



# NEWSLETTER

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## Does Anesthetic Management Affect Cancer Outcome?

*Editor's Note: This thought-provoking article by Dr. Durieux raises questions that have yet to be answered and perhaps expands our conventional view of patient safety.*

by Marcel E. Durieux, MD, PhD

### Introduction

The immune system has developed to protect us not only from infection but also from cancer. The perioperative stress response affects our immune system. Therefore, it might be expected that in patients undergoing cancer surgery (often associated with release of cancerous cells through the body) their defenses against metastasis are suppressed just at a time when they need them the most. This raises the question whether certain anesthetic techniques might improve the ability of the body to eliminate cancer cells and improve survival. Recent evidence suggests that this is indeed the case.

In this article, we will review the effects of surgical stress and anesthetic techniques and drugs on cancer and discuss the recent data suggesting that specific anesthetic management can improve patient outcomes by reducing cancer recurrence.

### The Stress Response and Cancer

Animal studies indicate that immune response control over the circulation of tumor cells and micrometastasis is carried out mainly through cell-mediated immunity (CMI), which includes cytotoxic T lymphocytes, NK (natural killer) cells, NK-T-cells, dendritic cells, and macrophages.<sup>1</sup> NK cells are important because they can naturally recognize and kill malignant cells. A number of inflammatory mediators, such as interferon (INF) and interleukin (IL),

specifically, (INF) $\gamma$ , IL12, and T helper 1 (Th1) cytokines, increase the cytotoxic activity of T- and NK cells, as do IL-4 and IL-10. Th2 cytokines are involved in increasing humoral immunity and suppressing the Th1 response, and the Th2 status is thought to play a negative role in oncological immune response.<sup>2</sup>  $\beta$ -adrenergic stimulation, which increases during stress states, suppresses NK activity and therefore promotes metastasis.<sup>3</sup> Human studies show that low perioperative levels of NK activity are associated with an increased cancer related morbidity and mortality.<sup>4,5</sup>

Angiogenesis, the growth of new capillaries from existing blood vessels, is essential for the growth of a cancer cell into a macroscopic metastasis. It is a complex multi-step process involving extracellular matrix components,<sup>6</sup> and is regulated by multiple angiogenetic factors, including interleukin 6, 8, and 1 $\beta$ , cyclooxygenase 2, nitric oxide, tumor necrosis factor, and insulin growth factor.

### Surgery, Anesthesia, and Cancer Metastasis

Surgery, although essential for tumor cancer treatment, suppresses immunity and therefore promotes metastasis. Growth of preexisting micro metastases and dissemination of malignant cells during the perioperative period is facilitated.<sup>7,8</sup> In addition, surgical stress activates angiogenesis, which contributes to neoplastic growth. It is conceivable that minimally invasive approaches, with

less effect on the immune system, might reduce these negative effects, but this is not known.

The specific anesthesia approach used is more likely to be of relevance as many animal studies have shown that the choice of anesthetic drugs and techniques profoundly influences the immune response and, as a result, cancer metastasis.

### Anesthetic Drugs

Melamed and colleagues demonstrated in rats that ketamine, thiopental, and halothane reduced NK cell activity and increased lung tumor retention or lung metastasis. The number of circulating NK cells per milliliter of blood was reduced by ketamine and thiopental significantly; halothane showed a similar but not significant result.<sup>9</sup> The effect of ketamine, in particular, may result from its adrenergic stimulating properties, which will suppresses NK cell activity and promotes metastasis.<sup>3</sup> In contrast, propofol does not affect metastasis, which may be related to its (weak)  $\beta$ -adrenergic antagonist properties.<sup>10</sup>

Postoperative pain therapy may play a very important role in metastasis after cancer surgery. Page and colleagues demonstrated in rats that the provision of pain relief attenuates the surgery-induced increase in metastatic susceptibility, likely because of the reduction in the stress response. They demonstrated that preoperative intrathecal administration of bupivacaine plus morphine and the perioperative systemic administration of fentanyl significantly enhanced the host resistance to surgery-induced increases in lung metastasis.<sup>11</sup> They suggested that the pain-alleviating effect of these drugs attenuated the surgery-induced promotion of metastasis rather than having direct effects on immunity, tumor cells, or other mechanisms.

On the other hand, opioids likely play a profoundly negative role. Morphine has been repeatedly shown to promote angiogenesis, and it promotes breast tumor growth in rodents.<sup>12</sup> It is well established that opioids inhibit cellular and humoral immune function in humans.

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# President's Report Highlights Accomplishments of 2008

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 2008 has been an active and rewarding year as the APSF pursues safety initiatives intended to further our vision that "no patient shall be harmed by anesthesia."

The APSF was able to continue in 2008 its increased funding of patient safety research that was initiated in 2007. This critically important expansion of research support is made possible, in part, by the full support (\$150,000 each) of named research awards (Cardinal Health Foundation, Anesthesia Healthcare Partners, Eisai, Inc., American Society of Anesthesiologists [ASA]), and the partial support of one named grant at the \$100,000 level by Covidien.

## Research

The APSF Committee on Scientific Evaluation chaired by Sorin J. Brull, MD, received 32 grant applications in 2008 for awards to begin in January 2009. In October 2008, the committee recommended funding 6 research awards, for a total of \$783,793. Among the named grants, was the first **APSF/ASA President's Endowed Research Award**. This award plus the **APSF/ASA Endowed Research Award** utilizes funds from the APSF endowment fund, which was made possible by contributions from ASA to the APSF over the past 20 years.

*The awarding of nearly \$800,000 for anesthesia patient safety research by the APSF in October 2008 makes the 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, more than 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 83 grants for a total of more than \$5.3 million. The impact of these research grants is more far-reaching than the absolute number of grants and total dollars, as APSF-sponsored research has led to other investigations and the development of a cadre of anesthesia patient safety investigators.

