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NEWSLETTER

The Official Journal of the Anesthesia Patient Safety Foundation

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APSF Funds 9 New Research Projects
Grants Exceed $1 Million

by Sorin J. Brull, MD

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

The application process continues with an electronic, online submission format that was introduced in 2005. The applications, as well as all the required attachments, are uploaded to the new APSF redesigned website (www.APSF.org), a process that facilitates the application review by members of the Scientific Evaluation Committee, improves the timeliness of response 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 awarded this year; for the first time in its 21-year-history, the Scientific Evaluation Committee of the APSF approved funding for 9 applications, for a total amount of support in excess of $1 million.

The second development is the continued increase in the number of named awards, including the inauguration of the **APSF/American Society of Anesthesiologists (ASA) Endowed Research Award,** made possible by the continuous and generous support of the ASA. This $150,000 award joins the 2 other fully funded named awards, the **APSF/Anesthesia Healthcare Partners (AHP) Research Award**, made possible by a $150,000 unrestricted grant from Anesthesia Healthcare Partners, and the **APSF/Cardinal Health Foundation Research Award**, made possible by a $150,000 grant from the Cardinal Health Foundation. The third major development is the inauguration this year of the **APSF/Merck Research Award**, made possible by a partial ($100,000) grant from Merck and Company.

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 patient safety and one of the founding members of the foundation—Ellison C. "Jeep" Pierce, Jr., MD. In his honor, the APSF Scientific Evaluation Committee continues to designate each year one of the funded proposals as the recipient of the **Ellison C. Pierce, Jr., MD, Research Award**. The selected nomination carries with it an additional, unrestricted award of $5,000.

For the year 2007 (projects to be funded starting January 1, 2008), 9 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 39 applications in the first round, 17 of which were selected for final review at the American Society of Anesthesiologists' (ASA) annual meeting in San Francisco, CA. As in previous years, the grant submissions addressed areas of high priority in clinical anesthesia. The major objective of the APSF is to stimulate the performance of studies that lead to prevention of mortality and morbidity from anesthesia mishaps. A particular priority continues to be given to studies that address anesthetic problems in healthy patients, and to those studies that are broadly applicable and promise improved methods of patient safety with a defined and direct path to implementation into clinical care. Additionally, the APSF is encouraging the study of innovative methods of education and training to improve patient safety, and methods for the detection and prevention of medication errors.

The APSF Scientific Evaluation Committee convened during the ASA Annual Meeting on October 13, 2007, in San Francisco for final evaluation and selection of the proposals. Of the 17 finalists, the members of the APSF Scientific Evaluation Committee selected the following 9 applications:

David J. Murray, MD—Professor, Department of Anesthesiology, Washington University School of Medicine, St. Louis, MO. Dr. Murray's submission is entitled *"Web-based Program for Ultrasound Training."*

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Inside:

President Reports on State of the Foundation

by Robert K. Stoelting, MD

As President of the Anesthesia Patient Safety Foundation (APSF), it is my privilege to report annually on the activities of the foundation during the past calendar year. I am pleased that 2007 has been an active and rewarding year as the APSF pursues safety initiatives intended to further our mission that *"no patient shall be harmed by anesthesia."* In addition to continuing safety initiatives (PCA safety, High Reliability Organization Theory, full disclosure after adverse anesthetic events) and new safety initiatives (technology training, fire safety), this past year included a greatly expanded investment by the APSF in the support of anesthesia patient safety research, both in the number of grants awarded (9 funded grants) and the total amount of the awards ($1,092,363). This critically important expansion of research support is made possible, in part, by the generous annual support ($500,000) of the American Society of Anesthesiologists (ASA) and by the full support ($150,000 each) of 3 named research awards (Cardinal Health Foundation, Anesthesia Healthcare Partners, American Society of Anesthesiologists) and the partial support of one named grant at the $100,000 level by Merck and Co., Inc.

Research

The APSF Committee on Scientific Evaluation chaired by Sorin J. Brull, MD, received 39 grant applications in 2007 for awards to begin in January 2008. In October 2007, the committee recommended funding 9 research awards, 7 at the $150,000 level. Among the named grants was the first APSF/American Society of Anesthesiologists Endowed Research Award at the $150,000 level. This APSF/ASA Endowed Research Award utilizes funds from the APSF endowment fund, which were made possible by contributions from the ASA to the APSF over the past 20 years.

The awarding of nearly $1.1 million for anesthesia patient safety research by APSF in October 2007 makes APSF the largest private funding source for anesthesia patient safety research in the world. I take extreme pride along with my colleagues in endorsing this level of patient safety research support from the APSF. Since the inception of the APSF grant program, nearly 400 grant applications have been reviewed by the APSF. When the first grants were funded in 1987, funding for anesthesia patient safety research was virtually nonexistent. Since 1987, the APSF has awarded 77 grants for a total of more than $4.5 million. The impact of these research grants is more far-reaching than the absolute number of grants and total dollars as APSF-sponsored research has led to other investigations and the development of a cadre of anesthesia patient safety investigators.

Technology Training

This issue of the *APSF Newsletter* contains a report of the APSF Board of Directors Workshop on "Formal Training Before Using Advanced Medical Devices in the Operating Room-Voluntary or Mandatory?" held on October 12, 2007, in San Francisco, CA. The background for this conference was the APSF's belief that all who apply advanced medical devices, which directly affect a patient's vital functions and immediate safety, should be certifiably trained prior to such clinical application. The manner in which such training is applied or successfully accomplished is not known, and requires deliberate investigation. For example, the most effective method of introducing a new anesthesia machine ("workstation") into the operating room has not been thoroughly investigated, despite recent and dramatic increases in the complexity of these machines.

Although the incidence of equipment-related events is infrequent, morbidity associated with these events may be catastrophic. Human error is the leading contributor to equipment-related problems. Logic would suggest that anesthesia professionals need directed training with new and complex anesthesia equipment prior to its clinical use. The question is, *"Should this training be voluntary or mandatory?"* How would a patient likely respond if asked whether training before using complex anesthesia equipment in the operating room should be voluntary or mandatory?

APSF Newsletter

The *APSF Newsletter* continues its role as a vehicle for rapid dissemination of anesthesia safety information with Robert C. Morell, MD, as its editor. The *APSF Newsletter* is sent to more than 80,000 recipients including the members of the American Society of Anesthesiologists, American Association of Nurse Anesthetists, American Academy of Anesthesiologist Assistants, and the American Society of Anesthesia Technologists and Technicians.

The Spring 2007 *APSF Newsletter* was a special "20th anniversary celebration issue" describing past, present, and future achievements and goals of the foundation. The first *APSF Newsletter* was published in March 1986 with John H. Eichhorn, MD, as the editor, a position he held until 2002. Other important issues present in recent editions of the *APSF Newsletter* included discussions of cardiac stents and risks during the perioperative period (Spring and Summer 2007 issues), report of a conference sponsored by Cardinal Health on intensive insulin therapy (Summer 2007 issue), and descriptions of catastrophic neurologic outcomes in patients undergoing general anesthesia in the "beach chair" position (Summer 2007

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The Official Journal of the Anesthesia Patient Safety Foundation

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Address all *general, contributor, and subscription* correspondence to:

Administrator, Deanna Walker
Anesthesia Patient Safety Foundation
Building One, Suite Two
8007 South Meridian Street
Indianapolis, IN 46217-2922
e-mail address: walker@apsf.org
FAX: (317) 888-1482

Address *Newsletter* editorial comments, questions, letters, and suggestions to:

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

APSF Accomplishments Diverse and Numerous

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issue). The Summer 2007 issue reprinted, with permission of The Doctors Company, an article by Ann S. Lofsky, MD, dealing with maternal cardiac arrests during labor and delivery. An important conclusion from this article was the observation that most cardiac arrests occurred within the first 30 minutes of the placement of the regional block. The Fall 2007 issue of the *APSF Newsletter* addressed the question of medication safety in an article by Drs. Stabile, Webster, and Merry entitled "Medication Administration in Anesthesia: Time for a Paradigm Shift."

Beginning with the Summer 2007 issue of the *APSF Newsletter* a special section entitled "Innovative Technology and Pharmaceuticals" was introduced with the goal of providing readers with educational information regarding new developments in those areas that may directly or indirectly impact patient safety. The APSF recognizes that it is inevitable that this column will discuss products, devices, or drugs that are also sold by corporate (financial) supporters of the APSF. The APSF will zealously guard against corporate bias in these articles and strive to provide full disclosure of the author's corporate involvement as appropriate.

The "Question and Answers" section of the *APSF Newsletter* is extremely popular as a resource for publication of safety questions submitted by readers and responses from members of the APSF Committee on Technology, chaired by Michael A. Olympio, MD. The "Dear SIRS" (Safety Information Response System) column in the *APSF Newsletter* continues to provide rapid dissemination of safety issues related to anesthesia equipment as provided by readers. This column is coordinated by Drs. Olympio and Morell.

Patient Safety Journal Section

During 2007, the APSF formalized a relationship with the International Anesthesia Research Society and their journal *Anesthesia and Analgesia* by creating a "Patient Safety Section" in the journal. Sorin J. Brull, MD, a member of the APSF Board of Directors and chair of the APSF Committee on Scientific Evaluation, serves as editor of this journal section.

Creation of this journal section dedicated to patient safety research provides a visible and peer-review forum for investigators working in this area of investigation.

In April 2008, the APSF will sponsor a panel at the annual congress of the International Anesthesia Research Society. The panel will address safety issues of patients with cardiac stents and anticoagulants in the perioperative period. Richard C. Prielipp, MD, chair of APSF Committee on Education and Training, will moderate the panel.

Communication

The APSF website (www.apsf.org) is coordinated by Jeffrey B. Cooper, PhD, APSF executive vice president for Strategic Planning and George A. Schapiro, APSF executive vice president for Development. All *APSF Newsletters* are available online. The APSF website continues to provide a monthly question for anesthesia professionals to register their opinions on patient safety topics. The monthly poll questions are developed by the APSF Committee on Education and Training.

The APSF and the ASA Committee on Patient Safety and Risk Management cosponsored a joint patient safety booth at the ASA annual meeting in San Francisco in October 2007. The booth content was developed by Drs. Joan M. Christie and Robert A. Caplan.

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

Dr. Terri G. Monk, chair of the DDTF/IOTA working group, is leading the committee charged to develop terminology standards for the perioperative period. The mission of this group is to merge all the existing standards for the perioperative period and to eliminate the overlap and redundancy that presently exist in perioperative terminology. Activities of the DDTF/IOTA have been entirely supported by the APSF and the vendors of information technology systems (see the APSF website for list of vendor supporters).

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

In October 2006, Dr. Monk's group successfully obtained funding from the VA Health Services Research and Development Merit Review Board. The goals of the funded study are to analyze archived data from disparate automated information systems and develop preliminary data standards that will allow the merging of data from disparate automated information systems. Ultimately it is hoped that these data will facilitate study of the role of intraoperative variables amenable to interventions by the anesthesia professional (heart rate, blood pressure, temperature, oxygen saturation, depth of anesthesia). Currently, there is only sparse evidence to support the impact of such interventions, reflecting the fact that hand-written anesthesia records make it difficult to aggregate data on intraoperative physiology across large numbers of patients.

Financial Support

Financial support to the APSF from individuals, specialty and component societies, and corporate partners in 2007 has been most gratifying. This sustained level of financial support makes possible the undertaking of new safety initiatives, the continuation of existing safety initiatives, and increased research funding. In 2007, the APSF awarded $1,092,363 in research dollars to patient safety investigators representing more than 50% of the APSF income for the year.

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

Concluding Thoughts

The year 2007 was saddened by the loss of Arthur S. Keats, MD. Dr. Keats was the first chair of the APSF Committee on Scientific Evaluation and guided the APSF's early efforts in creating a "home" for investigators pursuing anesthesia patient safety research. He was a giant among his colleagues and his contributions will be a lasting memory to his skills as an anesthesiologist, teacher, and scientist.

The APSF was pleased to welcome Drs. Lorri A. Lee and Ann S. Lofsky as "consultants" to the Executive Committee during the year 2007.

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

Best wishes for a prosperous and rewarding year 2008.

Robert K. Stoelting, MD
President

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Deadline for Submission is June 2, 2008

Murray Receives E.C. Pierce Research Award

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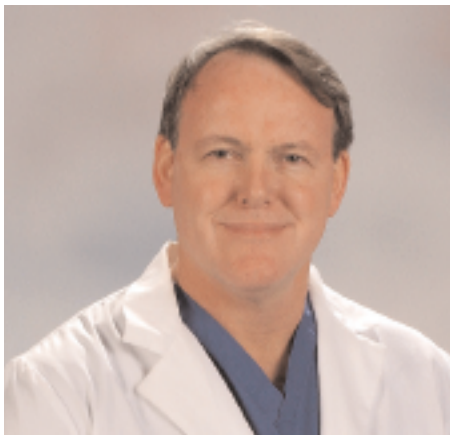
Background: Ultrasound guided central line insertion is recommended as a technique that could improve the safety of central venous access. The **goal** of this proposal is to develop and validate a web-based training program that could be used to train physicians in the implementation of ultrasound guided central venous access. During the project, a set of tiered adaptive training exercises developed at Washington University School of Medicine will be transferred to the web and data will be collected for assessment and validation of the training. One of the goals of this approach is to determine whether web-based training and simulation are effective instructional tools. **Implications:** The main objective of the project is to provide a validated interactive training program for physicians that will enhance the adoption of ultrasound guidance during central venous access and ultimately improve patient safety by decreasing the potential for vascular injury.

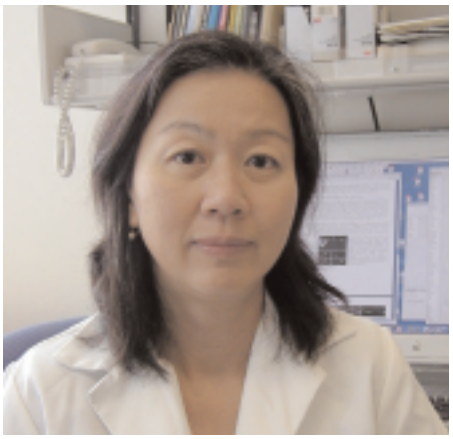
In addition to receiving the requested funding of $149,992 for this project, Dr. Murray is also the recipient of the **Ellison C. Pierce, Jr., MD, Research Award**, which consists of an additional, unrestricted award of $5,000.



Thomas J. Ebert, MD, PhD—Professor, Department of Anesthesiology, Medical College of Wisconsin, Zablocki VA Medical Center, Milwaukee, WI. Dr. Ebert's research proposal is entitled ***"Obstructive Sleep Apnea and Adverse Perioperative Outcomes."***

Background: Obstructive sleep apnea (OSA) is a common medical condition, occurring in approximately 80% of patients with symptoms. It is associated with substantial morbidity and a 40% 8-year mortality rate if left untreated. In the surgical patient, it is often first suspected in the preoperative anesthesia interview, but there is no quick and reliable method to determine its presence or severity. This information is critical because OSA is an independent risk factor for untoward events in the postanesthesia period, during which one-third of these patients will develop significant respiratory and cardiac complications and have a longer hospital stay, often including unplanned ICU admission and/or tracheal reintubation. **Goal:** the investigators will study 200 patients with documented OSA who are scheduled for elective in-patient surgery. The investigators will track screening information (including co-morbidities), the sensitivity, specificity, and the positive or negative predictive power of 4 screening tools, and the frequency and type of postoperative complications. These data will be used to develop a logistic regression model to determine the strongest predictors of adverse postoperative outcomes. **Implications:** This research will evaluate pre-surgical patients with OSA and will identify co-morbid conditions and screening tests with a strong predictive power for adverse postoperative respiratory and cardiac events. Adequate OSA screening has the potential to identify at-risk patients and to enable special perioperative management to reduce adverse postoperative outcomes.

Dr. Ebert's proposal was funded at the requested amount of $150,000 and his application was designated as the **APSF/American Society of Anesthesiologists (ASA) Endowed Research Award**, made possible by an unrestricted, $150,000 grant from the ASA.



Jacqueline M. Leung, MD, MPH—Professor, Department of Anesthesiology and Perioperative Care, University of California at San Francisco, San Francisco, CA. Dr. Leung's research proposal is entitled ***"Pathophysiology of Postoperative Delirium."***

Background: Because of changing demographics in the United States, more patients undergoing major surgery are now over 65 years of age. Compared with younger patients, the older patients tend to have more concurrent medical conditions, more severe illnesses, and poorer clinical outcomes after surgery. Of the adverse outcomes, postoperative delirium and cognitive decline are particularly common among this group of patients. Postoperative delirium is associated with longer hospital stays, poor functional outcomes, and higher health care costs. A milder form of acute cognitive changes, known as postoperative cognitive decline (POCD), may be associated with long-term declines in daily functioning. Despite the prevalence and clinical importance of postoperative delirium and cognitive decline, no specific causative factor has yet been identified for these 2 conditions, and no preventive therapy is currently available. The **goal** of this research proposal is to investigate the pathophysiology of postoperative delirium and cognitive decline in older patients undergoing major surgery. **Implications:** The results of this investigation will lead to an improved understanding of the pathophysiology of 2 significant morbidities, postoperative delirium and cognitive decline, and lead to an appropriate management strategy to minimize the occurrence of these adverse events.

Dr. Leung's grant was funded at the requested level of $149,800 and was designated as the **APSF/Anesthesia Healthcare Partners (AHP) Research Award**, made possible by an unrestricted educational grant in the amount of $150,000 from the Anesthesia Healthcare Partners.

