospital length of stay and mortality. Data from 18,035 non-cardiac procedures were analyzed and revealed that the relative risk of mortality was significantly greater in patients with a combination of low MAC and low MAP. Low BIS levels further increased relative mortality. The same group (A880) reported that 48% of the 18,035 non-cardiac procedures had at least one "triple low" episode (low MAP, low BIS, and low MAC). Increased duration of low MAP, low BIS, and low anesthetic concentration increased the incidence of 30-day readmission and postoperative mortality, while impairing postoperative recovery (pain, complications, and excess length of stay). Lastly, abstract (A354) evaluated the effects of vasopressors on mortality in patients with the "triple low" combination. Among 17,067 patients who were evaluated, those who had a "triple low" and were rapidly treated with vasopressors had mortality similar to the reference group of 7%. However, when vasopressor treatment was delayed in patients with

"triple low" episodes, mortality increased to approximately 20%. This may suggest that early intervention may attenuate the long-term effects of the "triple low" combination.

Perioperative Complications in Patients with Coronary Stents

Two studies examined patients undergoing surgery with bare metal (BMS) or drug eluting (DES) stents and associated morbidity and mortality. The POSTSTENT study (A5) measured the incidence of postoperative complications in patients undergoing cardiac surgery. Among 219 patients with stents, 34% of patients had complications. Twenty-two percent of patients had bleeding complications (after 94% of patients stopped clopidogrel approximately 8 days prior to surgery and 8% of patients stopped aspirin approximately 5 days prior to surgery). Four postoperative coronary thromboses were detected (2 of which were on days 32 and 59). Sixty-day mortality was 2.3%. Risk factors for all postoperative complications included female sex, urgent surgery, cardiopulmonary bypass, and withdrawal of clopidogrel < 5 days. Another study from the same investigators (A1571), examined the incidence of perioperative complications associated with patients undergoing non-cardiac surgery with BMS or DES. Aspirin was discontinued in 53% of patients (with a mean duration of 6 days prior to surgery), while clopidogrel was stopped in 83% of patients (with a mean duration of 7 days prior to surgery). Twenty-three percent of patients experienced a postoperative complication. Excessive bleeding accounted for 17% of these complications. Sixty-day mortality was 4.7%, while age and vascular surgery were identified as risk factors for bleeding complications. These 2 large studies indicate that patients with coronary stents still have significant perioperative morbidity.

This brief review summarized only a small number of the important abstracts on patient safety presented at the 2009 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.

Drs. Greenberg, Murphy, and Vender are affiliated with the Evanston Northwestern Healthcare Department of Anesthesiology. They also serve on the APSF Editorial Board.

Support Your APSF
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Safety—

Exhibits Feature Patient Safety Strategies at ASA Meeting

by John H. Eichhorn, MD

Patient safety, as always, was a prominent theme of both the Scientific and the Technical Exhibits at the ASA Annual Meeting in New Orleans, October 17-21, 2009. There were significant ongoing and new patient safety concerns as well as safety improvement strategies.

In the Scientific Exhibits, airway concerns were not as prominent as in recent years, but there were airway entries. One extensive exhibit from the University of North Carolina reflected a larger common theme of the overall meeting because it presented support for the idea that optical laryngoscopes are superior to conventional laryngoscopes in negotiating endotracheal tube placement in typical difficult airway situations. Illustrations documented anatomical circumstances in which traditional alignment of larynx, pharynx, and mouth opening is nearly or completely impossible and how an optical device that functionally "sees around the corner" can facilitate relatively easy intubation in such patients. Various innovative devices were featured in other exhibits, several intended to help with spontaneously breathing patients during MAC and TIVA, including a return of the demonstration of a face tent fashioned essentially from a plastic bag demonstrating the transformation of basic nasal cannula administration of oxygen into a much higher concentration (40-60%) delivery device—while also facilitating CO₂ sampling for ventilation monitoring.

3-D imaging was prominent, especially in an exhibit from the University of Rochester illustrating the creation of models of a patient's airway, neck, or brachial plexus using a scanner, an ultrasound image, and a new computer program. Likewise, an exhibit from the Harvard's Brigham and Women's Hospital showed 3-D imaging of thoracic epidural catheter placement, both for real time clinical care and for a teaching video to present and illustrate access/placement techniques.

Safety concerns about anesthesia providers manipulating and using large-bore temporary dialysis catheters filled with high-concentration heparin have existed for many years, and an exhibit from the Medical College of Wisconsin presented a safety protocol and a plan for accrediting anesthesia caregivers to handle and manage these catheters.

Also related to intravenous access were demonstrations of 2 (St. Luke's Roosevelt, New York, and Utrecht, Netherlands) new "vein finders" utilizing infrared-based technologies that can "see" veins underneath the skin, either with "night-vision-like" goggles or transillumination of an extremity into an IR camera feeding an image on an adjacent screen. Both are particularly intended to help place peripheral IV cannulae in pediatric patients.

An exhibit from the Advocate Illinois Masonic Medical Center correlated perfectly with the APSF Directors Workshop on cerebral perfusion pressure ("How Low Can you Go?") when it featured "the evolution and safety" of deliberate intraoperative hypotension with specific suggestions on its safe and successful use.

A perennially controversial topic was featured in an exhibit from the University of Florida. The concept that supplemental oxygen administration to a spontaneously breathing patient can prevent pulse oximetry monitoring from detecting hypoventilation was highlighted, along with the complementary recommendation to limit whenever possible patients (with postop pain medication, sedation, etc.) to room air, thus enabling the pulse oximeter to enhance safety by showing the early fall in hemoglobin saturation resulting from impaired respiration.