## APSF Newsletter

The APSF Newsletter continues its role as a vehicle for rapid dissemination of anesthesia patient safety information with Robert C. Morell, MD, as its editor. Lorri A. Lee, MD, has assumed the role of associate editor. The circulation of the APSF Newsletter exceeds 83,000 recipients including members of

the ASA, American Association of Nurse Anesthetists (AANA), American Academy of Anesthesiologist Assistants (AAAA), and the American Society of Anesthesia Technologists and Technicians (ASATT).

Important issues presented in recent editions of the APSF Newsletter include the report of the October 2007 APSF Workshop on "Formal Training and Assessment before Using Advances Medical Devices in the Operating Room." This report was written by Michael A. Olympio, MD, chair, APSF Committee on Technology, and concludes with this recommendation: "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."

The Spring 2008 APSF Newsletter carried the front page headline, "If my spine surgery went fine, why can't I see?" followed by an article written by an anesthesiologist (now retired) who experienced perioperative visual loss after major spine surgery. This article was followed by an update on perioperative visual loss, a comprehensive review of informed consent, and a spine surgeon's perspective. It is the hope of the APSF that these articles will increase awareness of perioperative visual loss, encourage appropriate informed consent, and stimulate research that may reduce or eliminate this perioperative complication.

Other topics presented in recent issues of the APSF Newsletter included "New Guidelines Available for Pre-Anesthesia Checkout," written by Drs. Feldman, Olympio, Martin, and Striker; "Medication Administration in Anesthesia: Time for a Paradigm Shift," written by Drs. Stabile, Webster, and Merry; and "Beach Chair Position may Decrease Cerebral Perfusion: Catastrophic Outcomes Have Occurred," written by Drs. Cullen and Kirby. The article by Cullen and Kirby resulted in a letter to the editor from James Munis, MD, discussing the physiology of blood pressure levels during anesthesia and the misconceptions associated with blood pressure and cerebral perfusion.

The Questions and Answers and Dear SIRS (Safety Information Response System) columns in the APSF Newsletter provide rapid dissemination of safety issues related to anesthesia equipment in response to questions from readers. These columns are coordinated by Drs. Olympio and Morell. A section in the APSF Newsletter entitled *Innovative Technology and Pharmaceuticals* is intended to describe innovative technological or pharmaceutical developments that may impact patient safety. It is inevitable that this column may discuss products that are sold or distributed by entities that have or continue to support the

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## NEWSLETTER

The Official Journal of the Anesthesia Patient Safety Foundation



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# Prospective Studies Needed to Validate Retrospective Data

## “Cancer,” From Page 49

### Neuraxial Anesthesia: Animal Data

The use of epidural anesthesia alone improves postoperative outcome, attenuates the surgical stress response, and prevents inhibition of the system. In addition, regional anesthesia decreases the requirement for inhaled anesthetics and intravenous opioids, both of which have been shown to decrease the activity of natural killer cells. When administered intrathecally in small quantities, opioids do not exert the same immunosuppressive effects seen after systemic administration. This finding has significant clinical relevance, as epidural and spinal blockade is usually supplemented with small doses of opioids, and this practice is likely safe.<sup>13</sup> Furthermore epidural analgesia blunts effectively the neuroendocrine response and thereby decreases the production of epinephrine and norepinephrine, which reduce NK cell activity.

In a mouse model it was shown that laparotomy during sevoflurane anesthesia significantly increased the number of liver metastases as compared with sevoflurane anesthesia plus spinal anesthesia. The addition of intrathecal local anesthetics attenuated the suppression of tumoricidal function of liver mononuclear cells, presumably by preserving the Th1/Th2 balance. Thereby it reduced the promotion of tumor metastasis.<sup>14</sup>

### Neuraxial Anesthesia: Human Data

Two retrospective studies demonstrate that the long-term outcome for patients undergoing cancer surgery is better if they receive neuraxial anesthesia.

Exadaktylos et al. suggested in a retrospective analysis that paravertebral anesthesia and analgesia for breast cancer surgery reduces the risk of recurrence or metastasis during the initial years of follow up. This study reviewed data from 129 patients undergoing mastectomy and axillary dissection for breast cancer.<sup>15</sup> The follow-up time was  $32 \pm 5$  months (mean  $\pm$  SD). Recurrence- and metastasis-free survival was 94% (95% confidence interval, 87–100%) and 82% (74–91%) at 24 months and 94% (87–100%) and 77% (68–87%) at 36 months in the paravertebral and general anesthesia patients, respectively ( $P = 0.012$ ). These data suggest that neuraxial anesthesia might be more effective than postoperative chemotherapy to reduce metastasis.

A retrospective study from the same group studied men undergoing radical prostatectomy under general anesthesia with morphine analgesia as compared with general anesthesia combined with epidural analgesia. The authors found that the epidural technique was associated with a 65% reduction in biochemical recurrence of prostate cancer

defined by increased prostate specific antigen postoperatively [Biki B. *Anesthesiology* In Press]. A potential mechanism was reported in a prospective study with patients undergoing transurethral resection of the prostate. It was found that spinal anesthesia may result in less immunosuppression after surgery and that the ratio of Th1/Th2 cells was higher compared to general anesthesia.<sup>2</sup>

It is too early to recommend specific kinds of medications for the anesthesia regime or to recommend a regional technique. At this time, the mechanisms underlying these benefits are unclear. Is it the reduction in stress response provided by regional anesthesia the important factor, the reduction in opiate use, or the reduction in inhaled anesthetic requirement? The latter is suggested by a study that followed 4,329 melanoma patients and reported that substituting the use of local anesthesia for the procedure (as compared with general anesthesia) was an independent, favorable prognostic factor for less recurrence of tumor. In fact, choice of general anaesthesia for primary excision of melanoma was associated with a decrease in the survival rate, with a relative risk of 1.46 ( $P < 0.0001$ ).<sup>16</sup> If reducing volatile anesthetic requirements or opiates is the main factor, it might be possible to obtain similar benefits using drugs like dexmedetomidine or intravenous lidocaine.<sup>17</sup>