Mark D. Rollins, MD—Assistant Professor, Department of Anesthesiology and Perioperative Care, University of California at San Francisco, San Francisco, CA. Dr. Rollins' research proposal is entitled ***"Supplemental Oxygen: A Reduction in Pulse Oximetry Sensitivity, or an Increased Margin of Safety?"***

Background: Patients receiving opioids for pain control or sedation for procedures outside the operating room are at risk for respiratory depression, apnea, and hypoxia. The primary monitor currently used to detect these possible complications is pulse oximetry. Supplemental oxygen may mask respiratory depression by decreasing the sensitivity of pulse oximetry until the patient is severely compromised, yet several prospective studies demonstrated supplemental oxygen improved safety in patients

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ASA, AHP, Merck, and Cardinal Health Join APSF in Funding Major Anesthesia Safety Research Projects

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receiving postoperative opioids and conscious sedation. For a given oximetry alarm threshold, supplemental oxygen may result in either an increased or decreased rate of desaturation and thereby affect the time to intervene. The investigators will use opioid only and opioid with propofol models of gradual, progressive respiratory depression to study various degrees of hypoxia with and without supplemental oxygen in healthy volunteers. The primary **goal** is to better understand the impact of supplemental oxygen on the margin of safety that pulse oximetry monitoring provides for respiratory depression, and the utility of new transcutaneous arterial carbon dioxide monitoring in detecting respiratory depression. **Implications:** This information has the potential to improve patient safety, decrease morbidity, and guide future patient research.

Dr. Rollins application was funded at the requested level of $150,000, and was designated as the **APSF/Cardinal Health Foundation Research Award**, made possible by an unrestricted educational grant in the amount of $150,000 from the Cardinal Health Foundation.

Benjamin A. Kohl, MD—Assistant Professor, Department of Anesthesiology and Critical Care, University of Pennsylvania, Philadelphia, PA. Dr Kohl's research proposal is entitled *"Identifying a Novel Mechanism for Perioperative Hyperglycemia in Cardiac Surgery: A Role for Incretins."*

Background: Hyperglycemia is a common and reproducible phenomenon in the cardiac surgical population. Numerous investigations have implicated hyperglycemia with increased perioperative morbidity and mortality. Recent data suggest that poor *intraoperative* glycemic control may be deleterious. As a result, the American College of Endocrinology, in conjunction with the American Society of Anesthesiologists, published a position statement that outlines goals for perioperative glycemic control. While insulin therapy has been the mainstay of treatment, it has become apparent that this strategy is frequently unsuccessful and potentially deleterious because of lack of precision in controlling serum glucose levels. The **purpose** of this grant is to evaluate a novel strategy to reduce insulin resistance, maintain euglycemia, and avoid the negative consequences of hypoglycemia during cardiac surgery. Incretins are a group of gut-derived factors that potentiate glucose-stimulated insulin secretion. One of these hormones, Glucagon-Like Peptide 1 (GLP-1) stimulates the synthesis and secretion of insulin from pancreatic β-cells and inhibits glucagon secretion from pancreatic α-cells, both in a glucose-dependent manner. **Implications:** The investigators will perform a randomized, double blind, placebo-controlled study to evaluate the efficacy of a continuous GLP-1 infusion, compared with standard insulin therapy in treating perioperative hyperglycemia. These studies will help elucidate the molecular mechanisms of perioperative insulin resistance and lead to better glycemic control of patients undergoing surgery.

In addition to receiving the requested funding of $150,000 for his project, Dr. Kohl is the recipient of the **APSF/Merck Research Award**, made possible by an unrestricted, partial educational grant in the amount of $100,000 from Merck and Co., Inc. His project was funded at the requested level of $150,000.

Asokumar Buvanendran, MD—Associate Professor, Department of Anesthesiology, Rush University Medical Center, Chicago, IL. Dr Buvanendran's research proposal is entitled *"Patients after Minor Surgery with Monitored Anesthesia Care: Is It Safe to Drive?"*

Background: Patients are currently advised to refrain from driving motor vehicles or from using public transportation unescorted for a 24-hour period if they undergo any minor ambulatory surgical procedure with monitored anesthesia care (MAC). These recommendations arose from research carried out on anesthetic agents that were utilized in the 1970s. However, recently introduced short-acting anesthetics may facilitate rapid recovery and an earlier return to normal daily activities. In addition, current simulation technology has advanced greatly, providing highly detailed and accurate driving simulation tests as well as comprehensive evaluations not available previously. This offers the opportunity to study the influence of the newer anesthetic agents on driving performance. The **goal** of the proposed study is to compare newer short-acting anesthetic agents (propofol, benzodiazepine, opioid) utilized during MAC, to determine if a particular pharmacological agent, or a combination of agents, impairs driving performance as evaluated by driving simulator assessment at time of discharge from the ambulatory center after minor surgical procedures. The 3 critical measures of driving performance selected are weaving, reaction time, and number of collisions. If any of the experimental MAC conditions show statistical equivalence with baseline at the time of discharge, for all 3 critical measures of driving performance, then that anesthetic regimen can be designated as "safe to drive." **Implications:** The present investigation will help determine the degree to which driving skills are affected by the treatment, and provide evidence-based justification for whether the restrictions for driving are warranted.

The requested funding for this study in the amount of $149,775 is made possible by a grant from the APSF.

Zeev Friedman, MD—Assistant Professor, Department of Anesthesia and Pain Management, Mount Sinai Hospital, University of Toronto, Toronto, Canada. Dr Friedman's research proposal is entitled *"Evaluation of an Anatomically Guided, Logically Formulated Airway Measure to Predict Difficult Intubations."*

Background: Adverse airway events are responsible for a majority of serious anesthesia complications. A simple and reliable bedside test that improves the ability to predict difficult intubations may help reduce the incidence of these events. Numerous investigations have attempted to predict difficult intubation by using simple bedside physical examinations. The most widely used and investigated maneuvers are the Mallampati score, the

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Airway Management and Lipid Emulsion Rescue Are Subjects of 2008 Grants

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distance from the thyroid notch to the mentum (thyromental distance), the distance from the upper border of the manubrium sterni to the mentum (sternomental distance), and a combination of factors. The **goal** of the proposed study is to validate a novel method for predicting difficult intubations. The necessary line of vision (NLV) for intubation follows the direct line that light will travel between the larynx (superficially represented by the thyroid cartilage) and the upper incisors to reach the anesthesiologist without being obstructed. This new test measures a ratio of 2 parameters directly affecting the difficulty of achieving the necessary NLV for intubation. It is based on the rationale that to view the larynx during direct laryngoscopy, one must displace the tongue past the direct line of sight between the larynx and the operator. The difficulty of achieving the NLV is influenced by how far the tongue has to be displaced and by the space available to accommodate it. The authors hypothesize that this new test will accurately predict those patients in whom anterior displacement of the tongue, and hence visualization of the larynx, will be difficult. **Implications:** The ability to accurately predict difficult intubation is a critical first step in avoiding airway catastrophes. It allows for proper preparation of alternative techniques and a different, safer approach to airway management.

The requested funding for this study in the amount of $45,730 is made possible by a grant from the APSF.

Dan J. Kopacz, MD—Medical Education and Research Institute of Colorado, Colorado Springs, Colorado; Clinical Associate Professor, University of Washington School of Medicine, Seattle, WA. Dr. Kopacz's research protocol is entitled *"Absorption of Intravascular Drugs by Intravenous Infusion of Lipid Emulsion."*

Background: The dangers of local anesthetic toxicity became apparent in 1979 when 8 deaths were reported after the accidental intravenous administration of bupivacaine. Attempts to treat this disastrous complication have mainly been supportive (standard ACLS protocol), extreme (cardiopulmonary bypass), but rarely successful. Recent animal studies and case reports have documented the efficacy of intravenous lipid emulsion in the treatment of accidental intravenous local anesthetic overdose. One explanation for its efficacy is that lipid emulsion acts as a "sink" to absorb these lipid soluble local anesthetic agents—preventing them from acting on the heart. A second theory suggests that the lipid emulsion provides additional "fuel" for the heart at a time when the local anesthetic is blocking the heart's ability to efficiently utilize fatty acids as an energy source. It is presently unknown to what degree the lipid emulsion binds the local anesthetic in the bloodstream. Current suggestions for the amount and timing of lipid administration in this scenario have also been empirically derived. The **goals** of this study are to determine the mechanism of lipid emulsion in the scenario of local anesthetic overdose, and the degree to which lipid emulsion binds local anesthetic in the bloodstream. **Implications:** This study will establish the basis for subsequent determination of the most effective regime for administration of lipid emulsion as a rescue medication in the treatment of accidental intravenous local anesthetic overdose.

The requested funding for this study in the amount of $22,379 is made possible by a grant from the APSF.

David B. Mayer, MD—Associate Professor, Department of Anesthesiology, University of Illinois at Chicago, University of Illinois Medical Center, Chicago, IL. Dr. Mayer's research protocol is entitled *"Facilitating Patient Safety through Resident Handoff Training."*

Background: In 2006, The Joint Commission (TJC) started requiring organizations to implement a new patient safety goal aimed at improving communication between providers. Root cause analyses of anesthesia-related sentinel events in 2005 concluded that poor communication was the leading cause of adverse outcomes in the operating room, being a factor in almost 80% of the reported sentinel events. In response to a survey about what is most needed to improve safety and efficiency in operating rooms, two-thirds of physicians and nurses cited better communication. Of particular interest is the communication process of "handing off" the care of a patient from one provider to another. Based on previous work, the **goal** of this research project is to create an instructional training module to facilitate successful hand-off communications among anesthesia residents in the operating room. The project will also facilitate the development and production of educational materials (toolkit) needed for the training module. **Implications:** This proposal seeks to provide a faculty development workshop with protocols and toolkits that will be launched in conjunction with the APSF at the 2008 ASA Annual Meeting. This workshop will enable anesthesiology program directors to implement the hand-off training module in their own departments, facilitating transfer of up-to-date information regarding the patients' previous care, treatment, and services, as well as current condition and any anticipated status changes.

The requested funding for this study in the amount of $124,687 is made possible by a grant from the APSF.

On behalf of the 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.

Sorin J. Brull, MD
Chair, APSF Scientific Evaluation Committee

Make Your Opinion Count!

Take the APSF Monthly Poll on the APSF Website at

www.apfs.org

Formal Training and Assessment Before Using Advanced Medical Devices in the Operating Room

APSF Workshop Explores Attitudes, Evidence, Comparisons, and Recommendations for Training on the Use of Complicated New Equipment

by Michael A. Olympio, MD

The convergence of a number of factors led to the development of an APSF Vision, which states, "All anesthesia professionals who utilize advanced medical devices that can directly affect a patient's vital functions and immediate safety, will be certifiably trained prior to such clinical application." Those factors included 1) the dramatically increased complexity of modern anesthesia workstations, 2) a preponderance of human error as a cause of equipment-related incidents, 3) the inadequacies inherent in conventional in-service training, 4) the known advantages of intensive training in complex tasks, and 5) the evidence reflecting failures to complete non-mandated training. The most effective manner to successfully accomplish such training is not known and requires deliberate investigation.

The goals for an APSF Board of Directors' Workshop were to: 1) define the problems and shortcomings in conventional training, 2) demonstrate the limitations and impediments inherent in mandating training, 3) describe new approaches to training that might be more successful, 4) consider analogous endpoints and successes from the aviation model, 5) explore the medico-legal and regulatory pressures driving such efforts, and 6) promote discussion and targeted efforts at implementation. The workshop was successful in gathering approximately 72 persons from the medical, nursing, technical, administrative, regulatory, insurance, government, aviation, and safety industries to participate. All of the stated goals were addressed.

The problems encountered in conventional (typically referred to as "in-service") training include a lack of commitment by manufacturer and/or clinician, a lack of time, inadequate focus on, or lack of content, and a lack of evaluation of learning. Strong leadership is required to achieve a high participation rate, particularly among physicians. Training will enhance user satisfaction, application of advanced features, resource utilization, and potentially patient safety. Previous reports have indicated a low participation rate among academic physicians who are not mandated to attend training, although a majority of those who do participate believe training is valuable, should be mandatory, but must be practical and applied. Some centers have already mandated introductory training on new machines, utilizing a variety of approaches to levels of complexity, duration, scheduling, and testing. A detailed review of the published literature revealed very little data on prospective, randomized trials demonstrating advantages of intensive training, but the few that exist, do indicate significant advantages. Unpublished and subjective reviews of equipment hazard and critical incident reports indicate a low percentage of critical incidents are training-related. One ASA organization (Committee on Equipment and Facilities), however, is recommending training, demonstration of competence, and check-out, prior to using anesthesia gas delivery equipment. Despite the paucity of medico-legal liability ascribed to a lack of training, efforts and statements that promote mandatory training may create *de facto* local standards of care. Records of training should be maintained by hospital administrators, who ultimately have control over training mandates. Analogies to aviation suggest that training on anesthesia equipment should be precisely focused on new and clinically relevant features, primary failure modes, and prevention and recovery. This perspective should be widely communicated to clinicians. Closed claims related to anesthesia equipment have increased substantially in the most recent 5-year analysis, although claims related to gas delivery equipment remain low at only 2% of the total. Human error is an overwhelming culprit in these claims, and death or brain damage is frequent (75% of outcomes). Focus on recurring failures is again emphasized. Hospital administrators are challenged by the costs of providing ancillary technical assistants, who sometimes serve as surrogates for inadequately trained clinicians. Clinical leaders struggle to overcome the impact of time constraints, costs, resource shortage, as well as complacency when attempting to train clinicians. Some anesthesia leaders argue that mandated, extensive device training programs are unnecessary and irrelevant because there is such a low incidence of equipment problems leading to adverse outcomes. They propose that deploying resources to implement evidence-based solutions to other major morbidities would have far greater yield for patient safety. The collective opinions of safety-minded attendees at this annual workshop seem to indicate that selective and focused training or demonstration of competence should be mandated, but only after consultation, communication of risk, and culture change are effected. Industry must provide seamless and standardized interfaces and novel training programs to lessen risks and reduce burdens on clinicians.

In summary, the APSF has developed a consensus statement in favor of requiring a process for training and/or demonstration of competence. Details follow.

Summary of Workshop Presentations

Defining the Problems in Conventional Training

Caroline Coyle, General Manager Anesthesia Care, GE Healthcare described the technological convergence of minimization, automation, intelligent deliveries, virtualization, remote control, access of information, and globalization that now defines our modern anesthesia workstations. Originally composed of pneumatic and mechanical systems for ventilation, fresh gas, and volatile agent delivery, the modern anesthesia machine may now feature electronic and computer feed-back control of these systems. For example, ventilation modes now include volume correction and sensing of patient breathing with synchronization, and both fresh gas and volatile agents may be controlled completely electronically through keypad entry of desired settings. Monitoring of the patient and control of the machine are now integrated, and streams of data are fed to automated information management systems (AIMS). Coyle posed the question, "Will this technology result in safer patient outcomes and what does this mean for training?" and suggested that conventional in-service needs to be replaced by more advanced and effective training in order to achieve reliable benefits from this technology. She compared the results of 2 recent training programs at academic installations that differed in their duration of participation, willingness to follow company-prescribed training, and the use of clinician specialists. The hospital that received only 25% of the prescribed training and did not effectively train or employ clinician-specialists, consumed 6 times the amount of service calls (46% of which were training deficiencies) and required extensive clinical follow-ups, when compared to the hospital that received the full company-prescribed training. Common problems were related to the ignorance of checkout procedures and machine calibrations and the misunderstanding of alarms and backup modes. Coyle also described mistaken perceptions about the equipment, greater operating costs (e.g., increased absorbent usage), delayed starts, and a limited ability to take advantage

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Randomized Studies Need to Support Value of Training

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of advanced operating features. In stark contrast, there was only one training-related issue in the other institution. She referenced a prior report stating that most clinicians thought training should be mandatory, and concluded that education would benefit all of us. Exactly what the best mechanism is and how it is best accomplished is uncertain, but first, cultural and political barriers must be addressed and customers must appreciate the need for advanced training. Coyle concluded that the benefits from mandating training would be seen in a very short period of time

Experience, Limitations, and Success in Mandating Training

Michael A. Olympio, MD, co-moderator of the workshop and leader of the APSF Technology Training Initiative began with the assertion that inadequate training was perceived as a national problem. He cited a news article describing controversies over training vs. promotion of high-tech medical devices, and referenced one single, prospective, controlled trial demonstrating how intensive training caused more effective application and troubleshooting of a new anesthesia machine during a simulated crisis. Olympio further described consistent evidence that human error is responsible for the majority of equipment failures, and that more training is required to overcome such failures, according to leading experts. He summarized the factors leading to the development of the previously described (*APSF Newsletter* Fall 2006) Technology Training Initiative, particularly referring to manufacturers' observations that many clinicians do not show up for training, and their perception that very few even care about it. That initiative attempted to mandate extensive training on new, advanced anesthesia machines at this author's institution. Rates of completion of the entire training program declined from student nurse anesthetist to CRNA/resident, and most dramatically to faculty, as the one group for whom training was not specifically mandated. However, participation in hands-on workshop training was similarly very high among all 4 groups, consistent with the participants' opinion that it was the most effective component for learning. Olympio described the afterthoughts of the chair, Raymond Roy, PhD, MD (whose workshop presentation is described below), who did not mandate training for the faculty. Roy initially felt such training should be viewed as a safety initiative without mandate, but after the low participation results, he felt training should be mandated *after* faculty buy-in with negative consequences to those who failed to obtain it. Participants overwhelmingly felt the training was valuable and 78% thought such training should be mandated. Olympio then emphasized the differences in the type of training Coyle's installations received, and reiterated the APSF Vision statement, that, as shown *"The manner in which . . . training is applied or successfully accomplished is not known, and requires deliberate investigation."*

In a related, ongoing study, Olympio and colleagues are collecting control data on the manner of training in recent installations. Four departmental examples varied in a number of important aspects including, but not limited to 1) the degree of mandate and consequences for failure to attend, 2) the extent and duration of the training program, 3) the size and numbers of trainees, 4) the provision of follow-up training, 5) the on-, or off-duty timing of the training, 6) the additional salary needed for relief clinicians, and 7) the attitudes toward training by some clinicians. Two of the 4 departmental leaders spontaneously commented on the negative attitudes of a few clinicians who did not want to attend training, using the words *arrogant*, or *resistant to change*. The early, retrospective nature of the data did not allow for precise numerical comparisons.