Several exhibits indirectly promoted patient safety by outlining educational efforts and programs to improve practitioners' skills (such as with ultrasound guidance for regional anesthesia), leading to safer care. One remarkable exhibit from the University of British Columbia featured caregiver education in real time. Computer scientists have developed "The Intelligent Anesthesia Navigator," which is an integrated expert system that could take the input from physiologic monitors, combine it with basic patient information, and then compute situation analysis, differential diagnoses, and (drawing from a preprogrammed library) expert advisories for action (including web link references for more details)—all in real time, in the OR, or at the bedside. When questioned, the exhibitors did not embrace the term "ultimate smart alarm," suggesting that was overly simplistic. Of all the exhibits, this was the most futuristic and also provocative because it offered a hint of where technology may take us in the decades to come.

The APSF Pierce Award for the best safety themed scientific exhibit went to the "CommunicatOR," from Thomas Jefferson University for the exhibition of a computer software based communications program that can be used in real time, including in the OR, to facilitate clinical communication with patients who do not speak English.

In the Technical Exhibits at the meeting, newer themes assumed some of the lead roles.

It was abundantly clear that this is the year of the video laryngoscope. In a variety of permutations and combinations (small screen on a laryngoscope handle or malleable stylet, fiberoptic camera connection of various direct and indirect scopes to small, medium, or large external viewing screens, or even some new wireless connections), electronic imaging of the airway was one of the two "biggest" product categories as far as number of devices, number of companies, and wide variations on the theme. Not to be completely outdone, various manufacturers of supraglottic airway devices

(LMA and others) displayed a host of new variants with differing details and claims for utility and even superiority in relevant clinical situations.

The other "big" theme was ultrasound applications. A great many manufacturers displayed devices for vascular access (including one that sends the ultrasound signal through the catheter being inserted) and for facilitating regional anesthesia. Another approach to emergency vascular access was featured in an expanded display of tools for rapid access and high flow intraosseous delivery of crystalloid, colloid, and blood.

An interesting product display featuring a wireless continuous temperature probe provoked more than a few discussions of the question of when all patient monitors, particularly in the OR, might become wireless and how cumbersome and even dangerous the usual tangle of monitoring wires (often 10 or more) can be at the "head of the table" during an anesthetic or, often even more so, during emergence at the end of an anesthetic.

Patient warming devices of various types (including imbedded in the OR table) seemed to stage something of a resurgence in the seemingly vast exhibit hall in New Orleans (and there appeared to be 2 new provider warming devices on display). One manufacturer suggested that the impending implementation of the SCIP guidelines on hypothermia at the time of admission to PACU and the use of that metric in part to determine reimbursement for anesthesia professional services contributed to the renewed emphasis on warming technologies and strategies.

Other observations: Real time monitoring of cardiac output and intravascular volume status, most often from endotracheal tube or esophageal probes was again touted as a patient safety advantage. Commercial displays of IR facilitated "vein finders" increased in number. Finally, with all the emphasis in the anesthesia patient safety literature and campaigns on OR medication safety and avoidance of medication errors by anesthesia professionals, there was only one exhibit featuring prepackaged anesthesia medication and one featuring an automated syringe label printer for OR use.

Overall, patient safety persisted as a focus among both types of exhibits at the ASA Annual Meeting. This emphasizes some of the innovative thinking that has contributed to improving anesthesia patient safety but also the significant safety challenges yet remaining.

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.

Letter to the Editor:

Postoperative Opioids Need System-Wide Overhaul

To the Editor:

In 2006, the APSF convened a conference on the dangers of postoperative opioids.¹ Although there was a consensus on improving monitoring and education, there was unanimous agreement that a policy of zero tolerance to patient harm from postoperative respiratory depression due to opioids should be adopted by all health care providers.

Almost 3 years later, I continue to receive medical records for expert review in tragic cases of "unexplained" cardiopulmonary arrest (CPA), followed by anoxic brain injury and death in postoperative patients receiving opioids. My anecdotal experience is reinforced by the "Sixth Annual HealthGrades® Patient Safety in American Hospital Study," dated April 2009, which found "failure to rescue", and postoperative respiratory failure as the #1 and #3 most common "medical errors" in Medicare patients.² Failure to rescue is defined as a death of a surgical inpatient with treatable complications.

New data from a comprehensive literature review on parameters that trigger rapid response teams (RRT-teams widely implemented in US hospitals to anticipate clinical deterioration prior to CPA) suggest respiratory derangements, such as tachypnea, bradypnea, and desaturation, are the predominant triggers for RRT.³ Another study finds respiratory depression as the most common etiology of a code blue emergency in patients receiving opioids at an academic hospital.⁴

My unpublished case series of 15 gives me valuable insights into the etiology of these sentinel events. Infrequent patient monitoring, with intervals as far apart as every 4 hours on the first postoperative night, is a major reason for the persistence of these events. "Failure to rescue" is a misnomer, since it is not a failure of the code team to resuscitate but a "failure to recognize" respiratory decompensation in a timely fashion. Long monitoring intervals allow hypoxia, hypercarbia, and changes in mental status to go undetected to the point that naloxone and epinephrine are no longer effective.

Secondly, misconceptions about the safety mechanisms of patient controlled analgesia (PCA) persist, and are largely attributed to a lack of education. Nurses have testified that the lockout mechanism and hourly opioid limit on the PCA machine is a foolproof safeguard against a patient from receiving "too much pain medicine." Physicians testify that the opioid regimen prescribed in a sentinel event was "within normal limits." Any opioid dosing regimen is not a "normal" regimen but a "starting" regimen, which must be titrated to optimum pain relief by frequent and meticulous clinical assessment, without suppressing respiratory drive to dangerous levels. Physicians experienced in acute pain management know this can be a delicate and time consuming task, more so now that as many as 12.5 million people in the US take opiates for nonmedical use, and many multiples thereof take opiates for chronic ailments.⁵ The belief that opioid-induced respiratory depression occurs only in opioid naïve patients is a fallacy. Chronic opiate users offer difficult

acute pain management challenges, requiring dosages and delivery systems well outside of "normal limits." They are predisposed to central sleep apnea and ataxic breathing, which may become decompensated postoperatively in the presence of residual anesthetics and sleep deprivation.⁶ These patients are frequently involved in sentinel events. Lastly, despite the JCAHO Sentinel Event Alert on PCA by proxy, the ability of someone other than the patient to hit the PCA button, remains a dangerous safety flaw in the PCA system.