It should be realized that all these studies were retrospective. Long-term prospective studies will be required (and several have been initiated) before we will know if the choice of anesthesia technique for cancer surgery has a significant impact on patient safety in the long run. Since 90% of cancer-related death is due to metastatic development, rather than directly related to the primary cancer, the potential for improving patient outcome is very significant.<sup>18</sup>

## Conclusion

For many years, laboratory studies have suggested that our anesthetic drugs and approaches may impact tumor metastasis after cancer surgery. Techniques that prevent stress responses and increases in catecholamines, and that limit requirements for volatile anesthetics and opiates, seem effective in reducing the incidence of metastasis. Two retrospective clinical trials have demonstrated significant reductions in recurrence rates in breast and prostate cancer if neuraxial anesthesia was employed. We will have to await the results of prospective trials before definitive conclusions can be drawn, but there is at least a strong suggestion that anesthetic practice can affect patient safety for years after the surgical procedure.

*Dr. Durieux is Professor of Anesthesiology and Neurological Surgery at the University of Virginia Health System in Charlottesville, VA.*

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# APSF Initiatives Foster Exciting and Bright Future

## "President," From Page 50

APSF financially. The APSF will strive to disclose those relationships as appropriate.

### Electronic Newsletter

The APSF is exploring various options in reducing costs including the possibility of converting the *APSF Newsletter* to an electronic format. Currently it costs about \$1.25 per copy to produce, print, and mail the quarterly issues of the *APSF Newsletter* to some 83,000 recipients. Over the year, the APSF has conducted surveys (APSF website, ASA website, AANA annual meeting, ASA annual meeting) asking readers their reaction to elimination of the hardcopy in favor of an *eNewsletter*. The results of these surveys suggest that up to 60% of readers would find an *eNewsletter* acceptable. Currently, all issues of the *APSF Newsletter* are available on the APSF website ([www.apsf.org](http://www.apsf.org)). One option may be to provide the quarterly issues of the *Newsletter* in an electronic format to all current recipients and offer a subscription to those who wish to also receive a hard copy. Your comments on an electronic newsletter would be most welcome ([stoeltling@apsf.org](mailto:stoeltling@apsf.org)).

### Communication

The APSF website <[www.apsf.org](http://www.apsf.org)> is coordinated by George A. Schapiro, APSF executive vice president for development. The APSF website includes a monthly poll question related to anesthesia patient safety issues. This poll question is coordinated by Richard C. Prielipp, MD, chair, APSF Committee on Education and Training.

Sorin J. Brull, MD, chair of the APSF Committee on Scientific Evaluation, continues as the Patient Safety Section editor for *Anesthesia & Analgesia*.

The APSF sponsored a panel at the 2008 Annual Congress of the International Anesthesia Research Society (IARS) on perioperative anticoagulant management of patients with cardiac stents. This panel was organized and moderated by Richard C. Prielipp, MD. A panel on fire safety moderated by Dr. Prielipp is planned for the 2009 IARS meeting.

The APSF was an "endorsing organization" for the World Health Organization Safe Surgery Saves Lives launch event held in Washington, DC, on June 25, 2008. John H. Eichhorn, MD, consultant to the APSF Executive Committee, represented the APSF at this event.

### Strategic Planning and Development

The APSF continues to fund and support "patient safety initiatives" with immediate and future implications for anesthesia professionals. In this regard, the APSF has contracted with the ECRI Institute to produce an interactive multimedia fire

safety video that parallels the *ASA Practice Advisory for the Prevention and Management of Operating Room Fires*. The APSF will pay the entire cost of this creating this educational product.

The APSF has agreed to provide a grant of \$60,000 to the Society for Pediatric Anesthesia (SPA) to partially support the start-up costs of establishing a registry (*Pediatric Anesthesia Quality Improvement Project: Wake Up Safe*) for adverse perioperative pediatric events. This grant combined with SPA support of \$50,000 and \$15,000 over 2 years from each of 10 participating hospitals will create the infrastructure for this registry. The APSF will provide an *ex officio* representative on the SPA Committee responsible for leading this project.

The APSF has endorsed a web-based survey on the use of muscle relaxants, neurophysiological monitoring, and reversal of drug effects.

The Data Dictionary Task Force (DDTF)/ International Organization for Terminology in Anesthesia (IOTA), chaired by Terri G. Monk, MD, continues to progress toward its goal of a common terminology of anesthesia terms that will allow the merging of data from disparate automated information systems. Ultimately it is hoped that data from automated information systems will lead to a better understanding of best practices and improved patient safety. To date the activities of the DDTF/IOTA have been entirely supported by the APSF and the vendors of information technology (see the APSF website for list of vendor supporters).

The APSF will sponsor a safety curriculum panel and a technology safety education panel at the 2009 annual meeting of the Society for Education in Anesthesia. These 2 panels will be funded by the APSF and organized by members of the APSF Board of Directors (Drs. Michael A. Olympio and Matthew B. Weinger).

### Medication Safety

The topic for the 2008 APSF Board of Directors' Workshop on Friday, October 17, 2008, was "Innovations in Medication Safety in the Operating Room." The workshop was organized and moderated by Jeffrey B. Cooper, PhD, APSF executive vice president. The goals of the workshop were to identify 1) *current possible solutions for medication errors in the operating room* and 2) *ideas for potential new processes to be developed and explored*. The report for this workshop appears in this issue of the *Newsletter*.