Olympio went on to describe a prospective, randomized, controlled, IRB-approved pilot study by the APSF Committee on Technology, *"An Outcomes-Based Comparison of Mandated vs. Non-mandated Anesthesia Machine Introductory Training,"* and its hypothesis that, "Mandating introductory training of complicated modern anesthesia machines will enhance user satisfaction, resource utilization, and the safe operation, understanding, and troubleshooting of the machine." The ambitious plan relies upon the joint cooperation of manufacturers and clinicians within the APSF and the cooperation of academic departments. Olympio described the efforts to develop standardized and valid assessment instruments that would address the necessity for mandating or not-mandating training. He emphasized that all programs would receive the same training, and that the mandate would be the only treatment variable tested.

To enhance the validity and the need for such a study, the APSF independently consulted the ASA Practice Parameters Research Team to "Determine the impact of medical device training on anesthesiologist knowledge, competence, and acceptance of devices." The researchers were asked to specifically focus on mandated and/or intensive training, and upon devices which were generally used by all anesthesia clinicians (i.e., anesthesia machines, infusion pumps, AIMS, and advanced airway devices). The consultants' extensive review of the literature found only 19 manuscripts that had evidence-based outcomes and no published trials of mandated vs. non-mandated training. Only 8 studies were related to the anesthesia machine, and only 2 of those were randomized controlled trials, both of which demonstrated improvements in operation and troubleshooting. The experts concluded that:

- More research is clearly needed
- It would greatly benefit the specialty
- A focus on whether mandatory training is necessary, would help policy makers determine the best implementation
- Simulation and hands-on training show a great deal of promise
- Randomized studies would potentially provide stronger evidence in support of these training methods.

An ECRI Institute database of 225 combined "Health Devices Alerts" and FDA MAUDE reports covering the past 5 years of "anesthesia training," and "anesthesia pre-use check" were studied by 2 committee members and were subjectively found to contain few events in which more extensive, focused training would have likely prevented the incident. They did, however, find many instances that involved providers not doing what they should have done, with even basic training. More importantly, the 2 reviewers felt that such voluntarily reported databases would be unlikely to report failures of training; such data would rather be located in inaccessible risk-management files. Numerically, Olympio estimated that only 8% of the 225 reports could be related to ineffective (or lack of) training. Finally, Olympio reported on a recent "recommendation" to the ASA House of Delegates by the ASA Committee on Equipment and Facilities that, "The Committee on Standards and Practice Parameters draft a Practice Alert recommending training and demonstrated competence in the use of any particular type of anesthesia machine or workstation, as well as completion and documentation of a pre-use checkout of that workstation, before an anesthesia provider uses it to deliver patient care."

Medico-Legal and Regulatory Issues in Technical Competence

Urs R. Gsteiger, Esq., Horton and Gsteiger, P.L.L.C. of Winston-Salem, NC, repeatedly emphasized that

Urs R. Gsteiger, Esquire

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Aviation Incidents Usually Related to Human Error

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there was not much case law involving the adequacy of technical training, and that the APSF was well ahead of the legal profession in discussing such matters. He described one example in which the lack of training on emergency operation of respiratory equipment was a cause of poor outcome and liability. Gsteiger noted that only one Federal statute, the Safe Medical Devices Act of 1990 is known to apply to such issues, but is directed to the manufacturer. This statute contains hospital reporting requirements, but does not contain direct training requirements. Furthermore, he commented that state medical boards could mandate licensure requirements for training, or could respond to complaints by taking action against improperly trained physicians, but no such activities were known to have occurred. Likewise, these actions have not been seen from other clinical providers, or from the Joint Commission. He suggested that hospital administrators, driven by medical staff or risk management, could effectively regulate device training, and that risk management is indeed where the database on lack-of-training issues is located. Gsteiger explained that hospital administration could force changes in credentialing if in fact the risk management group deemed that it were necessary. The legal issue that remains, however, is whether or not proper training would result in better outcomes. Only 2 reported cases in 50 states are known to have attributed liability secondary to lack of training, and they were described. Gsteiger emphasized that legal standards of care are based upon expert testimony by members of our own profession, and are not set by the jury. He then conjectured, "Does requiring training set a standard that otherwise may not exist?" Only the experts can testify that a failure to train violates the standard, and if influential groups mandate training, then it raises the possibility that such training does become a standard. In fact, Gsteiger argued that some professionals would already testify that training is mandatory. In summary, he recommended:

- Train users of device on their operation, features, and emergency procedures
- Keep records of training curriculum and attendance
- Require periodic recertification
- Make certification a prerequisite for credentialing

Gsteiger emphasized that if there were no adverse consequences for a failure to train, then it would not get done. Finally, he stated that clinicians should do what is safe and what we feel should be done.

Aviation Mandates, Validity, and Logistics in Flight Training

George Elliott, Vice President, Volant Systems introduced himself as a 15-year instructor pilot with the Air National Guard, and a 21-year veteran pilot trainer with US Airways. He and his group developed the standard by which all current scheduled pilot instructors are graded, and he is a consultant to time-critical risk and resources industries such as the US Marines, Navy, trucking, and NASCAR. He likened our specialty to those, as we must also make risky decisions in time sensitive domains. From the beginning of aviation, the US government realized the military applications of flight, and therefore established control over training in the early 1920s. Having paid for training, they wanted evidence of its effectiveness, and a return on their money. Elliott reminded the audience that since pilots die of their own training deficiencies, they too supported the efforts to regulate training. In the early 1990s the US government could no longer keep up with demand, and relinquished control of training to the individual airline companies. The frequency of mandatory retraining was cut in half to once per year, and consisted of incident-based scenarios, derived exclusively from actual complications encountered the previous year. If new equipment instruction could be computerized, then it was placed into e-learning modules and sent electronically to pilots. Elliott described how most critical incidents and accidents were not related to equipment failure, but rather to pilot failure related to increasing task loading and distractions in the cockpit. He concluded with recommendations to

- assess the level of risk
- balance the use of resources to minimize risk
- communicate risks and intentions
- debrief after conducting the mission.

Anesthesia Claims Associated with Equipment Misuse

Robert A. Caplan, MD, member of the APSF Executive Committee and the ASA Closed Claims Project Committee stated that equipment claims have increased to 17% of the total 7,328 closed claims through 2004, in contrast to 9.5% in the 1980s and 1990s. Increasing complexity could be responsible, but gas delivery equipment problems still represent only a very small (2%) proportion of the total 7,328 claims. Caplan went on to describe the most frequent equipment claims arising from central venous and arterial access catheters, indicating that for all equipment claims, the clinician's conduct was judged to be less than standard of care more frequently (44%) than for non-equipment claims (34%). Although equipment claims paid more frequently (64% vs. 51%), they paid significantly lower amounts (28-31% of non-equipment claims), and clinician misuse was 3-times more common than pure equipment failure. Caplan emphasized that analysis of closed claims indicates that we should look for recurring patterns of injury within categories of equipment-related injury to determine what to train. For example, one-half of gas delivery equipment claims arise from the breathing circuit and caused death or brain damage in 75% of cases. Misuse of the anesthesia machine itself is very rare, occurring in only 2% of cases. After describing other injury patterns for vascular access and warming, Caplan recommended

- searching for recurring patterns of injury,
- emphasizing simple principles, such as how to connect the breathing circuit, as shown.

Dr. Robert Caplan

He further indicated that misuse of equipment is frequently not reported in the literature.

Hidden Costs and Benefits of Credentialing Hospital Employees

Erwin R. Stainback, Director of Surgical Services, North Carolina Baptist Hospital, stated that training was a daunting task due to disparities in the influence the hospital has over the 4 types of anesthesia professionals (faculty, resident, CRNA, and student nurse anesthetist). In particular, his hospital has minimal influence over faculty physicians. Stainback described 4 examples of high technology device installations that required increasing numbers of support personnel as a substitute for adequate training. For example, currently 6 individuals and an additional 8 are being proposed to support the Surgical Information Systems (includes AIMS system), and they most frequently addressed issues related to inadequate training or understanding of the equipment. Similar needs were described for minimally invasive technologies, navigationally-assisted surgery equipment and laser technology, amounting to hundreds of thousands of dollars per year. Stainback explained that training accountability ultimately resides with the hospital Board and CEO, through the development of medical staff bylaws, and policy and procedure manuals, but effectively resides with the Chief CRNA, Resident Education coordinator, and Nurse Anesthesia Training Pro-

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Administrator Describes Impediments to Training

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gram coordinators, and Medical Staff leaders or Department chairs. He felt that practical simulation training was the most effective means, but highly inefficient as compared to classroom learning. Stainback described the impediments to training:

- Lack of national standard providing limited precedent
- Time restrictions due to push for productivity
- Cost challenges due to declining reimbursements
- Inadequate and/or inexperienced manufacturer training resources
- Complacency of provider in recognizing need for training
- Inadequate resource commitment in providing trainers, facilities and equipment.

He noted that the enforcement of training could be accomplished as an initial requirement for employment, or through suspension of pay, withholding pay increases, revocation of privileges, and lower level case assignments. And, if training were to be mandated, its effects could be studied through analysis of sentinel events, reduced support calls, reduction in technical support, increased life of capital, and re-education rates. Finally, Stainback described 2 successful training programs with robotic surgery and terra-recon, which required a certification ID prior to use of the equipment. He provided a vivid personal example of how his lack of training in the operation of sophisticated and expensive sports cars prevented his full enjoyment and appreciation of their capabilities in a unique driving experience.

Mr. Erwin Stainback

Mandating Formal Physician Training is NOT Realistic: The Contrarian View

Dr. Raymond Roy, PhD, MD, professor and Chair of the Department of Anesthesiology, Wake Forest University School of Medicine was invited to deliberately present this contrarian view (acknowledging his prior statements in support of training mandates). Roy indicated that this contrarian stance is based upon a different view of the significance of the problem. He emphatically and strongly presented the contrarian case that we do not know with certainty either the numerator or the denominator for equipment-related malfunctions. Even if we did, the overall risk of surgery is related to many other things, including medical risk, surgical risk, and provider errors. He quoted a Thailand study indicating an equipment-related risk of death of only 1/101,350, which was magnitudes below the provider risk and still further below total risk. Arguing that the elimination of every equipment problem would not change overall risk, Roy challenged us to put our efforts into major, proven interventions for decreasing perioperative morbidity (e.g., use of beta-blockers, use of shorter-acting muscle relaxants, use of local anesthetics to prevent ileus, timing of antibiotics, and the prevention of hyperglycemia and hypothermia). Roy went on to challenge the aviation analogy to anesthesia as inaccurate, since it is the pilot's job to operate the device, and pilots have ample time to learn about that device. He rather used the analogy of a rental car, in that we do not require training before driving away, and condemned the "engineering manual" approach to machine training as being contextually unrelated to clinical care. Roy suggested that machine training be incorporated into the clinical context of case presentations, lectures, or simulations, since the implementation of widespread training is hampered by the logistics of practice type, number of devices, and technical support. At his institution, machine training would require nearly 300 clinician-days in the first year alone. In summary, Roy argued that:

- Mandated training costs too much to address problems that occur with such a low incidence
- It is better to invest time and money in reducing anesthesia-related medical and surgical risks.

Charting an Effective Course of Implementation: Summary of Breakout Group Deliberations

Breakout group leaders were asked to consider the following issues within 4 separate audience groups:

- Validating the training program and assessment tools
- Promoting legal, regulatory, and industry mandates
- How to effect physician participation
- Steps to success: Where do we go from here?

Report from Group 1, led by Sorin J. Brull, MD

The group first considered the validation of training programs and assessment tools, and had a number of recommendations:

1. Focus upon what is new to the individual and/or new to the organization
2. Define whether the "new" technology is novel to the individual/organization, or whether it is new to the entire industry (i.e., an entirely new product)
3. Define the "value-added" of the new technology (e.g., new ST-segment trending capability added to "old" ECG machines)
4. Determine the "core criteria" for defining ***useful new technology***:
   a. Clarify whether this is an issue of safety or efficiency
   b. Determine whether the device or feature can be used in a high-stress situation, and
   c. Determine how the device or feature translates into clinical practice
   d. Realize that human factors design is critical in this new technology
   e. Create medically, not technically, oriented learning manuals
5. Evaluate new techniques of training
   a. Develop an "in-house"/manufacturing training program
   b. Train individuals first, but then ask them to train others (i.e., demonstrate understanding)
   c. Train super-users as resource personnel
   d. Don't forget to train for simplistic and effective backup strategies (such as use of the bag-valve-mask during anesthesia machine failure)
6. Ask who is paying for this training; ultimately the user always pays.

They subsequently addressed the question of how to effect physician participation, commenting that making the training mandatory is naïve and short-lived, and that it cannot be a long-term strategy; users must be motivated with incentives as a better and lasting plan. Eventually, peer pressure from a majority participation and credentialing, will lead to subsequent participation. Participation will be enabled markedly by *standardization*.

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Small Groups Share Training Perspectives

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Report from Group 2, led by Lorri A. Lee, MD

The initial part of the discussion centered on whether the design of the new advanced medical devices should be more simplistic so that less training would be required. Some advised that only innovations providing significant improvement in patient care or delivery of care should be introduced, as opposed to non-essential "flashy" features that increase the level of complexity. However, some industry representatives noted that the way they distinguish themselves from the competition is to provide these unique features. At a minimum, most members agreed that a standard nomenclature for features should be utilized, perhaps with help from the Data Dictionary Task Force. One example of the need for standardization was in the labeling of different ventilatory modes, such as SIMV.

Regarding the validation of training, many felt that knowledge and application skills could be combined into a single, more effective simulation test, as testing for knowledge alone frequently results in poor retention. Others noted that the number of calls to the company or super-user would be a very useful, objective measure of the adequacy of training. Participants expressed concern over the need for periodic retraining and new training as replacement machines are introduced.

The majority of the group believed that the Joint Commission would be the most appropriate regulatory body to oversee training for advanced medical devices, and, that hospitals would not necessarily support training for advanced medical devices unless it was required by the Joint Commission or some other entity such as P4P or Leapfrog group. The cost of such training would be assumed by the hospitals or provider group, and potentially transferred to the patient.

The question of how to effect physician participation was almost unanimously "mandatory training." Most group members did not think that physicians would spend the extra time for training if it were optional, and that perhaps it should be tied to the credentialing process. It was felt that the best way to initiate this process was to have entities such as the APSF make strong recommendations for it, with the ASA instituting standards or a patient safety initiative, and/or the Joint Commission or CMS requiring it.

Report from Group 3, led by Ann S. Lofsky, MD

The group discussed why physicians tended to be so noncompliant when training is offered but not required. The general consensus was that many feel that the use of devices is intuitive and that they simply don't need anyone to tell them what they can figure out for themselves. One quote was, "They think it's like video games," but, "many do not realize that newer machines are becoming increasingly complex." The feeling of this group was that training must be mandated to be effective and that the most likely body to be able to do that is the anesthesia department itself. The department is able to make its own requirements for membership and could penalize failures to attend mandated training through withholding of salary or deletion from the surgical schedule (for the self-employed). There was agreement that the stick works better than the carrot, and although equipment problems are rare, it does not mean we cannot require training. Departments mandate ACLS training all the time, even though cardiac arrests in the OR are rare events.

The group also discussed a recent training mandate in a large academic department for a new anesthesia machine. After some initial reluctance on the part of some group members, they all simply fell in line when it became apparent that there would be "no exceptions" to the decision by the department that training was compulsory and that there were economic consequences for failures to comply. Members of non-academic groups said they felt a similar approach would likely work in their own departments. There was further questioning about the knowledge/performance type of testing that followed the training, and these assessment tools were designed by the equipment company representatives and members of the department working together. Following training, the program simply issued a certificate of completion, arguing that it might confer less liability than a certification of competence. However, an attorney in the group questioned that supposition. The spokesperson for this program stated, "Partnering with the manufacturers was key," and they trained several super-users who then administered much of the training and testing to the rest of that department. Some group participants observed that training seemed to go better when provided by people who "do what you do" and who can answer clinical questions as well as questions about the machine itself.