Awareness under anesthesia (AUA) is a serious adverse event that has received much attention in the literature as well as the lay press. Although the BIS monitor was approved in 1996, its use did not become widespread in the US until 2003 when the FDA cited its value in preventing a "debilitating medical error."⁷ Awareness during anesthesia is thought to occur 20,000 to 40,000 times per year in the US.⁸ Hypothetically, if we assume 30% of the 350,000 to 750,000 CPAs a year are respiratory in origin, and 30% of these involve respiratory depression due to opioids and sedatives, one could deduce that a monitor that may reduce the risk of death or anoxic brain injury in 30,000 to 70,000 patients would be eagerly deployed. Yet only a tiny fraction of hospitals have implemented continuous respiratory monitoring with central surveillance. Although the few clinical studies relating continuous monitoring to improved outcomes are contradictory,^{9,10} many institutions that have implemented this technology offer testimonials of "near misses" or "saves" with their systems. Technical improvements that minimize false positive alarms, as well as the real time analysis of multiple, continuous physiologic channels using "smart alarms" are rapidly overcoming the limitations of earlier equipment. If institutions countrywide adopted the technology, the economies of scale would lessen the capital equipment expenditure that remains an impediment to implementation.

But the call from the APSF Committee for more "aggressive monitoring, better education, and increased outcomes research" in 2006 has gone largely unheeded.

The problem persists in the "blind spot" of the anesthesia closed claims database, because surgeons are most often responsible for acute postoperative pain control and the hospital for monitoring; thus, anesthesiologists are rarely named in a suit. It persists in hospitals of all shapes and sizes, as my sample includes sentinel events from small community hospitals to flagship academic medical centers.

There are glimmers of hope. A coalition of medical centers, industry, and nonprofit associations comprising the San Diego Patient Safety Task Force issued a "toolkit" on PCA Guidelines of Care that reduces the longest assessment interval from 4 hours to 2 hours.¹¹ The lay press has noted the failure to rescue as the major patient safety issue.¹² But this issue has not received the attention in the national media that AUA has received. Unlike AUA, there are no traumatized survivors for the morning talk show, only distraught

families wondering what happened to their loved ones, who are told that this is a "very unusual event."

A system-wide, multidisciplinary overhaul of the monitoring standards on our hospital general care floors is needed. Pronovost and colleagues have suggested that medicine emulate a successful commercial aviation public-private partnership, which has greatly improved the safety of the flying public.¹³ Given that the chance of dying on flight of a US air carrier is approximately 1 in 22 million, whereas the chance of death or serious injury upon walking into a US hospital is 1 in 90, that may be an excellent suggestion to consider for urgent implementation.

Frank J. Overdyk, MSEE, MD
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Disclosure: Dr. Overdyk is a paid consultant to several monitoring and pharmaceutical companies.

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Letter to the Editor:

Intraoperative Hyperventilation May Contribute to Postop Opioid Hypersensitivity

To the Editor:

I read Dr. Stoelting's recent editorial entitled "Dangers of Postoperative Opioids—Is There A Cure?" I believe that iatrogenic hyperventilation during anesthesia is an important factor in postsurgical opioid hypersensitivity.

Hyperventilation during anesthesia was founded on the questionable assumptions and observations of an earlier era. It does not increase oxygen stores. It increases morbidity and mortality in polio victims in iron lungs.¹ It causes drowning in unsuspecting underwater swimmers.² During anesthesia it impairs tissue perfusion and oxygenation, causes lung "stretch injury," decreases opioid clearance, "traps" opioids in brain tissues, and undermines respiratory drive. In contrast, carbon dioxide is benign, and mild respiratory acidosis is beneficial.^{3,4} "Permissive hypercarbia" combined with anesthesia enhances respiratory drive, increases cardiac output, improves perfusion and oxygenation, protects lung tissues, prevents opioid "trapping" in brain tissues,⁵ and provides advance warning of inadequate analgesia and muscle relaxation via spontaneous respiratory efforts.⁶

Many clinicians misunderstand the complex relationships between opioids, controlled ventilation, and respiratory drive. Carbon dioxide is continuously produced by metabolic activity throughout the vertebrate body. It dissolves into tissues in large quantities and slowly equilibrates with fluctuating environmental concentrations. Respiratory drive mechanisms adjust to maintain this equilibrium.⁷ In the presence of conscious awareness, respiratory drive is primarily regulated by blood bicarbonate that determines pH in brain ventricles. This form of respiratory drive is amplified by pain perception. Respiratory drive is secondarily regulated by carotid body chemoreceptors that detect hypercarbia and hypoxemia in blood. During normal sleep and anesthesia, these become primary. Hypercarbia causes the chemoreceptors to become exponentially hypersensitive to hypoxemia, but hypocarbia disables them.⁸⁻¹⁰

Mechanical hyperventilation rapidly and abnormally depletes CO₂ tissue reserves and blood bicarbonate. This can undermine respiratory drive for hours, until metabolic activity can replenish CO₂ levels.⁷ Hyperventilated patients usually breathe and oxygenate effectively, but their respiratory drive precariously depends on their conscious awareness of surgical pain and psychological stimulation that provides an artificial stimulus to breathe. During this vulnerable period, even very small doses of opioids can unexpectedly obliterate the sole remaining source of respiratory drive, whereupon seemingly awake, alert, and fully recovered patients unpredictably stop breathing. The results can be devastating,

because brain hypoxemia begins sooner than systemic hypoxemia. The danger may be greatest soon after surgical patients leave the recovery room and return to the conventional ward, where they are no longer closely monitored and stimulated. Monitors designed to detect the problem would likely generate so many "false alarms" as to be impractical.