### Financial Support

Financial support to the APSF from individuals, specialty and component societies, and corporate partners in 2008 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 2008, the APSF awarded nearly \$800,000 in research dollars to patient safety investigators. *This amount plus the production of the fire safety video and the grant to the Society for Pediatric Anesthesia reflects an investment of nearly \$1 million in patient safety research and initiatives.*

Contributions to the APSF from all sources in 2009 represent an unknown quantity based on the recent events in the economy. The APSF can only monitor the effects of these changes and adjust its budget (principally anesthesia patient safety research awards) based on income.

### Online Donations

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

### APSF as a Unique and Separate Foundation

Occasionally there are those who advocate the merging of all ASA foundations either administratively or as a single entity. As President of the APSF, I believe this would not be in the best interest of the APSF and the value it brings to patients and anesthesia professionals. My reasons for this position are described in the November 2008 *ASA Newsletter* in an article entitled, *APSF: A Unique and Distinct ASA Foundation* (<http://www.asahq.org/Newsletters/nlarchives.htm>).

### Concluding Thoughts

The year 2008 was saddened by the loss of Ann S. Lofsky, MD, who served as a consultant to the Executive Committee. Dr. Lofsky was a frequent contributor of patient safety articles to the *APSF Newsletter*. Her contributions to anesthesia patient safety will serve as a lasting memory to her special place in the efforts of the APSF to achieve its vision that "*no patient shall be harmed by anesthesia.*"

APSF is pleased to welcome Mark A. Warner, MD, and Steven Sanford, JD, as members-at-large to the APSF Executive Committee. Patricia A. Kapur, MD, has joined the APSF Executive Committee as a consultant.

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

Best wishes for a prosperous and rewarding year 2009.

Robert K. Stoeltling, MD  
President

# APSF Funds 6 New Grants

by Sorin J. Brill, 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, on-line submission format that was introduced in 2005. The applications, as well as all the required attachments, are uploaded to the newly redesigned APSF website ([www.apsf.org](http://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 continues to award; similar to last year, the APSF has committed a total of \$1M to support research and educational projects dedicated to patient safety.

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

In addition to the *Clinical Research and Education and Training* content that is the major focus of the funding program, the APSF continues to recognize the patriarch of what has become a patient safety culture in the United States and internationally, and one of the founding members of the foundation—Ellison C. "Jeep" Pierce, Jr., MD. In his honor, the APSF Sci-

entific Evaluation Committee continues to designate each year one of the funded proposals as the recipient of this prestigious nomination, the **Ellison C. Pierce Jr., MD, Research Award**. This recognition carries with it an additional, unrestricted award of \$5,000.

## APSF Named Awards:

**APSF/American Society of Anesthesiologists (ASA) Endowed Research Award**

**APSF/Anesthesia Healthcare Partners (AHP) Research Award**

**APSF/Cardinal Health Foundation Research Award**

**Ellison C. Pierce, Jr., MD, Research Award**

## New This Year:

**The Doctors Company Foundation Ann S. Lofsky, MD, Research Award**

**APSF/American Society of Anesthesiologists (ASA) President's Endowed Research Award**

**APSF/Eisai, Inc. Research Award**

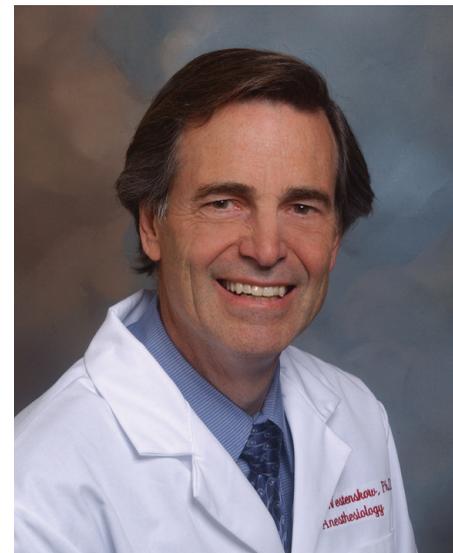
**APSF/Covidien Research Award**

The APSF has also inaugurated this year **The Doctors Company Foundation Ann S. Lofsky, MD, Research Award**. This award is made possible by a \$5,000 grant from The Doctors Company Foundation that will be awarded annually for the next 5 years to a research project deemed worthy of the ideals and dedication exemplified by Dr. Ann S. Lofsky. Dr. Lofsky was a regular contributor to the *APSF Newsletter*, a special consultant to the APSF Executive Committee, and a member of the APSF Board of Directors. Her untimely passing cut short a much-valued and meaningful career as an anesthesiologist and as a dedicated contributor to anesthesia patient safety. It is the hope of the APSF that this award will inspire others toward her ideals and honor her memory.

For the year 2009 (projects to be funded starting January 1, 2009), 6 grants were selected for funding by the APSF Scientific Evaluation Committee (for names of committee members, please refer to the list in this issue). The APSF Scientific Evaluation Committee members were pleased to note that they reviewed a total of 32 applications in the first round, 12 of which were selected for final review at the American Society of Anesthesiologists' (ASA) annual

meeting in Orlando, FL. 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 18, 2008, in Orlando for final evaluation and selection of the proposals. Of the 12 finalists, the members of the APSF Scientific Evaluation Committee selected the following 6 applications:



**Dwayne Westenskow, PhD**—Professor and Director of Bioengineering, Department of Anesthesiology, University of Utah, Salt Lake City, UT.