The economics of equipment training was next discussed. Participants realized that anesthesia groups may want training for different reasons than do the manufacturers. They may be trying to prevent clinical problems while the manufacturers may be trying to prevent service calls and technical questions. Clearly, the training needs to meet the needs of both while still being time and cost efficient. Ultimately the purchasing group pays for the training, but there was a consensus that this should probably be bundled in with the cost of the equipment "at a high enough level" rather than as a line item, so that there isn't a tendency to scrimp on training in order to save money. One group member commented that training should be more modern and accessible to physicians in the OR. Since most anesthesia providers are quite computer literate, training could be available online. (Although many ORs now have Internet access, it was felt attention should not be diverted from patient care for this process.) Having computer training online would make it easier for locum-tenens who might be coming into the department to train at home in advance of their scheduled OR time.

Finally, the group suggested and agreed that the APSF should issue an opinion piece, perhaps in their *Newsletter*, regarding the necessity of mandatory training so that anesthesia department heads can start thinking about how they might implement this in their own facilities. This group included the representative from The Joint Commission to the APSF, who stated in response to a question, that The Joint Commission would not usually get involved at this point in time, but if "leaders such as this organization" or other designated "experts" developed a consensus that technical training was crucial, then The Joint Commission might step in to require it of all accredited facilities. The comment was made that although equipment problems have been rare, they are likely to increase with increasing complexity of machine design unless we do something now about training.

Report from Group 4, led by Matthew B. Weinger, MD

Several key points were discussed by this group:

1. Why do the user interfaces of these devices have to be so complex that they require substantial training? Participants were aware that extensive research supports the assertion that training is a very weak risk mitigation strategy. To minimize device-related adverse events, the device's user-interface must be designed correctly for the intended uses, users, and use environments. Given an experienced cohort of users, the design should incorporate human factors engineering principles and prior experience (positive transfer) to minimize the need for more than cursory or focused training, particularly for routine and frequent device operation.
2. Why isn't the user interface of similar devices even more standardized, like automobiles? If they are going to be so complex, then maybe there will need to be greater presence of sales representatives or anesthesia assistants helping us to use these devices.
3. Some training, however, is essential, and it should be mandatory. Evidence is overwhelming that if you don't mandate it, then folks won't do it. Furthermore, complex equipment may be viewed simply as a "black box" whereby resident physicians (and community physicians) do not currently have even fundamental basic knowledge, and trainees do not get the technology training they need.

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APSF Develops Training Recommendations

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4. What should we be training? The "Top-10" things you need to know, such as key features, key failures, differences between old and new, routine and common use scenarios, and trouble-shooting. More importantly, should clinicians be granted the option to "test-out" if they are accomplished self-learners?
5. How should we train? Use quick-reference guides, tutorials (e.g., *Explore!® Aestiva®/5, or Virtual Fabius GS*), experiential learning in simulation. Or, could the devices have a "simulation mode" that allowed in situ simulation or just-in-time training of key features, adverse conditions, etc.?
6. Promoting legal, regulatory, and industry mandates: If hospitals buy the equipment, they should insist upon training as a condition for use, make it part of their credentialing, and insist upon maintenance of certification.
7. Where do we go from here? Require mandatory training on each and every piece of new equipment, especially new technologies, but keep it focused on the critical aspects. It must be succinct, timely, usable, and valuable. We need to change the culture; change the way that we introduce new equipment and assure competency, and we must instill a greater individual sense of responsibility and accountability. We should partner with other entities, including the NPSF, The Joint Commission, NQF, IHI, and CMS.

Audience Discussion

A brief audience discussion period followed the group presentations. Participants stated that it would take progressive thinkers to move such an effort forward, but insurance companies could propel such an effort by reducing premiums for those who participate. Another comment emphasized the necessity for clinician "buy-in" first, then mandate, such that professionals would have the opportunity to control, modify, and improve their own training requirements. Several echoed the sentiment that the failure of faculty participation in the Wake Forest pilot program was the result of a failure to consult with the participants first, and that such a buy-in was recommended by 2 speakers, Coyle and Roy. A stated perception of arrogance on the part of physicians who refused training was challenged by others, with the assertion that non-conformists might well be highly-trained, respected, and professional clinicians. Still others felt that general apathy was a leading cause of non-attendance at training sessions. An assertion that pilots had lots of time to train was challenged by an acknowledgement of their being frequently away from home even while not flying. Finally, in a requested show of hands as to who would favor recommending mandatory training requirements, all hands rose in favor of mandating training with the exception of only 1 attendee, who felt that the workshop presentations did not provide sufficient evidence to require mandated training.

Conclusions and APSF Recommendations

In consideration of 1) the increased complexity of modern anesthesia equipment, 2) a preponderance of human error as a cause of relatively infrequent equipment-related failure, 3) the inadequacies of conventional in-service training and failures to complete non-mandated training, 4) the advantages of, but paucity of scientific evidence for intensive and directed training, and 5) medico-legal perspectives on training, the APSF makes the following recommendations:

Although existing literature does not describe frequent adverse anesthesia events owing to the anesthesia professional's lack of understanding of equipment, the APSF believes the logic is compelling to require confirmation of competency before using unfamiliar and/or complex anesthesia equipment that can directly affect patient safety. In this regard, the APSF believes that each facility should develop a required, formal process to assure that anesthesia professionals have received appropriate training and/or demonstrated competence in the use of such medical devices. Manufacturers should refine and initially offer this training. This required process for administering training and/or for demonstrating competence should be efficient, timely, and pertinent in addressing new critical features and relevant failure modes. The most effective manner to successfully accomplish this training and testing is not known and requires deliberate investigation.

Dr. Olympio is Professor of Anesthesiology at Wake Forest University Baptist Medical Center and Chair of the APSF Committee on Technology.

Participants use small group facilitated discussion to develop recommendations for technology training at the 2007 Board of Directors Workshop at the 2007 ASA Meeting in San Francisco, CA.

ASA Meeting Exhibits Sharpen Patient Safety Focus

by John H. Eichhorn, MD

While patient safety certainly persisted as a general theme of the 2007 ASA Annual Meeting exhibits which incorporated many engaging presentations, the specific topics of airway management techniques and ultrasound-guided needle placement received more than the usual attention.

Among the Scientific Exhibits, 20 of the 63 represented programs (several involved with simulation as a teaching tool), groups or causes, leaving 43 original exhibits. Eleven of these concerned airway management techniques.

Reinforcing the adage "everything that's old is new again," Drs. T. Wu and H. Chou from Kaiser in California reinforced with an elaborate display a concept first published in 1993 that many difficult direct laryngoscopies are due to the "tongue-in-the-neck" phenomenon in which the base of tongue is large and low in the hypopharynx (with a long mandibular-hyoid distance). Multiple X-rays, photos, and case reports made the point dramatically. The conclusion is a recommendation to incorporate into every preoperative airway assessment an evaluation of the distance from the hyoid bone directly cephalad to the inferior edge of the mandible with longer distances, e.g., greater than about 3 cm, suggesting possible difficult mask ventilation and/or direct laryngoscopy that can be anticipated and thus more easily overcome.

As often stated in this report, the induction of deep unconsciousness and muscle relaxation ***before*** genuine confirmation that a patient's airway can be managed and accessed is still one of the least improved and most dangerous things anesthesia professionals do. While the actualization of a simple routine real-time preoperative image and analysis of airway anatomy is still a Star-Trek type fantasy, a team from the Cleveland Clinic presented a very compelling exhibit of virtual reality 3-D reconstruction of airway anatomy in patients who have preop CT/MRI of the head and neck (often ENT or trauma patients with airway questions). Because the image is digitized and online it can be accessed and processed by specific (open source) software (for MAC) to yield a truly remarkable and strikingly detailed virtual image of the airway that can be fully manipulated and explored. It is thus possible to view this virtual airway exactly as the patient would appear through a fiberoptic scope and verify airway access or plan specifically a fiberoptic intubation in situations of distorted anatomy. Creation of such plans has allowed many patients who otherwise would have had awake intubations to have pre-mapped asleep fiberoptic intubation.

Continuing the theme of airway issues, making the process of extubation safer, particularly by doing a "reversible" extubation leaving a stylet in place, was the focus of one exhibit. Another showed a new device that removes the stylet from a just-placed endotracheal tube automatically, without any assistance and without compromising the line of sight into the larynx. A new angled laryngoscope blade (which fits a traditional handle) with a lens and an insufflation port was offered as another approach to managing difficult airways where the larynx is not seen with standard blades. Likewise, a new pair of devices involving a supraglottic airway through which a rigid intubating stylet is fitted was suggested as an improved approach to otherwise difficult or impossible airways. One other popular exhibit allowed visitors to compare 3 different video-assisted laryngoscopes side by side on an intubation mannequin. There was an exhibit of a teaching device developed in Wales, UK, that measures force and direction of the laryngoscope blade being used (in a conventional manner) to intubate a simulation mannequin; results suggested faster learning curves for trainees exposed to this teaching regime.

The other significant recurrent theme was the utility of ultrasound guidance (various makes and models) for correct needle placements—both for blocks (neuraxial, plexus, and peripheral) and for cannulation of veins (particularly the internal jugular and subclavian via a supraclavicular approach) and even peripheral arteries in difficult circumstances when intra-arterial monitoring is needed but difficult to obtain. Models and videos were presented in several exhibits and one included a simulator used at New York University to teach the use of ultrasound to guide peripheral block needles.

A large team from Robert Wood Johnson in New Jersey presented a simple concept for use during monitored anesthesia care when the patient needs supplemental oxygen for safety and has nasal cannulae placed. In essence, a plastic bag is used to make a tent over the patient's face in a specific manner to specifically prevent CO_2 rebreathing but that raises the enclosed FiO_2 to over 40%.

Finally, while not traditional direct patient safety topics, 2 Scientific Exhibits presented applications of classic Oriental medicine, one from Japan involving the use of acupressure to resolve intractable pain and the other from Virginia Commonwealth University to enhance preoperative evaluation by palpation of certain arteries and acupuncture points as well as observation of the patient's tongue.

In the Technical Exhibits, many manufacturers followed themes similar to those in the Scientific Exhibits. Also, information management/technology systems were numerous, each implying, either directly or indirectly, positive patient safety implications. Each of the simulator manufacturers had an elaborate display with opportunities to try the product.

Airway tools were ubiquitous. Intubating and video laryngoscopes of various shapes and sizes permeated the displays. A new model of micro video camera is intended to fit to the forehead of an anesthesia trainee (or dental student) so that the supervising faculty can see exactly what the trainee sees and thus tailor teaching and suggestions to exactly what the trainee is doing. The system looks much like a standard surgical headlight common in all ORs and it attaches to the same type of light source. The video image, however, is transmitted wirelessly to a receiver that is connected to any available monitor. In the equipment exhibits, a new airway device is an endotracheal tube stylet that protrudes 2 cm out the distal end of the tube and has a soft, somewhat flexible tapered point that will smoothly traverse the larynx—the purpose of which is to avoid trauma to the vocal cords from the edges at the tip of a regular tube. Another new shape was a brand of oral airway that is wide and flat and offered as particularly helpful with mask ventilation.

Ultrasound devices to facilitate correct needle placement in all applicable circumstances were prominent in the exhibit hall, each touting its particular features and advantages. On another tack, 2 manufacturers exhibited new systems to diagnose obstructive sleep apnea at home in the preoperative period. When a patient gives a suggestive history or has anatomic likelihood, such a system of sensors and a recorder can be sent home with the patient. Ventilatory patterns from either chest plethysmography or expired breath are sensed and recorded in a computer memory along with pulse oximetry measurements. Then, when the patient arrives for preoperative preparation prior to an anesthetic, the computer files can be downloaded and analyzed in real time—within a few minutes—providing a report that includes evaluation for sleep apnea/airway obstruction.

Patient warming devices again seemed to receive less emphasis from exhibitors. The singular exception was the expanded presentation of an air- and noise-free patient warming system that uses a radiant fabric that can adapt easily to various sized patients in various positions (and can also be connected to a vest to be worn by chilled anesthesia providers). Cited advantages are increased energy efficiency and decreased risk of infection transmission to anesthetized patients. Also, intraoperative medication error prevention was the emphasis of exhibits from services providing pre-filled syringes and/or bar-code readers to help insure 100% correct medication administration.

Interestingly, a new emphasis on concern for dangerous risks from postoperative pain medication, especially opioid PCA, appeared this year. Apparently, cases of excessive ventilatory depression and resulting hypoxemia associated with

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Safety Abstracts Stand Out at ASA

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

Over 2,200 abstracts were presented at the 2007 American Society of Anesthesiologist Annual Meeting in San Francisco, CA. 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.

Sedation Outside of the Operating Room

Propofol is commonly administered for sedation during upper and lower endoscopy. Two studies monitored sedation levels by utilizing 2 technologies (Bispectral [BIS] and Patient State Index [PSI]). In a study of 98 colonoscopy patients (A1014) monitored with a PSI, at least one airway intervention was required in 66.3% of patients, and 80% of interventions occurred at a Patient State Index (PSI) of <70. In a larger endoscopy study enrolling 202 patients (A44), the average BIS value during the procedure was 49.3. These studies suggest that propofol sedation during these procedures was associated with BIS/PSI levels commonly associated with general anesthesia and not moderate sedation, and that clinicians skilled in airway management should be immediately available if propofol is used. When monitored anesthesia care was delivered for endoscopic procedures by anesthesiologists, it appeared that no serious complications were noted among 2,766 high acuity cases (A497).

Risks of Non-Cardiac Surgery Following Coronary Stents

Previous small studies have observed a high incidence of adverse events following surgery after bare-metal (BMS) or drug-eluting stent (DES) placement. Two abstracts reported a relatively low frequency of adverse events in this patient population. A retrospective investigation from the Mayo Clinic (A798) examined data from 349 patients who underwent non-cardiac surgery within 2 years after placement of a DES. Perioperative ischemic events occurred in only 4.6% of patients, and 13% of patients required a red blood cell transfusion. Preliminary data were also presented from large multi-center international registry (POSTENT) established to examine the incidence of morbidity and mortality in surgical patients with previous stent placement (A193). In-stent thrombosis developed in 3.3% of 215 patients, and 4.7% of patients died within 60 days of surgery.

Adverse Events Associated with Aprotinin

The safety of aprotinin has been questioned in recent investigations. Several abstracts examined this issue. A review of a large registry of patients undergoing cardiac surgery at Duke (A240) revealed a greater rise in postoperative serum creatinine in patients receiving aprotinin, although the need for dialysis was not increased. A survival analysis of this same registry revealed a reduction in long-term survival in patients receiving aprotinin (A242). An investigation from the University of Tennessee compared 150 patients who received aprotinin to 150 historical controls who did not receive the drug (A243). No differences in any outcome measures were observed, with the exception of a higher incidence of renal dysfunction in the aprotinin group. These databases highlight the continued need for large randomized trials to assess the safety of aprotinin.

Anesthesia Workspace Contamination & Hand Hygiene

Several abstracts discussed the disappointing hand washing compliance among health care providers. First, it was identified that despite using standard disinfectants to clean in the morning, before the start of cases, and at the end of the operating day, there existed a remainder of >10 colony forming units (CFU) in approximately 52% of the inanimate sites tested (A1788). Types of organisms recovered include coagulase negative staphylococcus, beta and alpha hemolytic streptococcus, corynebacterium, and staphylococcus aureus. The author emphasized the need for sterile barrier techniques, aseptic medication administration, and frequent hand washing to mitigate the amount of contaminated areas. Three abstracts addressed the poor hand hygiene compliance of health care staff at varying points in their careers. Abstract A2140 examined the hand washing practices of 131 new interns when examining a standardized patient. Approximately 35% of the interns did not wash their hands prior to, and 95% did not wash their hands after, examination of the patient. Another abstract (A2141) examined hand-washing adherence among anesthesiology residents during their obstetric anesthesia rotation. During the first 2 weeks of the rotation, only 6.7% of observed epidural catheter placements were associated with proper hand hygiene prior to the procedures. This rate increased to almost 81% when the residents were given both explicit instructions on how to properly engage in hand hygiene and a handheld bottle of alcohol-based handrub. Similarly, A2139 developed a protocol for 90 second-year medical students to observe hand washing practices in several different ICUs. Hand washing compliance was found to be 30-35% among physicians and slightly better among nurses. Only 37% of the medical students involved reported that they would stop someone who had not washed their hands for fear of a poor grade by their superiors. This indicates that a cultural change is needed for improvement in quality care and hand hygiene compliance to curb the escalating amount of preventable nosocomial infections nationwide.

Diabetes and Insulin

Several posters examined the effect of diabetes and insulin therapy on outcomes following surgery. Investigators from Duke observed that preoperative hemoglobin A1c levels were predictive of postoperative acute kidney injury in both diabetic and non-diabetic cardiac surgery patients (A969). The same investigators noted that higher preoperative hemoglobin A1c levels were independently associated with increased mortality after primary cardiac surgery (A972). In a retrospective study from Belgium, cardiac surgical patients treated with a tight glucose control protocol (blood glucose 80-110 mg/dL) were compared to subjects in whom blood glucoses were maintained <150 mg/dL (A1209). Significant reductions in renal dysfunction, renal failure requiring dialysis, and in-hospital mortality were noted in the tight glucose control group. In other abstracts, intraoperative use of insulin was associated with a lower incidence of atrial fibrillation following cardiac surgery (A970) and trends toward reductions in troponin release in vascular surgical patients (A973).