Critical Care specialists have already embraced permissive hypercarbia. Anesthesiologists could profit from their example. The simple remedy of replacing hyperventilation with permissive hypercarbia that enhances respiratory drive can improve safety and outcome by preventing unexpected respiratory depression, rendering opioids more predictable, and facilitating greater opioid dosage to control stress.

Lewis S. Coleman, MD
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See "Letters" Page 67



The APSF Committee on Education & Training awards the Ellison C. Pierce Research Award for Best Scientific Exhibit at the 2009 ASA Annual Meeting in New Orleans. Dr. Richard Prielipp, APSF Committee Chair, presents the award to Rammy I. Alam, D.O. (immediate left of Dr. Prielipp) of Thomas Jefferson University Hospital. Dr. Alam and his colleagues, Brad M. Taicher D.O. and Richard H. Epstein, M.D., exhibited their novel "CommunicatOR" - a software program that facilitates communication between non-English speaking patients and their anesthesia providers. Pictured in photo (left to right) are: Maria Magro, Deborah Lawson, John O'Donnell, Rammy Alam, Richard Prielipp, Brad Taicher, Tricia Meyer, and Kevin Cardinal.

AANA's 76th Annual Meeting Highlights Education and Wellness

by M. Roseann Cannon-Diehl, CRNA, MH

Continuing education, wellness, networking, and mentorship formed the framework of the 76th Annual Meeting of the American Association of Nurse Anesthetists (AANA) held in San Diego, CA, August 8-12, 2009.

Despite a down economy, more than 3,000 Certified Registered Nurse Anesthetists (CRNAs), student nurse anesthetists, and distinguished guests were lured to the AANA Annual Meeting by a week of educational offerings, social and charitable events, and a 192-booth Exhibit Hall, not to mention the desirable Southern California location. The event completes the association's annual fiscal-year cycle of meetings which includes the Fall Assembly of States for state association leaders (November), the Assembly of School Faculty for nurse anesthesia educational program administrators and instructors (February), and the Mid-Year Assembly in Washington, DC, for state leaders and other members interested in legislative and regulatory issues and lobbying on behalf of their profession (May).

Education remains the heart of the AANA Annual Meeting. A wide variety of lectures, poster presentations, and hands-on workshops covering the gamut of practice-related innovations and issues were available for attendees.

Among the many topics covered this year were the following:

- "TIVA for Neuroanesthesia" and "Current and Future Concepts in Neuroanesthesia" presented by Michael Rieker, CRNA, DNP.
- "The Effect of Pain on Leukocyte Cellular Adhesion Molecular and Inflammatory Mediators" presented by Charles Griffis, CRNA, PhD.
- "Suspension of Disbelief: Using Simulation in Healthcare and Nurse Anesthesia Education" presented by Celeste Villanueva, CRNA, MS.
- "Evidenced-Based Resources for Clinical Anesthesia Practice: Surfing the Net" presented by AANA Practice Committee Chair John McFadden, CRNA, PhD (as part of the AANA's initiative focusing on evidence to support all anesthesia practice standards and guidelines).
- "Healthcare Disparities in the World of Anesthesia" presented by Rossana Bizzio, CRNA, MS, and Tony Umadhay, CRNA, MSN, at the Forum on Diversity and Inclusion (as part of the AANA's ongoing efforts to create opportunities in anesthesia for minority nurses and become a more culturally, racially, and ethnically diverse professional association).

Always popular hands-on workshops covering regional anesthesia and other techniques were well-attended throughout the week.

The AANA's Wellness Program, which recognizes and addresses the demands that the high-stress profession of anesthesia places on CRNAs and student nurse anesthetists, remains an important focus of the Association. The overall program includes a highly effective Peer Assistance program now in its 26th year, a regular *NewsBulletin* column called "Wellness Milestones," and information and support materials for members and their families to help them deal with stress-related issues that affect their health and overall well-being. At the Annual Meeting, wellness-related activities include a Wake-Up Walk for Wellness with hundreds of participants, a Wellness booth, and the Jan Stewart Wellness Lecture. This year's featured speaker was Jeanne Stawicki, CRNA, a former smoker turned mountaineer and marathon runner who is in the Guinness Book of World Records for having scaled the tallest mountains and completed a marathon on each of the 7 continents. Her topic was "Ordinary to Extraordinary."

Another wellness-related presentation at the Annual Meeting was "Condition Critical: The Inflammation Epidemic" by Floyd Chilton, PhD, noted author of the best seller "Inflammation Nation."

The AANA has long recognized its student members as "10 percent of our membership, but 100 percent of our future." As such, numerous Annual Meeting activities are geared toward student advancement in the profession and the Association. The Student Luncheon, Student Focus Session and Reception, Student Mentoring Program, and the College Bowl are all sought after and well attended by the 1,000-plus students who participate in the meeting.



AANA Practice Committee Chair John McFadden, CRNA, PhD, presented a lecture on "Evidence-Based Resources for Clinical Anesthesia Practice: Surfing the Net" during the AANA's Annual Meeting in San Diego

Finally, the AANA's philosophy has always been to give something back to the city that hosts the Annual Meeting. The Annual Party with a Purpose, sponsored by Baxter and held on Sunday night during the meeting, raises money and collects donations of toiletries and other life necessities for a local charity.