Dr. Westenskow's Clinical Research submission is entitled "*User Interface to Prevent Intravenous Infusion Pump Errors.*"

**Background:** The unintentional administration of incorrect medication doses through intravenous infusion pumps results in dangerous and frequent errors occurring in hospitals. A primary factor in the misuse of infusion pumps is the complicated and unintuitive nature of the user interface. The study's objective is to

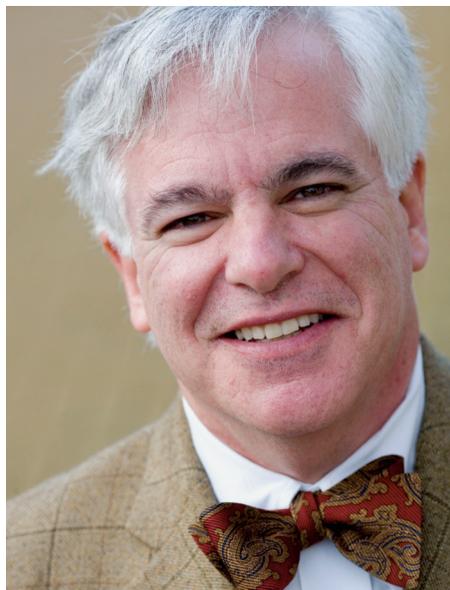
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## Dr. Westenskow Receives Ellison C. Pierce, Jr., MD, Research Award

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improve the user interface and thereby reduce the frequency of drug administration errors. In order to accomplish this goal, the interdisciplinary team will first conduct a Failure Mode and Effects Analysis (FMEA) using 2 commercially available infusion pumps. **Implications:** This analysis will describe usability issues with the interfaces. Using this information, the team will then develop a human factors-centered user interface, implemented on a touch-screen and located on the anesthesia workstation. Wireless communication will be used to remotely control infusion pumps that are located close to the patient’s intravenous access. Thus, a major source of error in the operating room will be reduced and patient safety will be improved.

In addition to receiving the requested funding of \$149,938 for his project, Dr. Westenskow’s application was designated as the **APSF/Cardinal Health Foundation Research Award**, made possible by an unrestricted, \$150,000 grant from the Cardinal Health Foundation. Dr. Westenskow is also the recipient of the **Ellison C. Pierce, Jr., MD, Research Award**, which consists of an additional, unrestricted award of \$5,000.



**Daniel Raemer, PhD**—Associate Professor of Anesthesia, Harvard Medical School, and Bioengineer, Department of Anesthesia and Critical Care, Massachusetts General Hospital, and Center for Medical Simulation, Boston, MA.

Dr. Raemer’s Education and Training project is entitled “*Challenging Others in the Operating Room: Testing an Educational Patient Safety Initiative for Anesthesia Faculty.*”

**Background:** This patient safety education project is aimed at teaching anesthesiologists a guideline and conversational technique for challenging surgeons, nurses, and other anesthesia providers when they have a concern about the actions, judgment, or behavior of others. The guideline is modified from military aviation and is known as the *health care two-challenge rule*. The conversational technique is modified from the organizational studies literature known as *Advocacy/Inquiry (A/I)*. **Objective:** An experiment will be conducted to determine whether a combination of didactic presentation, cognitive aid, and a role-play exercise is effective in getting anesthesiology faculty to effectively challenge others according to the prescribed rubric. A second experiment will be conducted to determine if a simulation experience in addition to the combination of the didactic presentation, a cognitive aid, and a role play exercise are effective for anesthesiologists’ learning to challenge others according to the prescribed rubric.

The educational interventions will be assessed within a realistic simulation center with 2 experiments. First, a double-blind controlled pre-post-test experiment will evaluate whether anesthesia faculty can learn to apply the conversational technique after exposure to a didactic presentation, a cognitive aid, and a role-play. The second experiment will compare those who have had the experience of participating in the first experiment with those who have not for their proclivity and skill in challenging others in an operating room simulation. Trained blinded raters will assess their adherence to the rubric.

The authors will use qualitative coding of debriefing sessions to test the hypothesis that there are significant barriers to challenge in the operating room. A survey of the anesthesia faculty will be used to examine the hypothesis that there is a difference between espoused values and actions when challenge opportunities are presented. **Implications:** If the guideline and conversational technique can be efficiently and effectively taught to an entire academic faculty, a greatly enhanced prospect exists for changing the culture in the operating room to one where patient safety challenges are expected and well received.

In addition to receiving the requested funding of \$149,967, Dr. Raemer’s application was designated as the **APSF/American Society of Anesthesiologists (ASA) Endowed Research Award**, made possible by an unrestricted, \$150,000 grant from the American Society of Anesthesiologists.



**Anahi Perlas, MD, FRCPC**—Assistant Professor, Department of Anesthesia, University of Toronto, Ontario, Canada.

Dr. Perlas’s Clinical Research project is entitled “*Gastric Ultrasonography: A Non-invasive Tool to Determine Gastric Volume. Development of a Quantitative Model.*”

**Background:** Pulmonary aspiration of gastric content is a source of major morbidity and mortality in the fields of emergency medicine, anesthesia, and intensive care. It plays a role in 9% of all anesthesia related deaths, and the presence of a “full stomach” is a risk factor for the development of pulmonary aspiration. However, at the present time there are no non-invasive validated tools that are immediately available at the bedside to assess gastric volume, and risk assessment to guide anesthetic management remains sub-optimal. Widely available and non-invasive, ultrasonography could be an ideal tool for this purpose. **Objective:** The authors propose to conduct a prospective, observer blinded, randomized study to validate the use of portable 2 dimensional (2D) ultrasound imaging to assess gastric volume. Specifically, the authors plan to determine in a controlled experiment if there is a correlation between gastric antral cross-sectional area (GAA) as determined by 2D ultrasound, and known volumes of intragastric fluid. After a fasting period of 8 hours, 36 healthy volunteers will be randomized to ingest water in 1 of 6 volumes (0 mL, 50 mL, 100 mL, 200 mL, 300 mL, and 400 mL). They will then be scanned in a standardized fashion by 2 independent sonographers blinded to the volume ingested to identify a cross section of the antrum, and GAA will be determined. **Implications:** If a correlation between GAA and intragastric fluid volume is confirmed by this study, it will be a first important step in the validation of ultrasonography