Transfusions and Adverse Outcomes

The administration of PRBCs has been associated with an increase in morbidity and mortality in cardiac surgical patients. Two abstracts examined this important topic in other patient populations. Perioperative data from all patients undergoing hip fracture surgery over a 3-year period were analyzed (A1441). In propensity-matched patients, transfusion was a significant predictor of death (relative risk = 3.76). In contrast, transfusion of PRBCs was not independently associated with increased postoperative morbidity or mortality in patients following endovascular aortic repair (A1673). Another abstract discussed the changing tide of transfusion practices. Abstract A285 identified transfusion practices among 1000 transfusions in 2004 in Tunisia. Transfusion thresholds depended upon indication and included 6.16 g/dl (± 2.03) for urgent medical pathologies, 6.22 g/dl (± 1.6) for chronic medical pathologies, 7.74 g/dl (±2.49) for urgent surgical pathologies, 10.38 g/dl (± 2.2) for elective surgery, and 6.15 g/dl (± 2) for urgent obstetrical pathologies. These thresholds certainly suggest a turn toward a restrictive pattern of transfusion given the rising acknowledgment of complications associated with them.

Transfusion Requirements and Normothermia

As previously mentioned, blood transfusions might be associated with increased morbidity and mortality. Two abstracts performed meta-analyses examining 10 (A201) and 14 (A196) studies respectively involving hypothermia as it relates to transfusion requirements.

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Safety Abstracts Address Sleep Apnea

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Both studies demonstrated an increase in transfusion requirements with hypothermia. Normothermia was associated with a 16% (A196) and 22% (A201) reduction in blood loss. One abstract studied risk factors for generating postoperative hypothermia in a retrospective fashion. In evaluating over 10,000 cases, abstract A186, found that the starting OR temperature, age, length of anesthesia care, BMI, and gender all played a role in temperature change perioperatively. Inexperienced trainees had a small effect on occurrence of post-operative hypothermia as well. Another abstract utilized Six Sigma methodology to evaluate rates of perioperative hypothermia (A496). Temperature evaluation and operating room temperature were identified as contributors to hypothermia in this abstract. By utilizing a temporal artery thermometer (TAT; Exergen Corp., MA) in the PACU as well as decreasing the range of temperatures that were possible in the laminar flow air handler in the operating room, this group improved their postoperative normothermia rates from 55% to 88% (A496). Perioperative normothermia continues to be an important quality improvement measure nationally.

Transfer of Care in the Operating Room (OR)

Two abstracts addressed the transfer of care of anesthesia staff during prolonged cases. Abstract A1782 examined 243,832 anesthesia cases and concluded that the incidence of adverse events increased with the number of anesthesia providers involved regardless of ASA physical status or case length. In fact, when comparing 1 attending/1 assistant vs. 2 attendings/2 assistants, the relative risk of adverse events was 0.53 ($p<0.001$). In another abstract (A1785), transfer of care to another provider was already identified as a potential patient hazard. Therefore, this group devised a 1.5-hour training session with 12 first-year anesthesia residents to educate them on effective handoff of care in the OR. The important characteristics of effective communication included up-to-date information exchange, eliminating distractions, and 2-way interactive dialogue that allowed for questions and verification of information. Video scenarios were also included in this training session. All 12 residents reported that this program met or exceeded their expectations and was helpful in improving patient safety. Outcome data on the utility of educational programs to curb miscommunication during handoff of care needs to be collected.

Obstructive Sleep Apnea

As the obesity epidemic in the United States continues to escalate, obstructive sleep apnea (OSA) remains a serious health concern that will affect the delivery of anesthesia worldwide. One abstract (A935) examined OSA and its relation to increased postoperative complications. Among 181 patients who tested positive for OSA by polysomnography, there was a statistically significant increase in postoperative complications (30% OSA vs. 15% Non-OSA). Respiratory complications were most common (23% OSA vs. 9% Non-OSA). Furthermore, OSA patients tended to require more therapy, including prolonged supplemental oxygen, additional monitoring, admission to intensive care unit, and readmission within 30 days. Another abstract (A920) examined OSA patients and difficult mask ventilation and intubation. Adult patients scheduled for surgery completed a screening questionnaire from the Apnea Risk Evaluation System (ARES™). Patients who were identified as high-risk were asked to use the ARES™ Unicorder, a validated portable OSA diagnostic device. Patients were stratified into 3 OSA severity groups by their apnea-hypopnea indices (AHI): none, mild (AHI 0-20 events/hr), moderate (AHI 21-40), and severe (AHI >40). Information was collected by review of anesthetic records and included mask ventilation grades, laryngoscopic views, and ease of tracheal intubation. Those patients with severe OSA (AHI>40 events/hr) had an increased incidence of both difficult mask ventilation and intubation compared to patients with mild OSA. This indicates the potential for the severity of OSA to affect important airway practices executed by anesthesiologists.

This brief review summarized only a small number of the important abstracts on patient safety presented at the 2007 Annual Meeting. The abstracts referenced do not necessarily reflect the opinions of the authors or the APSF. 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.

7 PCA Systems Integrate Monitoring

"Exhibits," From Preceding Page

aggressive narcotic pain management, even starting in the PACU but usually associated with general care floors and often at night, are being much more widely recognized. Seven systems in which patient monitoring (usually oximetry and/or capnography) were integrated with PCA pumps were shown as exhibits. Most are interlocked so that alarm signals from the patient monitor(s) not only call for help but will automatically prevent additional PCA doses from being administered.

Overall, patient safety persisted as a key focus of both types of exhibits at the ASA Annual Meeting. This continued emphasis recognizes both the current success in improving patient safety and also the significant 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.*

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Dear SIRS

The Role of ECRI in Medical Device Incidents

S AFETY
I NFORMATION
R ESPONSE
S YSTEM

Dear SIRS refers to the Safety Information Response System. The purpose of this column is to allow expeditious communication of technology-related safety concerns raised by our readers, with input and responses from manufacturers and industry representatives. This process was developed by Drs. Michael Olympio, Chair of the Committee on Technology, and Robert Morell, Editor of this newsletter. Dr. Olympio is overseeing the column and coordinating the readers' inquiries and the responses from industry. **Dear SIRS** made its debut in the Spring 2004 issue.

Dear SIRS:

As coeditors of this column, it is very important that we explain to our readers what established methods of device reporting and improvement already exist within the United States. Although this column may be interesting and well-intended, it is not capable of being an authoritative or scientific means of improving medical device safety.

For this, we turn to our experts, and want them to explain how to handle your device safety issues. Engineer Albert de Richemond, representing ECRI Institute, is a member of the Board of Directors of the APSF, and has been most helpful in promoting our efforts in patient safety. What can he clarify for each of us? How does **Dear SIRS** differ from ECRI Institute problem reporting?

Michael A. Olympio, MD
Robert Morell, MD
Coeditors

In Response:

Drs. Olympio and Morell asked me to provide guidelines for you on clinician reporting of adverse events with medical devices. Reporting of such incidents for the betterment of health care should be considered whenever a patient or staff member is harmed or is likely to have been harmed by a medical device or therapy. Reports can be communicated to ECRI Institute, to your state department of health, to the US Food and Drug Administration (FDA), or to Dear SIRS. **Dear SIRS** and ECRI Institute may provide direct feedback to the reporter; most governmental reporting systems do not.

Medical devices sometimes fail. Users occasionally make errors. These adverse events include such incidents as patient injury or death, near misses (an error that was caught before it caused harm), misdiagnosis, inadequate or inappropriate therapy, and never events (e.g., wrong site surgery, overdose, retained instrument, surgical fire). As a result of an adverse event, patient care can be adversely affected. However, with proper foreknowledge, many device-related incidents can be avoided—either through improved device design or user training. That is where problem reporting comes in. Collecting and studying problem report information not only can help investigators identify the cause of an incident, but it also can help warn others in time to prevent similar incidents through "work-arounds" or device improvements.

ECRI Institute strongly encourages health care providers, patients, and manufacturers to report medical-device-related incidents and deficiencies to us so we can determine whether a report reflects a random failure or one that is likely to recur and cause harm. Our Problem Reporting Network (PRN) began operation in 1971 and became the model for the medical device problem reporting systems that followed. The PRN program is described on the Internet at http://www.ecri.org/PatientSafety/ReportAProblem/Pages/default.aspx. Confidential reports can be electronically submitted to ECRI using our Problem Reporting Network form available through the website.

Each report we receive is logged into our system and is individually discussed by our scientific and engineering staff at our weekly triage meeting. In cases where we can provide guidance related to the report, we inform the reporting party of our findings and opinions. Otherwise, we monitor the situation for developing trends of similar problems. As soon as members of our staff determine that specific device hazards and problems may exist, we inform the manufacturers and encourage them to respond constructively and correct the problem. (The problem reporter's identity and facility are never revealed without permission.) In many cases, we publish the results of our investigations of reported problems—along with appropriate warnings and recommendations—in *Health Devices and Health Devices Alerts*.

About half of the US's state departments of health now require reporting of adverse events. Most of these programs are intended to improve the quality of health care by collecting information and disseminating reports about the problems and solutions. To do this, some states have newsletters or other methods of publishing information. A listing of the various state codes concerning adverse event reporting can be found at: http://www.nashp.org/_docdisp_page.cfm?LID=2A789909-5310-11D6-BCF000A0CC558925. Depending on the state requirements, facilities may be required to act to correct the reported problem in various ways.

In cases where a serious injury or death results or is likely to have resulted from an adverse event, hospitals may also be required to report the problem to the device manufacturer or to the FDA under their MedWatch program or the MedSun program, which is a subset of MedWatch with 350 participating facilities. The FDA encourages voluntary reporting of adverse events.

See "ECRI," Next Page

ECRI, Dear SIRS and FDA Have Complementary Roles

"ECRI," From Preceding Page

Under the FDA MedWatch program, reports may be sent to the device manufacturer or to the FDA. The decision on whom to send the report to depends on the seriousness of the incident and whether the manufacturer is known. See the FDA MedWatch reporting website (http://www.fda.gov/medwatch/how.htm) for details and reporting forms.

MedWatch data are collected in the Manufacturer and User Facility Device Experience (MAUDE) database. This database is publicly searchable and does not contain the name of the reporter, the facility, or the patient. In cases of serious device issues, the FDA can legally act through the marketplace to prevent further harm, e.g., device recalls, prohibition of device sales. Through the MedSun program, some reported problems and solutions are discussed in the *MedSun Monthly Newsletter* that is sent to participating facilities.

Potentially, there are various legal repercussions when an adverse event occurs. Your facility's risk management department, which would likely file the needed reports, should be made aware of the incident so they can knowledgeably help in dealing with the event. The fact that a medical device was involved in an adverse event does not in itself trigger a mandatory report. For each event, it is important to ask whether or not the event can be attributed to the device, or whether the device was or may have been a factor in the death or injury.

Medical device problem reporting requirements are not satisfied by publication in **Dear SIRS**. While reporting problems to **Dear SIRS** is helpful in disseminating medical device information to a broad audience, it may not help solve the underlying cause of the problem. Additionally, legal problems may argue against publication in **Dear SIRS**. However, because bringing problems to light helps solve them, we recommend reporting to the proper authorities and to **Dear SIRS**, if possible.

In summary, **Dear SIRS**, ECRI Institute, state, and FDA programs gather adverse event information in order to inform the health care community (including clinicians, suppliers, and consumers) about potential problems and how to prevent them. If you become aware of an incident in which a patient or staff member was harmed or was likely to have been harmed, reporting to the various authorities should be considered and may be mandated under state or FDA programs.

Editor's Note:

We thank Engineer Albert de Richemond and the ECRI Institute for this valuable and detailed information and emphasize that harm is not a prerequisite to reporting. In fact, **Dear SIRS** is typically not suitable for incidents involving harm to patients or staff members.

Dr. Adsumelli's Team Wins the 2007 E.C. Pierce, Jr., MD, Award for Best Scientific Exhibit

Presentation of the 2007 E.C. Pierce, Jr., MD Award for the best scientific exhibit (left to right): Kevin Cardinal, CRNA; recipient Dr. Rishimani S. Adsumelli; Richard Prielipp, MD; Deb Lawson, AA; Tricia Meyer, PharmD.

A Response to Maternal Hemorrhage, With a Proactive, Multidisciplinary Approach to Reduce Mortality and Morbidity was the subject of the scientific exhibit which received the 2007 E.C. Pierce, Jr., MD, Award for the best scientific exhibit.

Dr. Adsumelli's team from SUNY at Stony Brook University, Department of Anesthesiology, used a multidisciplinary rapid response team and protocols for risk stratification, preparation and management of maternal hemorrhage.

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.

Anesthesia Patient Safety Foundation (APSF)

2008 GRANT PROGRAM

Guidelines for Grant Applications Scheduled to Start January 1, 2009

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

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

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

APSF is also proud to announce the availability of 2 named awards, **made possible by generous, unrestricted grants of $150,000 each**:

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

PRIORITIES

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

Highest priority is given to

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

AREAS OF RESEARCH

Areas of research interest include, but are not limited to

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

REVIEW PROCESS

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

SCORING

Studies will be scored on

- Soundness and technical merit of proposed research with a clear hypothesis and research plan;
- Adequacy of assurances detailing the safeguarding of human or animal subjects;
- Uniqueness of scientific, educational, or technological approach of proposed research;
- Applicability of the proposed research and potential for broad health care adoption;
- Clinical significance of the area of research and likelihood of the studies to produce quantifiable improvements in patient outcome such as increased life-span, physical functionality, or ability to function independently, potential for reductions in procedural risks such as mortality or morbidity, or significant improvements in recovery time;
- Ability of research proposals to maximize benefits while minimizing risks to individual human research participants. Each proposal should proscriptively enunciate the criteria for instituting rescue therapy whenever there is the remotest possibility of an untoward adverse event to a human research volunteer. In some instances, the rescue therapy may be triggered by more than one variable (e.g., duration of apnea [in seconds], oxygen saturation <90 %, etc.). Additionally, the protocol should specify the nature of the rescue procedure(s), including the rescue therapy and dosages, and the responsible personnel. If other departments are involved in the rescue process, the application should specify if such departments are to be informed when a new volunteer is participating in the trial.
- Priority will be given to topics that do not have other available sources for funding.
- Proposals to create patient safety education content or methods that do not include a rigorous evaluation of content validity and/or benefit will be unlikely to attain sufficient priority for funding.

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

BUDGET

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

ELIGIBILITY

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

See "Grant Guidelines," Next Page

Grant Application Submission Date—June 2, 2008

"Grant Guidelines," From Preceding Page

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

Applications that fail to meet these basic criteria will be eliminated from detailed review and returned with only minimal comment. A summary of reviewers' comments and recommendations will be provided to applicants only if requested from the Scientific Evaluation Committee Vice-Chair.

AWARDS

Awards for projects to begin January 1, 2009, will be announced at the meeting of the APSF Board of Directors on Saturday, October 18, 2008 (2008 ASA Annual Meeting, Orlando, FL).

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, 2008.

PAPERLESS APPLICATIONS

All applications and accompanying documents MUST INCLUDE

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

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

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

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

APPLICATION FORMAT

I. Cover Page

A. Title of research project

B. Designation of proposal as *"Clinical Research"* or *"Education and Training"*

C. Name of applicant with academic degrees, office address, phone number, fax number and e-mail address

D. Name, office address, and phone number of departmental chairperson

E. Sponsoring institution and name, office address, phone number and e-mail address of the responsible institutional financial officer

F. Amount of funding requested

G. Start and end dates of proposed project

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

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

A. Introduction

1. Objectives of the proposed clinical research or education and training project.
2. Background: reference work of other authors leading to this proposal and the rationale of the proposed investigation or project. Describe the relationship to the priorities highlighted in the first paragraph of the APSF guidelines. Include copies of in-press manuscripts containing pilot data, if available.
3. Specific aims: what questions will be answered by the investigation? If applicable, what hypothesis will be tested? For an educational project, what are the specific learning objectives or objectives of the methodology being developed?
4. Significance and applicability: briefly describe the historical prevalence and severity of the morbidity and mortality of the studied anesthesia mishaps. Quantify the potential improvements in patient outcome or recovery time and identify how the proposed work can be broadly applied to reduce procedural risks in health care.
5. If the application is a resubmission, describe changes from prior application, and specifically address the reviewers' comments point-by-point.

B. Methods to be employed

1. Describe data collection procedure, specific techniques, and number of observations or experiments. For educational projects, describe how the effects of the intervention program will be assessed. Qualitative methodologies are acceptable.
2. Describe types of data to be obtained and their treatment, including statistical and/or power analyses, if indicated.
3. Point out and discuss potential problems and limitations of the project.
4. If appropriate, include a statement of approval of this proposal by the institutional committee reviewing human or animal investigations, or a statement that approval has been requested.

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

A. Personnel (limit salaries of individuals to NIH Guidelines)

B. Consultant costs

C. Equipment

D. Supplies

E. Patient costs

F. Other costs

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

H. Budget justification - CLEARLY and completely justify each item, including the role of each person involved in the project. If computer equipment is requested, explain why such resources are not already available from the sponsoring department/institution. **NOTE:** Failure to adequately justify any item may lead to reduction in an approved budget.

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

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

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

VI. Letter from the departmental chairperson indicating

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

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

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

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

GUIDELINES FOR PREPARATION OF APPLICATIONS AND ELIGIBILITY REQUIREMENTS CAN BE OBTAINED FROM THE APSF WEB PAGE: **http://www.apsf.org**

The original application must be submitted electronically to the website no later than Monday, June 2, 2008. Once the completed application is uploaded, an automatic confirmatory email will be generated and sent to the Chair of the Scientific Evaluation Committee:

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

Q&A

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

Older Machines—Maintain or Replace?