The 2010 AANA Annual Meeting will be held in Seattle, WA, August 7-11, 2010.

M. Roseann Cannon-Diehl, CRNA, MH, was chair of the FY2009 AANA Program Committee.

A Statement by the Executive Committee of the APSF

From time to time, the Anesthesia Patient Safety Foundation reconfirms its commitment of working with all who devote their energies to making anesthesia as safe as humanly possible. Thus, the Foundation invites collaboration from all who administer anesthesia, all who supply the tools of anesthesia, and all who provide the settings in which anesthesia is practiced, all individuals and all organizations who, through their work, affect the safety of patients receiving anesthesia. All will find us eager to listen to their suggestions and to work with them toward the common goal of safe anesthesia for all patients.

ANESTHESIA PATIENT SAFETY FOUNDATION (APSF)

2011 GRANT PROGRAM

Guidelines for Grant Applications to be Selected on October 16, 2010 (ASA Annual Meeting),
and Scheduled for Funding Starting January 1, 2011

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 is \$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 2010-2011 funding cycle, the APSF is placing a specific emphasis on PATIENT SAFETY EDUCATION and MEDICATION & DEVICE SAFETY.

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, Merit 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.

The APSF inaugurated **The Doctors Company Foundation Ann S. Lofsky, MD, Research Award** in 2009. This award is made possible by a \$5,000 grant from The Doctors Company Foundation that will be awarded annually for the next 5 years to a research project deemed worthy of the ideals and dedication exemplified by Dr. Ann S. Lofsky. The recipient of this nomination will receive an additional, unrestricted award of \$5,000. It is the hope of the APSF that this award will inspire others toward her ideals and honor her memory.

ANTICIPATED 2010-2011 NAMED AWARDS

APSF/American Society of Anesthesiologists (ASA) President's Endowed Research Award (\$150,000)

APSF/American Society of Anesthesiologists (ASA) Endowed Research Award (\$150,000)

APSF/Eisai, Inc. Research Award (\$150,000)

APSF/Covidien Research Award (\$100,000)

PRIORITIES

The APSF accepts applications in 1 of 2 categories of identified need: CLINICAL RESEARCH and EDUCATION AND TRAINING. Each year, we strive to fund at least 1 grant in each of the 2 categories. Highest priority is given to:

- Studies that address peri-anesthetic safety 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.

AREAS OF RESEARCH

Areas of research interest include, but are not limited to:

- New clinical methods for prevention and/or early diagnosis of mishaps;
- 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/nurse anesthetist/anesthesiologist assistant 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;

- Development, implementation, and validation of educational content or methods of relevance to patient safety; and
- Development of innovative methods for prevention of medication errors.

PROPOSALS WITH LOW
LIKELIHOOD OF FUNDING

- Proposals that do not have a clear and direct link to near-term improvements in patient safety.
- Basic science proposals involving cells, tissues, or animals. Whole animal studies may be considered, however, if testing of a critical patient safety hypothesis in human studies is not feasible.
- Research proposals that have other available sources for funding.
- Proposals to create patient safety education curricula or that propose methods that do not include a rigorous evaluation of content validity and/or benefit.

NOTE: Applicants are encouraged to read the latest summary of funded APSF grants in the Spring 2004 *APSF Newsletter*. http://www.apsf.org/resource_center/newsletter/2004/spring/06grant.htm

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; and
- Ability of research proposals to maximize benefits while minimizing risks to individual human research participants. Each proposal should clearly describe 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 the personnel responsible for oversight. 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.

NOTE: Innovative ideas and creativity are strongly encouraged. New applicants are advised to seek guidance from an advisor or mentor skilled in experimental design and preparation of grant applications. Please include the mentor's CV with the application as part of the Appendix. Poorly conceived ideas, fail-

See "Grant Guidelines," Next Page

Grant Application Submission Date—June 1, 2010

“Grant Guidelines,” From Preceding Page

ure 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.

EDUCATIONAL and TECHNOLOGY PROJECTS

Proposals involving the development of educational curricula, training interventions, software, or technology should include a formal assessment of their impact using meaningful measures relevant to patient safety. In addition, for new metrics or tools, the proposal should include an analysis of their reliability and validity.

BUDGET

The budget request must not exceed \$150,000 (including a maximum of 15% institutional overhead). Projects must not exceed 2 years in duration, although shorter anticipated time to completion is encouraged. Unused funds must be returned to the APSF if: 1) funds remain after completion of the project (i.e., actual expenditures were less than the budgeted funding); or 2) the project is not completed within the approved time period.

PROJECT DURATION

It is the stated purpose of the APSF to support successful applications and ensure delivery of high quality results that improve patient safety. We encourage applicants to be realistic in their proposals both in terms of objectives and time required for completion. On rare occasion, the committee may vote to extend the funding cycle at no cost, but such extensions will require a detailed explanation from the applicant, and may not involve significant changes in the initial approved proposal. Substantive changes in protocol may require that funds be returned and that a new application be submitted. Requests for extension, if approved, must include a detailed progress report that outlines any preliminary conclusions.

ELIGIBILITY

Awards are made to a sponsoring institution, not to individuals or to departments. Any qualified member of a sponsoring institution (hospital, university, clinic, etc) in the United States or Canada may apply. Only 1 person may be listed as the principal investigator. All co-investigators, collaborators, and consultants must be listed. Applications will not be accepted from a principal investigator currently funded by the APSF. Re-applications from investigators who were funded by the APSF in previous years, however, will be accepted without prejudice.

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

Applications that fail to meet these basic criteria will be returned without review by the scientific committee. A summary of reviewers' comments and recommendations will be provided to all applicants within 8 weeks after grant selection.