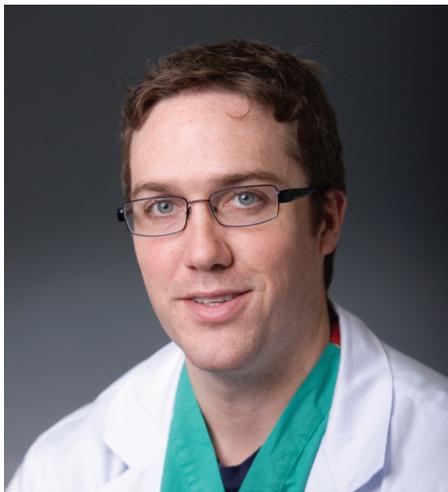
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## Perlas Examines Gastric Volume, Earns Lofsky Research Award

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as a tool to determine intragastric volume; this may ultimately lead to better evaluation of aspiration risk to guide safe anesthetic management, and will prevent a possibly life-threatening complication.

In addition to receiving the requested funding of \$24,068, Dr. Perlas’s application was designated as the APSF/American Society of Anesthesiologists (ASA) President’s Endowed Research Award. Dr. Perlas is also the recipient of The Doctors Company Foundation Ann S. Lofsky, MD Research Award, which consists of an additional, unrestricted grant of \$5,000.



**Randy W. Loftus, MD**—Anesthesiology Resident (graduated 6/08) and Critical Care Fellow (started 7/09); Department of Anesthesiology and Critical Care Medicine, Dartmouth-Hitchcock Medical Center, Lebanon, NH.

Dr. Loftus’s Clinical Research project is entitled “*Assessment of Routine Intraoperative Horizontal Transmission of Potentially Pathogenic Bacterial Organisms and Associated Morbidity and Mortality.*”

**Background:** The high prevalence of health care-associated infections and evolving amplification of bac-

terial resistance are major public health concerns. Intraoperative horizontal transmission (one patient to another) of pathogenic bacteria by anesthesia providers likely occurs on a daily basis in operating rooms. Intraoperative bacterial contamination combined with ineffective postoperative decontamination strategies may lead to horizontal transmission and may in part explain these issues in both acute health care and community settings. The authors have previously demonstrated both a high magnitude of intraoperative bacterial contamination and vertical bacterial transmission (anesthesia work area to patient) exist: 32% of IV stopcock sets were contaminated with bacterial organisms, which was associated with increased patient mortality. Inadequate decontamination of the anesthesia work area despite adherence to current guidelines was also demonstrated previously. This evidence suggests a high likelihood for intraoperative horizontal transmission, leading to significant patient morbidity and/or mortality. **Objective:** the authors designed a prospective cohort study with the primary aim of verifying intraoperative horizontal transmission of bacterial organisms and associated morbidity/mortality. This information will then be utilized to identify and characterize breaches in both aseptic and decontamination practice, and will stimulate further work toward the development of intraoperative preventative measures. A multi-centered approach will be used to evaluate 200 randomly selected operative suites at each of 2 large academic medical centers over 3 consecutive months. The primary outcomes will include the rate of patient-to-patient (horizontal) transmission, patient (vertical) transmission, intraoperative contamination, and intraoperative cleaning efficacy. Secondary outcomes will include the species identification and antibiotic susceptibility of isolated organisms, bacterial origin, and the 30-day postoperative health care-associated infection rate and associated mortality. **Implications:** This work will ultimately lead to major improvements in intraoperative aseptic practice of anesthesia providers and a reduction in hospital-wide, health care-associated infections and amplification of bacterial resistance.

In addition to receiving the requested funding of \$150,000 for his project, Dr. Loftus’s application was designated as the **APSF/Anesthesia Healthcare Partners (AHP) Research Award**, made possible by an unrestricted, \$150,000 grant from the Anesthesia Healthcare Partners.



**Ehab S.A. Farag, MD, FRCA**—Assistant Professor of Anesthesiology, Cleveland Clinic Lerner College of Medicine, Departments of General Anesthesia and Outcomes Research, Cleveland, OH.

Dr. Farag’s Clinical Research proposal is entitled “*Effects of Lactated Ringer’s Solution versus Albumin and Alpha-2 Agonist Brimonidine versus Placebo on Intraocular Pressure During Prone Spine Surgery.*”

**Background:** Visual impairment or loss is a rare but devastating complication following neurosurgery, spine surgery, or cardiopulmonary bypass surgery. Visual loss following spine surgery has a reported incidence from 0.1 to 1%, and is expected to increase with the rise in complex instrumented spinal fusions. However, the cause of vision loss remains poorly understood; it appears to be multifactorial, and may

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## A Statement by the Executive Committee of the APSF

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

## Investigators Examine Means to Preserve Ocular Perfusion

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be related to impaired perfusion of the eye or occlusion of retinal vessels due to improper positioning. Increased intraocular pressure (IOP) is suspected, among other causes. Although unproven by a well-designed, prospective study, clinical experience suggests that fluid management using colloids and topical administration of an alpha-2-agonist will reduce IOP, facial edema, postoperative morbidity, and thus the incidence of visual impairment or loss. **Objective:** The authors will test the primary hypothesis that IOP and globe perfusion are better preserved with 5% albumin than lactated Ringer’s intravenous fluid replacement, and with brimonidine (an alpha-2 agonist) than placebo. The study will also test the secondary hypothesis that colloid administration decreases postoperative morbidity, time to recovery, and facial edema. This project is a prospective, randomized, pilot study of patients having prolonged, prone spine surgery in a 2 X 2 factorial design. Sixty patients (15 patients per group) will be enrolled. **Implications:** This study seeks to determine whether a simple, inexpensive change in clinical practice (intraoperative use of colloid and alpha-2 agonist) can preserve IOP and thus reduce the incidence of vision impairment or loss during prolonged spine surgery.