Q Dear Q&A,

Our facility has several anesthesia machines that have been in use for over 15 years. We have a couple of Ohmeda Modulus IIs , several Dräger Narkomed 2Bs, and one Narkomed 2C. After 2008, Dräger will no longer provide preventive maintenance for the Narkomed 2Bs. We are studying the feasibility of replacing the older machines. Do you know of any legal ramifications we could face by having a third party provide service for these older machines since Dräger will no longer service them? Is there a recommended time for replacement of older anesthesia machines and are they considered to be "end of life" after so many years?

Thank you,
Scott Tumlin, CRNA
Gadsden, AL

A Dear Mr. Tumlin,

There are no laws limiting the use of an anesthesia delivery system after the manufacturer has declared the system to be obsolete and will not provide support, service, or parts. However, the American Society of Anesthesiologists has published **GUIDELINES FOR DETERMINING ANESTHESIA MACHINE OBSOLESCENCE**, located on the web at http://www.asahq.org/publicationsAndServices/machineobsolescense.pdf

There are 2 issues of concern regarding the use of an anesthesia machine that the original manufacturer has declared obsolete and will no longer support:

1. Does the machine meet current safety standards? For example, does it have a hypoxic mixture guard to prevent the accidental delivery of a hypoxic gas mixture to the patient? Does it have an exhaled volume monitor? These are the issues addressed by the ASA document.
2. Can you obtain quality service that supports the machine to the level of the manufacturer's performance specifications? Can the service organization provide new original equipment manufactured (OEM) parts, or warranted remanufactured parts that meet OEM specifications, or are they using parts that they removed from other obsolete machine that may have serious reliability issues?

To expand on this service issue, be aware that proper service and support of an anesthesia system involves 3 main elements:

1. Factory Service Training (knowledge of function and design)
2. Factory Technical Support (troubleshooting knowledge and troubleshooting experience)
3. Parts availability to restore performance specifications and reliability.

Without service and support from the manufacturer, all parties involved assume the following risks:

1. Factory service training. Has the service technician been factory trained on the particular model of machine in question? Simply because the original manufacturer will no longer support a particular model of anesthesia machine does not mean that an independent service organization does not have the technical expertise to service an obsolete machine. It is important to confirm that your service technician has been factory trained on the machine in question.
2. Factory technical support. Original manufacturers, once a model of machine has been declared obsolete, will no longer provide technical support on the telephone or otherwise. If the service technician is unable to effectively troubleshoot the machine you are counting on their honesty and integrity to tell you that they cannot resolve the issue or suffer the consequences of using a potentially defective machine. In this case you may be assuming a very high risk.
3. Parts availability. The original manufacturer will not sell parts after they declare that they are no longer providing service for the machine. Some independent service providers may have new parts, access to new parts through original equipment manufacturers who may have sold the parts to the machine manufacturers, or they may have access to warranted remanufactured parts. Functioning parts removed from other obsolete machines are not usually acceptable due to reliability concerns. However, if a part to repair the unit is unavailable, then that unit must be removed from service until a replacement part can be obtained.

Real problems may exist with equipment purchased for office-based procedures. It is incumbent upon the anesthesia providers to inform those individuals who are responsible for anesthesia machine purchases, in office-based practices, that a machine may not be acceptable in terms of safety features. You may also question who is maintaining the equipment and how frequently it is serviced and what happens when the machine needs parts.

Unfortunately, remote areas of the hospital often get anesthesia machines that were retired from service in the operating room.

See "Q&A," Next Page

More Q&A

Determining Anesthesia Machine Obsolescence

"Q&A," From Preceding Page

This is a particularly bad practice because life support equipment that is used infrequently needs to have the highest reliability and latest safety features. These machines should be equipped with the same safety features as machines in the operating room; otherwise anesthesia providers could assume safety features are included and make assumptions that are not in the best interest of quality patient care. For example, a machine that has low flow and high flow oxygen flowmeters could easily be used to accidentally deliver a hypoxic mixture to the patient when this scenario could never happen in the main operating rooms.

In conclusion, the recommendation is to follow the **ASA GUIDELINES FOR DETERMINING ANESTHESIA MACHINE OBSOLESCENCE** and know the service provider. When in doubt, replace the anesthesia machines in question with newer units that meet all of the above criteria.

The APSF Committee on Technology

Letter to the Editor

Potential Safety Hazard Associated With "Green-light" Laser

To the Editor

Anesthesia providers frequently use size and color cues on syringes and medication labels to assist with rapid product identification. We recently experienced a potential safety hazard during "green light" laser resection of the prostate. "Green light" laser surgery involves passing a high powered Nd:YAG laser through a KTP crystal. This doubles the frequency and halves the wavelength of the laser producing a visibly green laser, which is highly absorbed by blood rich tissue. This emerging technique has several advantages over other surgical techniques and it is likely that "green light" laser prostate resection will become more prominent.[1] During this type of surgery, operating room personnel must wear appropriate protective eye shields, matched to attenuate light in the wavelength of the laser. In the case of the "green light" laser, the goggles are orange (a type of eye shield also commonly known as a "blue-blocker"). When using these goggles, the familiar blue color of opioid labels is transformed to be indistinguishable from the gray-scale labels used for local anesthetics (Figure 1). We wish to alert the anesthesiology community of this potential hazard. The lesson is a basic one—regardless of product size, shape, color, or other visual or tactile cues, one must always read the label.

James Hardy, MD
William Camann, MD
Boston, MA

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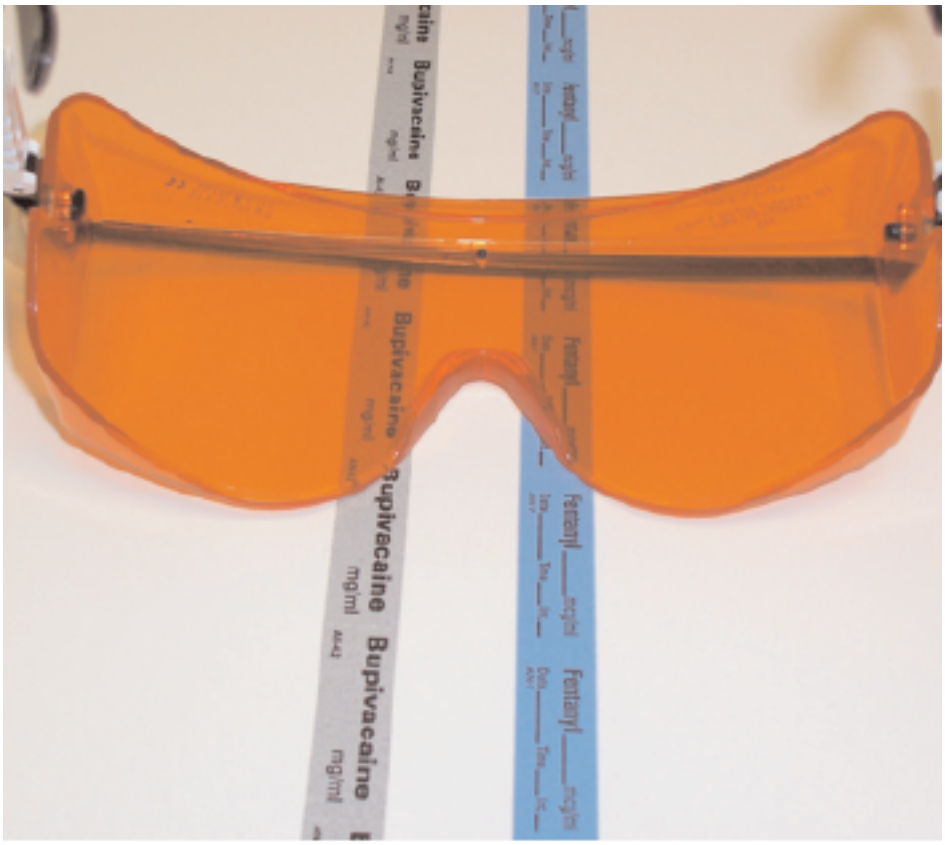

Orange goggles make blue labels appear as shades of gray.

Letter to the Editor:

Resuscitation After Maternal Arrest Clarified

To the Editor:

We commend Dr. Lofsky's recent review of 22 anesthesiology claims after maternal arrest "Doctors Company Reviews Maternal Arrests Cases," *APSF Newsletter*, 2007;22(2):28). However, we believe there were some very important omissions. In particular, failure to mention the critical importance for most parturients of cesarean delivery within 4-5 minutes of maternal cardiac arrest, when appropriately performed ACLS has failed to restore circulation. Dr. Lofsky presents data suggesting that the fetus may be more resistant to maternal hypoxia and hypotension than the mother and concludes that this "reaffirms the importance of the anesthesiologist's primary focus being the welfare of the mother." She further cautions, "This raises the question as to whether maternal resuscitation should ever be intentionally delayed in order to expedite delivery of the fetus." We are concerned that readers may take this to mean that immediate or early cesarean delivery would impede resuscitation and be harmful to the mother.

The best chance of fetal survival is maternal survival. While clinicians usually appreciate the fetal benefit from expeditious perimortem cesarean delivery, many are not aware that immediate delivery may also prove lifesaving to the mother.[1] Following delivery beneficial changes include immediate relief of aortocaval compression by the gravid uterus with consequent improved venous return and aortic output, improved pulmonary mechanics, and decreased oxygen demand. In 1968, Katz et al.[2] first demonstrated the fetal benefit of perimortem cesarean delivery within 5 minutes of cardiac arrest. More recently, they performed a 20-year review of maternal cardiac arrests described in the literature and found that in 12 out of 18 cases in which hemodynamic status was reported, maternal pulse and blood pressure returned immediately after cesarean delivery and in no case was there deterioration of the maternal condition with the cesarean delivery.[3] The American Heart Association's 2005 guidelines state that when maternal cardiac arrest is not immediately reversed by BLS and ACLS: *"The resuscitation leader should consider the need for an emergency hysterotomy (cesarean delivery) protocol as soon as a pregnant woman develops cardiac arrest."*[4] They further emphasize

> *"The critical point to remember is that you will lose both mother and infant if you cannot restore blood flow to the mother's heart. Note that 4 to 5 minutes is the maximum time rescuers will have to determine if the arrest can be reversed by BLS and ACLS interventions. The rescue team is not required to wait for this time to elapse before initiating emergency hysterotomy."*[4]

Only when uterine size corresponds to a gestational age less than 20 weeks is immediate delivery unlikely to benefit the mother. Between 20 and 23 weeks (before fetal viability), urgent cesarean delivery is likely to benefit only the mother; after 24 weeks it may benefit both mother and fetus. Even when delivery cannot be accomplished within 5 minutes, performing it as soon as is feasible usually will confer maternal benefit and may result in a healthy fetus.[2] The underlying cause of the cardiac arrest and the severity and duration of maternal and fetal compromise prior to arrest will also impact outcome.

Thirteen of the 22 arrests in the current series occurred after institution of regional anesthetic block (unintentional subarachnoid block in 7 out of 8 labor epidural catheter placements and spinal anesthesia for cesarean delivery in 5 cases). Resuscitation can be extremely difficult in the presence of high spinal anesthesia. Respiratory depression rapidly ensues, while the extensive sympathectomy causes massive vasodilation and block of the cardio-accelerator nerves (T1 to T4), severely impairing venous return and cardiac output. Combined with aortocaval compression caused by the gravid uterus and the low cardiac output state achievable by CPR, there may be minimal or no venous return or cardiac output until delivery is accomplished.

Dr. Lofsky highlights the difficulties and delays associated with transporting patients in extremis to the operating room. Cesarean delivery within 4-5 minutes of cardiac arrest and starting resuscitation may require that it be performed in the patient's room, or wherever the arrest occurs. It is noteworthy that, in the only case in Dr. Lofsky's series where the mother survived without neurologic impairment, the anesthesiologist immediately ventilated the patient with an Ambu-bag and the obstetrician accomplished a crash cesarean delivery within minutes while still in the labor room. We realize that some obstetricians believe that perimortem cesarean delivery always merits transfer to the operating room, even when a parturient is in cardiac arrest.[5] However, as Dr. Lofsky describes, transferring a patient undergoing ACLS is logistically challenging and time-consuming, will almost certainly result in interruption of chest compressions and monitoring, and overall will probably decrease maternal and fetal survival.[2,3] To optimize maternal survival and the chance of good neurologic outcome, institutions and medical personnel should make advance preparations designed to facilitate urgent cesarean delivery in non-operating room locations in this circumstance. Of course, CPR and ACLS should be continued throughout delivery, wherever this occurs.

The 22 cases of maternal arrest reviewed in this series should be a reminder that ACLS and CPR for parturients must be better taught to practitioners at all levels. Critical ACLS modifications for pregnant patients include always maintaining left uterine displacement of at least 15-30 degrees; placing the rescuer's hands several cm higher on the sternum to obtain better cardiac output with compressions; and, most important, consideration for immediate cesarean delivery in a patient who has not responded after 4-5 minutes of ACLS.[4] Familiarity with the most recent American Heart Association's recommendations for management of cardiac arrest associated with pregnancy[4] should be mandatory for all medical or nursing personnel who potentially provide care to pregnant women.

Brendan Carvalho MB, BCh, FRCA
Sheila E. Cohen MB, ChB, FRCA
Stanford, CA

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In Response:

I appreciate Drs. Carvalho and Cohen's discussion of the issues raised in my article. It does not seem to me that our views are mutually exclusive. My questioning a delay in maternal resuscitation to facilitate delivery was a response to the 7 cases in which mothers were transported out of their labor rooms prior to the institution of full BCLS and/or ACLS measures, although they were in arrest on arrival in the OR. Many of the nurses and anesthesia providers involved in those claims explained the urgency to transport as related to their concerns about a possibly dying fetus. Attention appeared to initially focus primarily on the non-reassuring fetal heart tones caused by maternal cardio-respiratory compromise, rather than on the mother's resuscitation.

I agree that we might need to reemphasize all alternatives for accomplishing cesarean section deliveries necessitated by maternal arrest (which is soon accompanied by fetal distress). With the design of many labor and delivery wards, it may simply be unreasonable to expect to get an unstable patient undergoing resuscitation onto the OR table within the 4 to 5 minute window described above. The one "near miss" case described in my article was unique both because the C-section was accomplished expeditiously in the labor room and because there was both immediate and uninterrupted resuscitation of the mother by the anesthesia provider.

Notably, 3 mothers in the series sustained brain damage even though their respiratory arrests occurred after the cesarean delivery of their babies. There were allegations in those cases that monitoring was inadequate and resuscitation provided too late. Timing appears to be critical and immediate resuscitation attempts imperative. I believe we are all in agreement that there should not be a delay in making an initial attempt to ventilate a mother and support her blood pressure for the sole reason of transporting her somewhere else. Within those first 4 to 5 minutes of maternal resuscitation, it is still A,B,C (Airway, Breathing, and Circulation) before D (Delivery).[1]

Ann S. Lofsky, MD

Reference

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Letter to the Editor:

Hazards of Beach Chair Position Explored

To the Editor:

We wish to thank Dr. Lofsky for her detailed and thoughtful letter concerning our presentation in the Summer 2007 *APSF Newsletter* regarding the beach chair position and decreased cerebral perfusion.[1] Although the 2 cases described in the newsletter article involved the use of labetalol, the other 2 cases described in our original article[2] were not given labetalol. One of us (DJC) subsequently reviewed another medical legal case wherein deliberate hypotension was induced using labetalol and deep inhalation anesthesia with desflurane resulting in very stable blood pressures in the arm of 80-90/45-60 for more than an hour but leading to very prolonged wake up and permanent cognitive neurological deficits.

Dr. Lofsky may well be correct that when labetalol is used in patients before they are placed in the beach chair position (for example, in a hypertensive patient to mitigate the effects of endotracheal intubation on blood pressure and heart rate), hypotension is likely to occur under general anesthesia when they are placed upright. However, an effective dose of labetalol to accomplish this goal is usually about 10 mg intravenously,[3] much less than the 50 mg dose used in case number 1. We expect treatment with direct acting vasopressor drugs by infusion or bolus will be effective in helping to maintain blood pressure at levels that will insure adequate cerebral perfusion in the upright position. We are not aware of any studies or case reports which describe acute heart failure and pulmonary edema under these circumstances, though this would be an interesting subject for further study.

As our article emphasized, we are extremely concerned about the use of deliberate hypotension in the beach chair position. Obviously, if an anesthesiologist/CRNA purposely induces deliberate hypotension with labetalol, he or she is unlikely to use vasopressors to reverse the resultant hypotension. As stated in the article, the major concern is that deliberate hypotension (regardless of how it is accomplished) in the sitting position risks inadequate cerebral perfusion leading to severe long-term neurological complications for no justifiable reason. A parallel concern is that inadvertent, unrecognized hypotension has the same effect.

We thank Dr. Lofsky for describing another risk factor, awareness of which will, we hope, improve the safety of performing shoulder surgery in the beach chair position.

David J. Cullen, MD, MS
Cambridge, Massachusetts

Robert R. Kirby MD
Gainesville, Florida

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To the Editor:

I read with interest the case presentation in the *APSF Newsletter* concerning the intraoperative stroke of a patient undergoing a shoulder procedure in the beach chair position. I wonder if the 50 mg dose of labetalol prior to induction is accurate? If so, I believe that we need to reevaluate how aggressive we should be with blood pressure control just prior to the induction of anesthesia. Many uncontrolled hypertensive patients present with dehydration and an elevated vascular resistance and become relatively hypotensive following induction.