AWARDS

Awards for projects to begin January 1, 2011, will be announced at the annual meeting of the APSF Board of Directors (2-3:30 PM) on Saturday, October 16, 2010 (San Diego, 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, 2010.

PAPERLESS APPLICATIONS

A complete Application Packet consists of the following documents, arranged in the following order:

- A. Application
- B. Budget and budget justification
- C. Applicant's curriculum vitae
- D. Departmental Chair's letter of support
- E. Applicant's "Acceptance of Grant Conditions" form; and
- F. Institutional Review Board approval or copy of submission letter

These documents must be converted to Adobe PDF format and merged as a SINGLE file. Should the applicant obtain the IRB approval after submission of the application packet (but prior to October 1), please upload the IRB Approval Letter as a separate Adobe PDF file.

Please name the PDF Application Packet file as: Lastname.Firstname-App-2010 (example: Smith.John-App-2010.pdf).

Please name the IRB Approval Letter file as: Lastname.Firstname-IRB-2010 (example: Smith.John-IRB-2010.pdf).

The complete Application Packet (Application, Budget justification, Applicant's CV, Chair's letter of support, Acceptance of Grant Conditions form, and IRB approval notification or, if approval not yet obtained, a copy of the IRB submission letter) **must be uploaded to the APSF website:** (<http://www.apsf.org/grants/application/applicant/login.aspx>).

Please follow the Application Format instructions carefully. Applications not conforming to all of the requirements will be returned without formal review.

APPLICATION PACKET

A. APPLICATION

- I. Cover Page -- This should include
 - 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. Names and affiliations of all investigators and consultants
- e. Name, office address, and phone number of departmental chairperson
- f. Sponsoring institution and name, office address, phone number, and e-mail address of the responsible institutional financial officer
- g. Amount of funding requested
- h. Start and end dates of proposed project
- i. Number all pages (bottom right corner) sequentially, starting with the cover page

II. Research Summary—A 1-paragraph description of the project (250-500 words).

III. Research Plan—Format: maximum of 10 double-spaced pages (excluding references); 1-inch margins; Times New Roman font; size 12.

NOTE: Appendices are strongly discouraged but, if used, should ONLY include either extensive data collection instruments that will be used in the project and have not been previously published, OR critical manuscripts that have been accepted for publication in a peer-reviewed journal but are otherwise not yet publicly available. The mentor's CV may be included in the Appendix.

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. Response to Reviewers' Suggestions. If the application is a resubmission, describe changes from prior application, specifically detailing how the revised application has addressed the reviewers' comments.
6. Preliminary Results. Provide as appropriate data from previous or pilot studies that

See “Grant Guidelines,” Next Page

Grant Application Submission Date—June 1, 2010

“Grant Guidelines,” From Preceding Page

demonstrate the significance, feasibility, and validity of your proposed work. If a new data collection instrument or analysis method is proposed, please provide evidence of its reliability and validity in this section.

b. Methods to be employed

1. Describe data collection procedure, specific techniques, and number of observations, subjects, or experiments. For educational projects, describe how the effects of the intervention program will be assessed. Qualitative methodologies are acceptable. Provide a justification for the sample size (power analysis).
2. Describe types of data to be obtained and their treatment, including statistical and 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, if the approval has not yet been obtained, a copy of the submitted application.

c. Discussion—Format: maximum of 2 double-spaced pages; 1-inch margins; Times New Roman font, size 12.

1. Interpretation of Results. Describe how you will interpret the results you have obtained and what you will do (and what it will mean) if you obtain results that are different than you expected.
2. Limitations. Point out and discuss potential problems and limitations of the project. Describe how you propose to address each study limitation.
3. Significance and Impact. Describe the impact of the proposed study on patient safety and the applicability of the expected results to clinical care or education in patient safety.
4. Future Directions. Describe how your proposal will lead to future patient safety research. What will be the logical next studies that could be performed?

IV. Timeline—Format: maximum of 1 double-spaced page; 1-inch margins; Times New Roman font, size 12. Provide a Gantt chart that describes by month the expected start and end date of each step of the project.

V. Protection of Human Subjects—Format: maximum of 2 double-spaced pages; 1-inch margins; Times New Roman font, size 12.

All APSF grants for clinical evaluations shall comply with national regulations governing Good Clinical Practices* and investigational drugs, biologics, and/or medical devices. Applicants should refer to appropriate guidance

documents published by their national regulatory authority.

The APSF grant proposal shall include a) A statement of approval of this proposal by the institutional committee reviewing human or animal investigations, or a copy of the submitted application; b) A sample patient informed consent form that describes the risks to human subjects enrolled in the study, and how the investigator will mitigate those risks. If there are residual risks, explain why the benefits of conducting the study outweigh those risks; c) A data safety monitoring plan of the study; d) Samples of all records and reports required by the national regulatory authority of the country in which the study is being conducted. For significant-risk studies in the U.S. that involve investigational use of drugs or devices, a statement of compliance to FDA regulations regarding an Investigational New Drug (IND) application** or an Investigational Device Exemption (IDE) application***

*ICH E-6 (R1) International Conference on Harmonization of Technical Requirements for Registration of Pharmaceuticals for Human Use. ICH HARMONISED TRIPARTITE GUIDELINE—Guideline for Good Clinical Practice: <http://www.ich.org/LOB/media/MEDIA482.pdf>

**21 CFR 312 Investigational New Drug (IND) Applications, which includes the conduct of clinical studies involving any new use of a drug except for the indicated use of a marketed drug in the course of medical practice: <https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfCFR/CFRSearch.cfm?>>

***21 CFR 812, Investigational Device Exemptions (IDE), which covers the procedures for the conduct of clinical studies with medical devices including application, responsibilities of sponsors and investigators, labeling, records, reports: <https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfCFR/CFRSearch.cfm?CFRPart=812>

B. BUDGET and BUDGET JUSTIFICATION

Please include all proposed expenditures. Indicate under each category the amount requested or provided from other sources.