In addition to receiving the requested funding of \$150,000, Dr. Farag’s application was designated as the **APSF/Eisai, Inc. Research Award**, made possible by an unrestricted, \$150,000 grant from Eisai, Inc.



**Randolph H. Hastings, MD, PhD**—Professor of Anesthesiology, Department of Anesthesiology, University of California at San Diego, VA San Diego Healthcare System, San Diego, CA

Dr. Hastings’s Education and Training proposal is entitled “*Educational Value of an Adjustable and Life-Like Laryngoscopy Simulator.*”

**Background:** Students need to perform between 20-80 direct laryngoscopies to develop a success rate of

90% or greater in normal patients. Expertise, equated to greater than 99% success, and skill with patients with a difficult airway will require a much greater practice base. Students can practice with airway simulators, but existing models are much stiffer than patients, and laryngoscopy in these mannequins is more difficult than in patients. Furthermore, the skills developed in training on one laryngoscopy trainer are specific to that particular model and do not generalize well to other anatomies, such as those of patients. **Objective:** Realistic, adjustable mannequins would be a great aid in teaching direct laryngoscopy skills. The investigators have designed and built a new airway mannequin for training direct laryngoscopy, which represents an advance in adjustability and realism. The size and range of motion of key anatomic features can vary over the normal range of human anatomy to provide the student with experience in different patient sizes and shapes. The model mannequin also incorporates force and motion sensors to provide feedback on how well the trainee is performing the procedure. Since the simulator is life-like and adjustable, experience with the mannequin may reduce the number of patient laryngoscopies needed to become proficient. The goal of this proposal is to determine whether the mannequin improves training in laryngoscopy. The desired outcome would be for students to begin intubating patients with a 90% or better success rate developed solely through simulator training, thus improving patient safety.

In addition to receiving the requested funding of \$150,000, Dr. Hastings’s application was designated as the **APSF/Covidien Research Award**, made possible by an unrestricted, partial \$100,000 grant from Covidien.

In addition to the 6 research projects, the APSF has also provided a grant for \$60,000 to the Society for Pediatric Anesthesia for support in creating an adverse events registry and has contracted with ECRI Institute to produce a fire safety video. Together with the 6 research awards, this represents an investment by the APSF of more than \$1 million in patient safety research and initiatives.

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.

*Dr. Brull is chair of the APSF Committee on Scientific Evaluation, member of the APSF Executive Committee, and Patient Safety Section editor for the journal Anesthesia & Analgesia in addition to being a Professor of Anesthesiology at the Mayo Clinic in Jacksonville, FL.*

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# Medication Mishap Mitigation Drives 2008 APSF Workshop “Syringe Swaps” in OR Still Harming Patients

by John H. Eichhorn, MD

“Innovations in Medication Safety in the OR” was the subject for the annual APSF Board of Directors’ Workshop held October 17 in Orlando, prior to the ASA annual meeting. Over 100 attendees included APSF directors, academic anesthesiologists, regulators, and industry representatives from several companies offering products intended to enhance the safety of medication administration during anesthesia care.

As introduced by Robert K. Stoelting, MD, APSF president, the vision of the activity was to help achieve a “six-sigma” or vanishingly small medication error rate in the OR. The proposed means to achieve this were identification of current possible solutions to OR drug errors as well as promotion of the exploration and development of new medication safety processes for anesthesia professionals.

Kick-off of the meaty presentations was by the workshop organizer/moderator, Jeffrey B. Cooper, PhD, of the Massachusetts General Hospital and APSF executive vice president, who fittingly harkened back to the very beginning of the concept of anesthesia patient safety as presented in his landmark 1978 publication of the “critical incident study.” That study was the first systematic study of human error as a cause of untoward anesthesia outcomes. Its results showed “syringe swap” or the unintended administration of an incorrect drug as the third most common cause of anesthesia critical incidents in the OR at that time. Dr. Cooper noted that the problem not only persists today but has increased proportionately as the inciting factor in adverse anesthesia outcomes because other events such as unrecognized breathing circuit disconnections (# 1 most common in 1978) have been virtually eliminated by the behavior-technology paradigm of “safety monitoring” in anesthesia care.

First up, presenting the history of anesthesia medication errors and types of solutions, was Dr. Alan Merry, chair of Anaesthesia at the University of Auckland, New Zealand, former chair of the Patient Safety Committee of the World Federation of Societies of Anesthesiologists, and currently leader of the anaesthesia group in the “Safe Surgery Saves Lives” campaign of the World Health Organization. He cited a 1995 survey in which 89% of responding anesthesia professionals acknowledged having committed a drug error and further detailed an extensive review of about 200 publications mentioning medication mistakes in anesthesia. The best data in the literature are from 2 prospective facilitated incident reporting studies that largely agree with many previous reports and suggest a rate of 1 reported drug error in about every 140 anesthetics, which, by definition, is an underestimate since unrecognized errors are not reported.

Dr. Merry noted that anesthesia providers are unique in that they both prescribe and administer drugs and do so at least 500,000 times in an average career, all the while facing confusing look-alike medication ampules and vials and, more recently, complex infusion pumps that have contributed to drug administration errors. As far as consequences of errors, one respected 2005 study showed a rate of 4 deaths per 1000 errors. As is true often in medical care, there is very little tolerance for mistakes that cause patient harm, and Dr. Merry cited one practitioner in New Zealand who was convicted of manslaughter after a fatal drug error.