I understand that the focus of this article was not the use of perioperative beta-blockers, but it highlights the push for more aggressive use of perioperative beta blockade and the potential negative effects. I am not blaming the outcome of this case on the beta-blocker use, but I do believe it was a contributing factor. Labetalol, besides lowering the blood pressure, will lower the cardiac output. What is good for the heart may not necessarily be good for the brain. Of late, there has been a push for indiscriminate perioperative beta-blocker use; it has almost been presented as a "magic bullet" to improve patient outcomes. To my knowledge there is no literature showing aggressive blood pressure control just prior to induction improves outcomes, especially in "healthy" patients. I am somewhat reassured that in the recent literature there has been information presented directing us to a more judicious use of perioperative beta-blockers. I do think there should be a greater dialogue between the cardiologist and anesthesiologist prior to the initiation of perioperative beta blockade, because when there is a disagreement about their appropriate use, the patient is frequently left confused and concerned about the judgement of his or her physicians. If anything, it may be wise to start with shorter-acting agents, assess the patient's response to induction, and proceed from that point.

Sam Budnyk
Destin, FL

To the Editor

My compliments to Drs. Cullen and Kirby for their lead article in the summer 2007 issue of the *APSF Newsletter* highlighting the risk of cerebral ischemic damage with the "beach chair" position for shoulder surgery. They clearly documented the devastating injury that can occur and the "ball-park" calculations for compensation of blood pressure that are required.

I suggest every one of those patients get an arterial line zeroed to the head. Neuroanesthesiologists have been doing sitting cases for decades, and I have never heard of a patient being brain injured from unrealized low cerebral perfusion. I don't think any *bona fide* neuroanesthesiologist would consider doing a sitting position case without this safety monitoring. Our orthopedic patients deserve the same level of diligence. If I try to balance the risk and cost of an arterial line against the terrible outcomes of the 2 cases in their report, it seems clear to me how we should proceed. I suggest we don't calculate, estimate, or extrapolate the blood pressure from a cuff to the top of the head. Just measure the pressure with an arterial transducer zeroed to the head and get it right each and every time. Our specialty really tries to have a zero tolerance for avoidable brain injury at surgery. A change of our practice seems in order to achieve this highest quality.

Roy F. Cucchiara, MD
Jacksonville, FL

Check out the APSF website at **www.apsf.org** and participate in the monthly APSF poll.

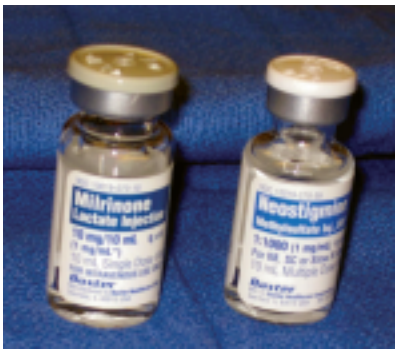
Letter to the Editor

Drug Error Averted

To the Editor:

We wanted to alert providers of another example of look-alike vials. Our hospital pharmacy mistakenly placed milrinone in our premade drug trays in place of neostigmine. Fortunately, we had no drug errors. It was caught quickly and corrected.

Nancy Buechier, CRNA
Scott Woodward, AA-C
Louisville, KY



Letter to the Editor:

The Problems of Posture, Pressure, and Perfusion

To the Editor:

In the Summer 2007 *APSF Newsletter*, Cullen and Kirby cite a dramatic case of cerebral infarction during shoulder surgery in the beachchair position.[1] This case was 1 of 4 apparent cerebral and/or spinal cord infarctions presented as a series by Pohl and Cullen in 2005,[2] as gleaned from medico-legal reviews by one of the 2 authors (DJC).

Most anesthesia professionals would not argue against maintaining blood pressure (BP) within a reasonably close range of preoperative values during any anesthetic, in the sitting position or otherwise; nor would I. But prescriptions for acceptable BP management should acknowledge the lack of relevant human data, and should also make reference to methodologic issues in assessing cerebral perfusion pressure (CPP). As such, I would like to point out several potential areas of controversy or ambiguity that may arise from a reading of Cullen and Kirby's article:

Of relevance to the author's, and others', concern for BP management in the context of baseline values, the other 3 cases presented in the original series had no preoperative BPs reported, and one case used a BP cuff positioned on the calf while in the seated position. By "preoperative values," I mean measurements obtained outside of the stress of the operating room and in an upright position, as per usual in a preoperative clinic, holding area, or exam room setting. It is therefore impossible to know by what percentage the patients' normal baseline BP was allowed to change during the anesthetics. Consequently, that series can offer us little or no quantitative guidance, absent the extremes beyond common sense and common practice.

Discussions, including Cullen and Kirby's, of BP management in the sitting position seldom take into account that the upright position is the normal position occupied by most human beings during most waking hours, and that no numerical "compensation" is made for the upright position when measuring BP in sitting, awake outpatients. That general anesthesia decreases BP in the sitting position is irrelevant to this point. The issue here is not whether interventions should be made to restore BP to approximately normal levels (as appropriately suggested by Drummond);[3] but rather, the more fundamental question of how BP should be measured in the first place—either before or after an intervention is made. If one argues that when the head is elevated above the heart, an "adjustment" should be made for a decreased CPP, then perhaps one should also explain why the same adjustment is not made for all ambulatory, upright, measurements. For example, why should we assume that a BP in the sitting position under anesthesia is any different with regard to CPP than the same BP measured in the same way in an awake patient sitting in a preoperative clinic?

Regarding the methodology of BP measurement, the practice of "compensating" for arm BP cuff readings in the sitting position extends back to 1954 when that advice was first published by Enderby,[4] and it has been followed uncritically ever since. The refinement of Enderby's advice in neurosurgical cases, where the arterial line has largely supplanted the BP cuff, applies the same assumption but by a different method. Raising an arterial line transducer to head level accomplishes by physical means the same thing as making a numerical "correction" to a BP cuff reading. Both adjustments make an intuitive assumption that the head is in a compromised position for perfusion when it is in its (normal) upright position relative to the heart. Implicit in that assumption, but rarely stated explicitly, is a correlative assumption: that the cerebral circulation is an "open" fluid path where a pump forces blood up to a higher elevation, and that it flows passively downward (like a waterfall in open air) back to the heart.

This conceptual model of the cerebral circulation is wanting for at least 5 reasons:

1) it does not match the anatomy of what we know is a closed, continuous fluid path that does not contain anywhere within it an open-air waterfall component;

2) it does not work when upside down or in weightlessness (but the actual cerebral circulation does);

3) it cannot explain the well-described phenomenon of venous air embolism (VAE) in mechanically ventilated patients;

4) it cannot explain the common observation, in sitting neurosurgical cases, of right atrial pressure (measured at heart level) being far below the expected value of the hydrostatic pressure of a 25-30 cm column of blood extending from the superior sagittal sinus down to the right atrium; and

5) it does not explain why the risk of VAE is in proportion to the degree of elevation of the perforation above the heart.

On the other hand, the conceptual model of the cerebral circulation as a "closed" circulation easily satisfies the 5 observations above. And inherent to a closed model is a very strong argument against making "compensations" for "perfusion pressure" by raising transducers or subtracting numerical adjustments from BP cuff measurements.

We don't, of course, monitor hemodynamics in a conceptual vacuum. Instead, we interpret the numbers we measure in the context of our best mental model of the circulation. One consequence of rejecting the "open" model is that we now have to distinguish carefully, when we talk about "pressure," between true perfusion pressure and transmural pressure. The practice of raising transducers to head level or making numerical adjustments to BP cuff readings in a closed circulation model actually "adjusts" for something very different from perfusion pressure—it adjusts for transmural pressure.

Why does this matter? Because only perfusion pressure, not transmural pressure, is associated with flow. And flow is what we are interested in. An arterial line measurement can be used to estimate perfusion pressure only if both inlet and outlet pressures on either side of the organ of interest are measured, and only if b*oth pressures are referenced to the same level.* By conventional definition, "perfusion pressure" is a pressure *gradient,* not a single point measurement at only one place in a circuit. Making inferences about perfusion based on a transmural pressure reading at only one point in the circuit can be misleading in certain circumstances. The sitting position is one of them. While it may seem intuitive that the "real" perfusion pressure to the brain is a single-point transmural pressure reading referenced to brain level (i.e., the transducer is elevated to the level of the head), this fails to take into account that the outlet (venous) pressure of the brain should also be considered in similar fashion.

Not only does elevating the head (to its normal day-to-day position) reduce cerebral arterial transmural pressure relative to the heart; so too, does elevating the head reduce the sinus and venous outlet transmural pressures relative to the heart, and by the same amount. For that reason, elevating the head does not, by itself, decrease cerebral blood flow so long as mean arterial pressure (MAP) at the level of the heart is not allowed to change. A change in transmural pressure at one point in the circuit—which is what a numerical "adjustment" of a BP cuff reading, or raising an arterial line transducer to head level tells us—does not imply a change in flow.[5,6]

A simple illustration may help to clarify this point: the flow rate of fluid through IV tubing is proportional to the relative height of the IV bag and the patient. The path that the IV tubing takes between the IV bag and the patient does not affect flow rate. The tubing can be looped down to the floor and then back up to the patient, or even looped up over the top of the IV pole and back down to the patient, and the flow will be the same in either case. If you make a mark at one point on the tubing and measure the transmural pressure (again, inside minus outside pressure) at that one point, it will be dramatically different depending on its position relative to the patient. The transmural

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Cerebral Perfusion Pressure Defined

"Pressure," From Preceding Page

pressure at your mark in the tubing may be negative (subatmospheric) if it is elevated above the IV pole; or it may be markedly positive if that point is dropped down to the floor below the patient. But in either case, flow through the tubing remains unchanged because perfusion pressure (inlet minus outlet pressure) is unchanged. Local transmural pressure at just one point cannot be substituted for perfusion pressure. They are completely different concepts, and should not be used interchangeably.

Returning to the cerebral circulation, if we say that "perfusion pressure" at the elevated level of the upright brain is lower, we are in fact referring not to *perfusion pressure*, but to a local *transmural pressure*. Perfusion pressure remains inlet (aorta) minus outlet (right atrium) pressure. If we insist on "compensating" for a fall in local (transmural) arterial pressure at the inlet of the brain (either by moving the transducer above the heart to head level; or by a numerical adjustment to a BP cuff reading), then to be consistent, we should also "compensate" for the corresponding fall in the transmural pressure of the brain's sinuses and veins when measured at the same level in the sitting position. That could be accomplished by also raising the CVP transducer to head level. If we do so, we will see that both inlet and outlet pressures have fallen, and by the same amount. Cerebral perfusion pressure remains unchanged and there is, in fact, no point in making the 2 self-cancelling "compensations." The standard definitions of CPP (CPP = MAP – CVP when CVP > ICP; CPP = MAP – ICP when ICP > CVP) remain unchanged, and there is no rationale for leveling MAP and CVP transducers at different heights when measuring CPP.

If one doubts that cerebral veins and sinuses have lower, even negative, transmural pressures in the upright position, then consider the well-described phenomenon of venous air embolism (VAE). In a mechanically ventilated patient who is making no inspiratory efforts, the same "siphon" effect that is inherent to a closed model of the circulation causes subatmospheric pressure in the IV tubing example also causes subatmospheric pressure in the elevated sinuses and veins of the head. This is how VAE occurs even in mechanically ventilated patients when the operative site is elevated above the heart, and it is also why the tendency for VAE is proportional to the degree of elevation of the operative site above the heart.

An open model of the circulation provides no explanatory power in this domain, and this limitation of the open model should be addressed in any discussion of the mechanism of VAE specifically; and in any discussion of hemodynamic monitoring in the sitting position generally. Among circulatory physiologists, the controversy between adopting an open versus a closed model of the cerebral circulation is just that: a controversy.[6] I am not advocating an uncritical acceptance of the closed model, along with its implications for hemodynamic monitoring. But I am advocating that the anesthesia and monitoring communities acknowledge and address, on its merits, arguments for and against both models. In this domain, where the "right" answer may very well be counterintuitive, it is especially important to allow physiology to lead the discussion.

Every day in almost every anesthetic, we make BP cuff measurements and infer something about whole body perfusion. That is a time-tested empiric relationship for which we have much experience and much data. I am not, of course, suggesting that we discount BP cuff readings in general just because they measure a local transmural pressure in the arm beneath the cuff. Nor am I suggesting that we allow blood pressure, properly measured and interpreted, to fall significantly below the patient's preoperative baseline. Instead, I am suggesting that we not make an unnecessary numerical adjustment for the use of BP cuffs in the sitting position. Such an adjustment is predicated on a false assumption made a half century ago about the physics and the physiology of CPP; and a confusion of transmural for perfusion pressure.

There is a great need to revisit the important question of "what is a safe blood pressure?" The cases referred to by Cullen and Kirby can offer a general wake-up call that even modest hypotension may be dangerous; and that we should be circumspect in agreeing to a surgeon's request for deliberate hypotension. But absent a case population denominator, or even sufficient documentation of baseline and equally-measured intraoperative BPs in the 4 cases presented, they can offer very little quantitative guidance to help explore the question. Most practitioners would not run their patients' BPs as low as those presented; regardless of where or how they were measured.

As a specialty, we may very well reexamine what we accept as best practice for BP management so that we are not losing patients on one tail of the susceptibility curve to bad outcomes. By all means, we should run the BP, measured normally in what is a normal human upright position, higher than in the cases presented until we know the answers. Most of us would anyway. But let's not add to our current ignorance of what a safe BP is, in general, by making an adjustment that may not make physiological sense, however timeworn it is. That is simply using a physiologically suspect means to achieve a laudable end. We don't need to do that. We can have our laudable end while still respecting, or at least acknowledging, that the underlying physiology is not as straightforward or as intuitive as many of us were taught. Adding an extra level of complexity through BP "adjustments" that fail to acknowledge or even take into account the basic physiological principles above will only obscure, not clarify, the eventual answer.

James Munis, MD, PhD
Chair, Division of Neuroanesthesia
Assistant Professor of Anesthesiology, Physiology, and Biomedical Engineering
Mayo Clinic College of Medicine
Rochester, MN

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Baxter Shares Perspective on Sevoflurane Safety

The recent communication by Dr. Evan Kharasch[1] regarding sevoflurane formulations contains a number of inaccuracies that prompt me to respond on behalf of Baxter Healthcare Corporation.

The chemical instability of sevoflurane in the presence of strong Lewis acids has played a role in a number of corrective action incidents since the introduction of the product in the early to mid 1990s. Specific lots of Abbott's Ultane product have been recalled on 2 occasions because of Lewis acid mediated degradation occurring in the bottled drug product.

Both of these incidents were attributed to contamination of the bulk sevoflurane drug product with strong Lewis acids by contact with improperly cleaned or maintained shipping containers, followed by a cascading degradation reaction of sevoflurane in which the glass container in which the product was marketed played a major role. In response to these incidents, Abbott Laboratories took 2 actions: an increase of water content to reduce the rate of reaction of sevoflurane with any strong Lewis acids that might be present, and perhaps more importantly, an elimination of the glass container that served as the source of the Lewis acids that drove the runaway degradation reaction observed in contaminated lots.

Lewis acid mediated degradation has also been implicated in the more recent reports of interaction of sevoflurane with the Penlon Sigma Delta vaporizer.[2] In this case, the source of the strong Lewis acids initiating degradation was found not to be the drug product but the vaporizer itself.

The Penlon Sigma Delta sevoflurane vaporizer has been distributed by Abbott Laboratories, and more recently by Baxter, for use by purchasers of the respective companies' sevoflurane products. Following the identification of the incompatibility between sevoflurane and the Penlon Sigma Delta vaporizer, Baxter has removed all Penlon Sigma Delta vaporizers distributed to its customers from service, and has endeavored to inform all purchasers of Baxter sevoflurane, known to be in possession of Penlon Sigma Delta vaporizers not provided by Baxter, of this incompatibility.*

Dr. Kharasch's discussion of the Penlon Sigma Delta vaporizer creates the impression that degradation only occurs with low-water sevoflurane.

Laboratory tests on the Penlon Sigma Delta vaporizer with Abbott's Ultane sevoflurane have been provided to Baxter and to a number of regulatory authorities around the world.[3] These results show that all sevoflurane products tested undergo some level of degradation in Penlon Sigma Delta vaporizers, and although Abbott's Ultane product degrades more slowly under the test conditions, it does degrade. Dr. Kharasch wrote a letter interpreting the results of such tests that was provided to regulatory authorities, in which he concludes that, "There was lesser, but apparent, degradation of Abbott sevoflurane" in Penlon vaporizers. We can only conclude that the role of water in the stability of sevoflurane in a vaporizer, and its fate during the administration of anesthesia, is incompletely understood.

In addition, Dr. Kharasch cites information regarding the identification of "potential Lewis acids (metal oxides)" on commercial vaporizers, and implies that this should be a cause of great worry and "vigilance" for the practitioner of anesthesia. He fails to note that 2 of the vaporizers within which hundreds of square centimeters of "potential Lewis acids" are exposed to the sevoflurane liquid and vapor (the GE/Datex-Ohmeda Tec 7 and the Dräger Vapor 2000) have been shown by Abbott's own testing to be completely compatible with all sevoflurane formulations, regardless of water content, with no degradation detected under accelerated study conditions. The reference to all metal surfaces in vaporizers as "potential Lewis acids," regardless of their demonstrated compatibility with sevoflurane of both high and low water content, would seem to be a generalization with limited scientific basis.