1. Budget. Enumerate in an itemized table all proposed expenditures broken down by year of the proposal.
 - a. Personnel (limit salaries to NIH Guidelines)
 - b. Consultant costs
 - c. Equipment costs
 - d. Supplies and supplies cost
 - e. Patient costs
 - f. Other costs
 - g. Total funds requested

II. 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.

III. Current and Prior Support. List all current or pending research support (federal, foundation, industrial, departmental) available for the proposed project to the principal investigator, co-investigators, collaborators, and the mentor, if applicable. List all other research support for the principal investigator, stating percentage of effort devoted to current projects, and percent of effort expected for pending projects.

IV. Facilities and Resources. List the facilities, equipment, supplies, and services essential for this project and indicate their availability.

C. APPLICANT'S CURRICULUM VITAE

Abbreviated CV of the principal investigator (maximum of 4 pages) and any co-investigators (maximum of 4 pages for each co-investigator).

D. LETTER OF SUPPORT

Please include a letter from the departmental chairperson indicating

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.

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

An agreement to return unused funds if the applicant fails to complete the project, and any remaining funds after the completion of the study.

E. "ACCEPTANCE OF GRANT CONDITIONS" FORM

Sign and date the Acceptance of Grant Conditions form and upload this form to the website as part of the complete Application Packet (see above).

F. IRB/ACUC APPROVAL

Please include the approval letter from the Investigational Review Board (IRB) or Animal Care and Use Committee (ACUC) or, if approval has not yet been received, a copy of the submitted application to IRB or ACUC.

The original application must be submitted electronically to the website no later than Tuesday, June 1, 2010. Once the completed application is uploaded, an automatic confirmatory email will be sent to the applicant and to the chair of the Scientific Evaluation Committee.

Sorin J. Brull, MD
Chair, APSF Scientific Evaluation Committee
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"Q&A," From Page 55

of the safety and quality of care, treatment, and services.

Professional societies are the entities that are more specific in issuing standards and recommendations for their membership. In addition to the information listed here, there are several recommended practices that the AORN has in reference to flexible endoscopes that were updated and published in this year's version of their recommended practices. One can probably put their hands on this book of documents through their Director of Surgery. Here are the referenced links:

<http://www.apic.org/AM/Template.cfm?Section=Topics1&TEMPLATE=/CM/ContentDisplay.cfm&CONTENTID=6381>

Item 23 discusses logs.

http://www.sgn.org/Resources/3_stdofinfectionFINAL1208_2.pdf

The bottom of page 8 and top of page 9 discusses logs. The American Society of Anesthesia Technologists and Technicians do not have a standard for practice at www.asatt.org.

Finally, a comprehensive response to this question would include reference to a bulletin issued December 3, 2009, from the FDA (<http://www.fda.gov/MedicalDevices/Safety/AlertsandNotices/ucm194411.htm>) for those consumers who currently process their intubation scopes in the STERIS System 1 processors: "The FDA has not determined whether the SS1 is safe or effective for its labeled claims, including claims that it sterilizes medical devices."

Thanks for your interest in the maintenance of safe patient care outcomes.

Lynne A. Thomas, BSN, RN, CGRN
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 Clinical Endoscopy Specialist
 Vice President of Education
 IMS The InstrumentReady Company

The information provided is for safety-related educational purposes only, and does not constitute medical or legal advice. Individual or group responses are only commentary, provided for purposes of education or discussion, and are neither statements of advice nor the opinions of APSF. It is not the intention of APSF to provide specific medical or legal advice or to endorse any specific views or recommendations in response to the inquiries posted. In no event shall APSF be responsible or liable, directly or indirectly, for any damage or loss caused or alleged to be caused by or in connection with the reliance on any such information.

Letter to the Editor

Infusion Pump Error Causes Harm

To the Editor:

We have recently been made aware of a clinical situation in which an excessive volume of local anesthetic was delivered via an epidural infusion pump. The programmed volume was inadvertently set incorrectly (off by a factor of 10 because of a misplaced decimal point). This resulted in permanent paralysis of an otherwise healthy individual. An easy way to decrease the chance of this occurring is to ask your biomedical engineers to program both hard and soft limits on the total hourly volume of drug (and other programmable parameters). Additionally, hospital policies should specify which providers are allowed to override soft limits (e.g., ward nurses, anesthesiologists). We hope that each anesthesia provider will evaluate the pumps being utilized for delivery of epidural infusions and make sure that these pumps are utilizing all available safety technology in order to guard against this potentially catastrophic complication. Older pumps without this technology should be replaced.

Alan David Kaye, MD, PhD
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APSF Executive Committee Invites Collaboration

From time to time the Anesthesia Patient Safety Foundation reconfirms its commitment of working with all who devote their energies to making anesthesia as safe as humanly possible. Thus, the Foundation invites collaboration from all who administer anesthesia, and all who provide the settings in which anesthesia is practiced, all individuals and all organizations who, through their work, affect the safety of patients receiving anesthesia. All will find us eager to listen to their suggestions and to work with them toward the common goal of safe anesthesia for all patients.

Letter to the Editor

Cause of Hypercarbia Questioned

To the Editor:

While reading the Spring edition of this *Newsletter*, I was struck by the report of Musgjerd et al. on hypercapnia during thoracoscopy. In 1994 we reported a similar case,¹ as did Amin et al² in 2002. In all 3 cases, the elevated EtCO₂ readings resolved after the inflow of exogenous CO₂ into the conducting airways was halted. In our case this occurred by surgical repair. In Amin's case the surgeons deflated the chest thereby removing the inflow gradient, while Musgjerd's team occluded the main bronchus of the affected lung with a bronchial blocker. What piqued my interest in Musgjerd's case though was the persistent arterial hypercarbia they observed after placing the bronchial blocker. They offered 2 possible explanations for this, but there is a third they did not mention, which prompted the writing of this letter.

After placement of the blocker they state the chest was re-insufflated with CO₂ to 8 mmHg, so presumably CO₂ could again enter the airway in the same manner as before. However, with the right main bronchus now occluded it is conceivable some degree of CPAP with 100% CO₂ may have been applied to the right lung. This would explain the persistent hypercapnia they saw, and perhaps why the elevated pCO₂ was not responsive to doubling the minute volume. What this does not explain is the >30mmHg EtCO₂ to pCO₂ gradient noted in Table 1, and I invite comment there.

I agree with the author's recommendation for a double-lumen tube in the setting of CO₂ insufflation. Any exogenous CO₂ entering the airway will then vent harmlessly into the room, and any absorption that occurs would seem to be of minor physiological significance. When double-lumen placement is difficult or impossible, a Univent tube might be a good second choice. On the other hand, I believe there may be cause for caution when using a bronchial blocker to stem the inflow of exogenous CO₂ during thoracoscopy.

Daniel Biles, MD
 Rutland, VT

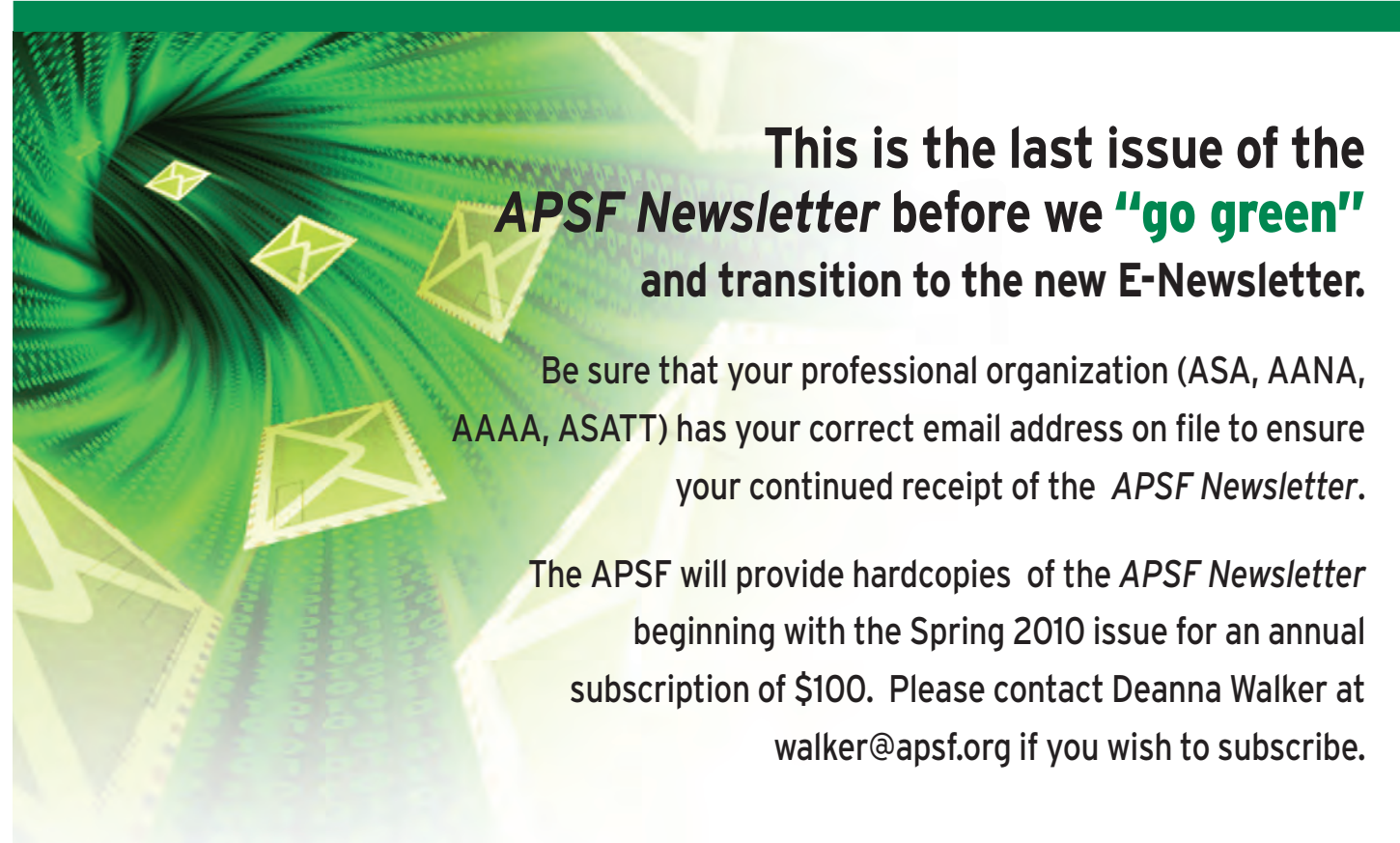
References

1. Biles DT, Carroll GJ, Smith MV, Flynn RT. Elevated end-tidal carbon dioxide during thoracoscopy: an unusual cause. *Anesthesiology* 1994;80:953-5.
2. Amin RM, Alkhashti MG, Galhotra K, Al-Sharhan A, Al-Manfohi H. Elevated end-tidal carbon dioxide during thoracoscopy. *MedGenMed* 2002;4:7.

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and transition to the new E-Newsletter.**

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