It is unfortunate that a widely distributed commercial sevoflurane vaporizer has been found to include materials of construction that are incompatible with sevoflurane, and that this finding was made only after many such units had been put into service around the world. We agree that vigilance, in preventing the exposure of the chemically fragile sevoflurane molecule tmo chemically incompatible materials, is prudent. Proper evaluation of the compatibility of vaporizers with sevoflurane under conditions of actual use and elimination of drug contact with materials capable of initiating the degradation of sevoflurane is, in the end, the only "safe" approach to the use of this popular and effective anesthetic.

* Baxter has been informed by Penion that the Penion Sigma Delta Sevoflurane vaporizer was redesigned in October 2006 and is designed for use with Sevoflurane, meeting the USP and European Pharmacopoeia standards, available in the market at that date. Baxter has not performed tests on the Penion Sigma Delta vaporizers produced after that date.

Francois Lebel, MD
Vice-President, Global Medical and Clinical Affairs
Baxter Healthcare, Medication Delivery

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Penlon Clarifies Vaporizer Modifications

Thank you for the opportunity to reply to the item written by Francois Lebel.

The Penlon Sigma Delta vaporizer was launched in 2001 and was designed for use with Sevoflurane formulations available at that time.

The recent communications from Dr Kharasch and Dr Lebel require some clarification. The Penlon Sigma Delta vaporizers they discuss were re-designed in October 2006 to eliminate the issues with potential of degradation. The vaporizer is now produced with a plastic (PTFE) coated internal surface and all potential for Lewis acid production has been removed. The vaporizer is now designed specifically for use with all Sevoflurane formulations meeting either USP or European Pharmacopoeia specifications regardless of formulation, wet or dry. I hope this provides clarification.

Andrew Watkins
Director of Development, Quality, and Regulatory Affairs
Penlon Ltd.

Malignant Hyperthermia Association of the United States Recognizes Contributors

At the recent American Society of Anesthesiologists conference in San Francisco, CA, the following outstanding contributors were recognized by the Malignant Hyperthermia Association of the United States:

MH Hotline Partnership Awards

James Chapin, MD, of the University of Nebraska Medical Center in Omaha, NE, and Dorming Wong, MD, of the California Anesthesia Associates Medical Group in Newport Beach, CA, were the recipients of the 2007 MH Hotline Partnership Awards. This award recognizes special cases in which the 24/7 MH Hotline was used to solve MH cases in real time via telephone or internet.

See "MHAUS," Page 87

Minrad Provides Packaging Perspective

The article by Dr. Kharasch entitled "Sevoflurane: The Challenges of Safe Formulation," published in the *APSF Newsletter*, Fall 2007, contains a number of inaccuracies and errors of omission. These lead to a number of scientifically unfounded concerns regarding the packaging of sevoflurane, the formulation (water content), and the compatibility of generic sevoflurane in anesthetic vaporizers.

As it now stands, there are 3 different types of containers and water content being used for sevoflurane:

- USP Type 111 Amber Glass — MINRAD very low water 65 ppm
- Polyethylene Naphthalate (PEN) — Abbott— high water> 300 ppm
- Aluminum, epoxyphenolic lined — Baxter — mid level water - 160 ppm.

Sevoflurane in USP Type III Amber Glass

The first company to receive regulatory approval for the marketing of sevoflurane as an anesthetic agent, Maruishi Pharmaceutical (Japan), was granted marketing approval to enter the Japanese market in 1990. The Maruishi product was packaged in USP Type III Amber glass. Subsequently, Maruishi licensed Abbott Laboratories, and in 1995 Abbott received FDA approval for the product in the United States and began to market sevoflurane in USP Type III Amber glass bottles.

There were no problems with the product, packaged in USP Type III Amber glass, in Japan or the US, until Abbott had a recall of three lots of sevoflurane (FDA D-054-7) in November 1996 due to contamination of the bulk API with rust (ferric oxide). There was no mention that the packaging, USP Type III Amber glass, caused the degradation nor was the degradation attributed to the water content of their product. In their correspondence sent to the FDA, they assured that the cause was known and that actions had been taken to correct the problem.[1]

There was a second recall of 22 lots of sevoflurane (FDA D-011-4) in September 1997 for a similar problem.[1] In correspondence with the FDA, it was again stated that the recall was due to contamination of the bulk API with rust (ferric oxide). As before, there was no mention that the packaging, USP Type III Amber glass, caused the degradation nor was the degradation attributed to the water content of their product.

Over the years it has been known that ferric oxide, and certain other metal oxides, would autocatalytically decompose certain halogenated ethers. Good manufacturing practices (cGMP) and great care are taken to avoid these contaminants.

The fact that USP Type III Amber glass was not mentioned is not surprising. Enflurane, isoflurane, and desflurane have all been packaged in this type glass for over 15 years without stability problems. Similarly, unadulterated sevoflurane has been packaged in this type glass by Maruishi and Abbott and is being packaged in this type glass by MINRAD without any degradation occurring. MINRAD has stability data at 40°C for a year and at 25°C for over 2 years, all with very low water content, and there is no indication of product degradation.

The surface of the USP Type III Amber glass consists of silicon hydroxide (SiOH), commonly called Silanol, which is formed by the reaction of silicon dioxide with moisture in the air as the glass is annealed in the Lehr to relieve stresses. Silanol is a weak Bronsted Acid, not a Lewis Acid, and does not cause degradation of any of the halogenated ether anesthetic agents, no matter what the water content.

Other Packaging

In 1985, we, then at Anaquest, carefully investigated the possibility of packaging enflurane and isoflurane in polymer containers as a way to reduce the shipping costs of the products. We found that none of the then available polymers were as suitable as USP Type III Amber glass for the packaging. More recently MINRAD, for the same reason, reviewed the newer polymers. A few polymers, polyethylene terephthalate (PET) and polyethylene naphthalate (PEN), appeared to have the required structural strength; however, both were rejected because of the potential for extractables. Both PET and PEN are polyesters and in the process of blow forming bottles with these polymers, there is a thermal degradation reaction that produces acetaldehyde and possibly ethylene glycol and acrolein. Since Minrad had data proving that USP Type III Amber glass had no extractables from the glass, we decided that the appropriate action was to continue to package our product in USE Type III Amber glass in order to preserve the quality of our product.

As a result of the Baxter recall of Penlon Sigma Delta vaporizers showing degradation of sevoflurane, there is now concern about the need for some sort of inhibitor to avoid the degradation of sevoflurane in vaporizers. Water may slow the rate of degradation when sevoflurane is exposed to an incompatible metal such as rust. But, as Clarine M. Callan, MD, stated in the Spring 1997 *APSF Newsletter*

After initiation by the valve material, a necessary part of the reaction involves the preferential consumption of moisture in sevoflurane. This reaction continues at a very slow rate until all the water is consumed, at which point reaction with the solution container rapidly occurs resulting in the pungent odor (SiF_4).

The "initiation" described is the rust catalysis of sevoflurane producing FW and other degradation products. In the *APSF Newsletter*, Summer 1997, a Letter to the Editor by Beverly C. Collins, CRNA, discusses the analysis of the many rust initiated degradation products. With HF being produced in the rust contaminated sevoflurane, the product is out of specification, and the pungent odor of HF will be detected independent of the container.

In his article, Dr. Kharasch creates the impression that all metal oxides are "potential Lewis Acids," an assertion that is not supported by scientific evidence. Abbott has circulated data of laboratory tests of sevoflurane vaporizers manufactured by CIE-Ohmeda, Dräger, and Penlon, using Minrad, Baxter, and Abbott-marketed sevoflurane under accelerated conditions, to many parties. One series of tests inventory the metal oxides, and their areas, present in the vaporizers. The results of these tests would lead one to the conclusion that degradation should be worse in Dräger vaporizers, a conclusion not supported by the second test series that quantified the actual degradation of the sevoflurane products in the vaporizers.

In the latter tests no degradation was detected in either GE-Ohmeda or Dräger vaporizers, independent of the water content, a fact not mentioned by Dr. Kharasch. Equally important was the fact that for all manufacturers, sevoflurane degraded in the Penlon vaporizers. Although the rate of degradation was apparently reduced by water, water did not prevent degradation from occurring. Dr. Kharasch is aware of this outcome because in a letter, also circulated by Abbott, from Dr. Kharasch to Mario Saltarelli, MD, PhD, Divisional vice president, Abbott Laboratories, Dr. Kharasch states the following:

- "There was lesser, but apparent, degradation of Abbott sevoflurane (1200 ppm HFIP, 1370 ppm total impurities, pH decrease from 6 to 5, and no apparent inorganic fluoride formation). With Penlon vaporizers, impurity concentrations were 1,400 times greater than specification (50 ppm) for Minrad and Baxter sevoflurane, and 27 times greater for Abbott sevoflurane."

See "Minrad," Page 86

Abbott Addresses Sevoflurane Formulation

To the Editor:

The article "Sevoflurane: The Challenges of Safe Formulation" by Evan Kharasch examines the potential patient safety implications of sevoflurane formulation differences. This letter outlines the safety measures taken by Abbott regarding its sevoflurane product, Ultane® 9also known as Sevorane® ([ex-US]).

Following a voluntary recall in 1996 due to physical changes of sevoflurane, Abbott identified several degradation products, including hydrogen fluoride (863 ppm). Abbott determined that the cause of degradation was a Lewis Acid-mediated reaction that occurred during shipping and transport. This reaction was inhibited by water.[1] Abbott subsequently reformulated Ultane® to contain >300 ppm water.

Recent studies confirmed the role of Lewis acids in the degradation of sevoflurane.[2,3] Another experiment investigated the potential breakdown of sevoflurane products in vaporizers.[4] Three sevoflurane formulations with differing water content (Ultane® [357 ppm water], Baxter sevoflurane [U.S.]]57 ppm water], and Minrad sevoflurane [19 ppm water]) were tested in 3 commercial vaporizers (GE Tec 7, Dräger 2000, and Penlon Sigma Delta). Each sevoflurane formulation was stored in each vaporizer type for 3 weeks using an accelerated stability model (simulating 3 month storage at room temperature). In the Penlon vaporizers, marked increases in hydrogen fluoride were measured in both low-water formulations [U.S. Baxter (444 ppm); Minrad (600 ppm)], indicative of sevoflurane degradation. However, no hydrogen fluoride was detected in the high-water sevoflurane formulation [Ultane® (<0.4 ppm)]. Additionally, degradation and hydrogen fluoride production associated with the low water sevoflurane formulations were accompanied by physical corrosion of the vaporizers, specifically etching of the sight glass and degradation of the metal filler port shoe. In early 2007, Abbott shared the results of these experiments with Penlon, Baxter, Minrad, and many regulatory agencies worldwide (including FDA [U.S], TGA [Australia], and MHRA [U.K]), as well as several academic experts. Abbott is conducting further studies.

Shortly after the completion of the Abbott studies, notices issued by the European Medicines and Healthcare Products Regulatory Agency[5,6] and a report in the journal *Anaesthesia*[7] revealed that some units of the Penlon Sigma Delta sevoflurane vaporizer (distributed by Baxter) were found to interact with low-water sevoflurane formulations, resulting in "degradation in some of the materials in use. This degradation [location] has notably been the filling port shoe and the Sight glass. It has made, in some cases, it difficult to establish the drug level in the vaporizer."[5] In both European Agency notices,[5,6] it was recommended that the vaporizers be removed from use.

Historically, Abbott has acted responsibly throughout the years to investigate potential problems with its sevoflurane product in order to ensure patient safety. These studies reflect our continuing commitment to product quality and patient safety.

Mario Saltarelli, MD, PhD
Divisional Vice-President
Neuroscience and Anesthesia Development
Global Pharmaceutical Research and Development
Abbott
Abbott Park, IL 60064

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Editor's Note:

The issues regarding the stability and formulation of sevoflurane are complex and controversial. The APSF Newsletter has endeavored to allow all interested parties to share their perspectives and respond to Dr. Kharasch's prior article.

Complex Chemistry Causes Controversy

"Minrad," From Page 85

- "Conversely, the higher water content in Abbott sevoflurane largely, albeit not entirely, protected against degradation by Lewis acids."

Further in the same letter, Dr. Kharasch ignores the fate of the methyl fluoride group that was cleaved at the ether oxygen in order to produce HFIP (hexafluoroisopropyl alcohol).

Subsequent investigation by Penlon concluded that the problem was caused by defects in the barrier coating of the aluminum alloy vaporizer body that exposed the product to the aluminum alloy surface. Penlon has taken steps to correct the defect and Quality Assurance testing is in progress to insure that their vaporizer is fully compatible with sevoflurane.

Since US 5,990,176, "Fluoroether Compositions and Methods for Inhibiting Their Degradation in the Presence of a Lewis Acid" specifically mentions the aluminum oxide in the USP Type III Amber Glass as a source of the supposed Lewis Acid, in 2000, Dr. Terrell did studies of the stability of sevoflurane using Type 3A molecular sieves (these molecular sieves are composed of aluminum oxide and silicon dioxide). The results of Dr. Terrell's experiments clearly showed that there was no degradation of sevoflurane independent of water content varying from 40 ppm to several hundred ppm. Recently the retained samples from Dr. Terrell's work were retested after more than 5 years of contact with unactivated alumina and silicon dioxide; there was still no indication of degradation of sevoflurane.

John C. McNeirney
Chief Technical Officer

Dr. Ross C. Terrell, PhD
MINRAD

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1. Abbott recall communications with the FDA obtained through the Freedom of information Act. Documents on file, MINRAD International, Inc.
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MHAUS Recognizes APSF Newsletter

"MHAUS," From Page 84

Dr. Wong called the hotline because he was dealing with signs of MH during a surgical procedure in a 72-year-old woman undergoing off-pump cardiac surgery. After much discussion, it was eventually concluded that the case was probably MH and the patient was recommended for a muscle biopsy at UCLA.

Dr. Chapin has volunteered his time as a hotline consultant for over 20 years.

Special Recognition for Outstanding Dedication to MH Award

Harvey K. Rosenbaum, MD, clinical professor of Anesthesiology at David Geffen School of Medicine at UCLA received a Special Recognition for Outstanding Dedication to MH Award for his leadership and vision in promoting the development of the MH Case of the Month on the Malignant Hyperthermia website (www.mhaus.org). Henry Rosenberg, MD, president of the Malignant Hyperthermia Association of the US stated that Dr. Rosenbaum, who has been a codirector of the MH biopsy center at UCLA, took the case of the month idea and developed the presentation and structure of the challenge. He personally wrote the first 14 cases.

Special Recognition Awards

Paul Allen, MD, PhD, of Brigham and Women's Hospital in Boston, MA, received the Special Recognition Award in recognition of his outstanding work in understanding the pathophysiology of MH and the development of a new animal model for MH.

Susan Hamilton, PhD, of Baylor College of Medicine in Houston, TX, received the Special Recognition Award for her outstanding work in understanding the structure and function of the ryanodine receptors and the development of a new animal model for MH.

Dr. Rosenberg said that Drs. Hamilton and Allen have been investigating the special characteristics of cellular structure and function in MH susceptibles. They worked through the details of developing an animal model that expresses the mutations that are responsible for rendering an individual animal MH susceptible. The animal model has already suggested that environmental temperature can modulate the development of an MH episode. The animal model will serve to provide greater information concerning the relation of DNA changes to the expression of MH.

Special Mention Manuscript Award

Laura Schleelein, MD, of Children's Hospital of Philadelphia received the Special Mention Manuscript for her manuscript *"Hyperthermia in the Pediatric Intensive Care Unit—Is it Malignant Hyperthermia?"* Dr. Schleelein and coworkers used MH hotline data to explore how often MH is expressed in the Pediatric Intensive Care Unit. An abstract of her work may be found in the compilation of annual meeting abstracts posted on the website of the American Society of Anesthesiologists (www.asaabstracts.com).

Media Award

This year's MHAUS Media Award recognized Robert C. Morell, MD, editor of the *APSF Newsletter* for his support of the educational mission of the Malignant Hyperthermia Association by encouraging the publication of information that relates to the clinical findings in MH.

Daniel Massik MHAUS Anesthesiology Resident Award

The Daniel Massik MHAUS Anesthesiology Resident Award was established through the generosity of an MHAUS founder, George Massik, in memory of his son Daniel. First place went to Frank Schuster, MD, of the University of Wurzburg, Department of Anesthesiology in Wurzburg, Germany, for his manuscript entitled *"A Minimally-Invasive Metabolic test Detects Probands at Risk for Malignant Hyperthermia."*

Dr. Rosenberg said the work of Dr. Schuster and his colleagues has creatively applied physiologic information about MH to developing a minimally invasive diagnostic test for MH that might reduce the use of the standard open muscle biopsy.

About MHAUS

Malignant Hyperthermia is an uncommon, inherited disorder, whereby patients who are at risk may develop life-threatening temperature elevation, muscle breakdown, and changes in body chemistry usually upon exposure to certain anesthetic gases. With rapid recognition of the changes accompanying the syndrome and administration of dantrolene sodium, mortality is averted.

MHAUS (www.mhaus.org) is a not-for-profit patient advocacy organization that is dedicated to reducing morbidity and mortality from MH and related syndromes by 1) improving medical care related to MH, 2) providing support information for patients, and 3) improving the scientific understanding and research related to MH and other kinds of heat-related syndromes. In its first 25 years of existence, MHAUS has contributed to the reduction of the MH-related death rate from 80% to less than 5%.

APSF Funds 9 Grants

- *Nine New Research Proposals Funded*
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Anesthesia Patient Safety Foundation
Building One, Suite Two
8007 South Meridian Street
Indianapolis, IN 46217-2922

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