Addressing types of possible solutions intended to help prevent anesthesia drug errors, Dr. Merry noted the need to address the dramatically increasing complexity in the anesthesia workplace (up to 41 steps involved in giving 1 traditional IV dose in the OR), and he evoked James Reason’s classic “Swiss cheese model” of human error in medical care, which explains that the coincidental lining up of “holes” or faults in the care system allows errors to slip through. Thus, is modern technology the answer for prevention? Computerized order entry, information management systems, and bar coding of medications have been offered as components of a potential solution to medication mistakes in anesthesia care. Valid as those elements may be, it was noted that a systematic review of anesthesia drug errors yielded a simple, basic 5-point checklist of remedial recommendations:

1. Read the labels.
2. Check the labels with a second person or a device before drawing up or giving a drug.
3. Labels must be legible.
4. Syringes must be labeled.
5. Workspaces should be formally organized, particularly to separate or even remove dangerous drugs (e.g., KCl).

Interestingly, the long-favored proposal about uniform color coding of drug labels was seen as equivocal in that it was little help in prospective studies. A variant involved color-coded syringe plungers (red for muscle relaxants, blue for narcotics, green for pressors, etc.) and that is under study. A confounding factor in all these considerations is the “cultural” fact that the average practitioner simply denies that he or she could make a drug error and sincerely believes that he or she is “better” than “others.”

Dr. Merry concluded by explaining one comprehensive system (of which he is an inventor and holder of a commercial interest) that is an automated anesthesia record and a drug administration tool

with pre-filled syringes and a bar code reader that causes the computer to speak out loud the drug being given. In one prospective study of the system, errors among all anesthesia drug administrations were reduced from 0.54% to 0.32%.

Robert Caplan, MD, member of the APSF Executive Committee, from Seattle’s Virginia Mason Clinic, has been one of the organizers of the ASA Closed Claims Study since its inception, and he reviewed the available data and their implications. Noting that the closed claims database by definition involves significant patient injuries, he reviewed 80 claims. Forty-four percent were the wrong dose, and more than 9 out of 10 of these overall, and every one in pediatric patients, were overdoses. Drug substitution accounted for 30% of the claims, contraindicated drugs were 10%, and mistimed drugs, 8%. Eighty-seven percent of drug error claims were judged by the review process to have been preventable, and 84% represented less than appropriate care. Sixteen percent of these claims were associated with permanent brain damage. Drug error claims significantly exceeded the rate and amount of associated payment compared to the closed claims overall. The claims led to a focus on overdoses and drug substitutions. Invoking the Toyota model of “forcing functions,” Dr. Caplan suggested that anesthesia drug administration should involve a self-check by the practitioner at the start of the process of giving a medication and then successive checks as required functions that might involve computerized order entry, pharmacist review, and/or a second-person review.

Tricia A. Meyer, PharmD, member of the APSF Committee on Education and Training and director of the Department of Pharmacy and assistant professor of Anesthesiology, Texas A&M Health Science Center, addressed the idea of how pharmacists can help prevent anesthesia drug errors. As background, she cited a US Pharmacopeia study of perioperative drug therapy that showed a 2.3-7.4% error rate. Noting that the actual process of administering drugs is where the majority of errors occur, and that “look-alike, sound-alike” drugs are involved in up to 50% of errors, she offered ideas for improvement. Pre-filled syringes from a pharmacy avoid several sources of error in the OR. Better labeling of ampules and vials used by anesthesia practitioners in the OR is important, including warning labels such as those that now often appear on muscle relaxants noting that the medication causes ventilatory arrest, but also including an additional clearly printed adhesive name/concentration label on each drug that is peeled off and used to label the syringe as the drug is drawn

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## Diverse Experts Share Perspectives on Medication Errors

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up. She noted that local anesthetics are particularly complex and maximum allowable doses poorly understood (and thus these should be specifically incorporated into the preoperative “time out”). Likewise, preoperative antibiotics should be chosen in advance so they can be prepared in correct dosage by weight in the pharmacy, which is particularly relevant to preventing pediatric overdoses. “High-alert medications” such as insulin and heparin, for all patients, but especially small children, should never be drawn or mixed in the OR but should come pre-filled from the pharmacy. All infusions should be in specific unique “standard OR concentrations,” preferably pre-mixed by the pharmacy. Also, allergy to sulfite preservatives in drugs is more common than appreciated, occurring in up to 1/100 patients. Finally, better communication from pharmacists to practitioners was offered as a key component in reducing drug errors. Bulletin boards in workrooms or by OR pharmacies can broadcast alerts/advice and show photos of new medication containers; helpful notes and suggestions can be included in drug trays and kits.

Member of the APSF Board of Directors and vice president of The Joint Commission (TJC), the omnipresent health care accrediting agency, Robert Wise, MD, shared an accrediting standards perspective on medication safety in the OR. He noted that TJC considers the OR a high-risk environment and cited various fatalities from OR medication accidents. TJC made medication labeling on the OR sterile field a 2005 national patient safety goal. Overall, the accreditation requirements are intended to minimize the confusion that leads to drug errors. All medications must be clearly labeled with drug name and strength. All original containers from which drugs are drawn should remain in clear view until after the end of the procedure. Then everything involving medications must be discarded after the case—no reuse of anything in any manner on another patient (although this unsafe practice has been documented to persist to this day, usually based on the standard fallacious reasoning: “I’ve never had a problem”). Dr. Wise advocated for strategies that will overcome this practitioner resistance as well as the need for and placement of more OR pharmacists. Also, Dr. Wise specifically noted that TJC seeks practitioner input and that he welcomed observations and ideas.

Timothy Vanderveen, PharmD, also is a member of the APSF Board of Directors. He is vice president of a division of Cardinal Health, a corporation that markets products used in medication administration. He addressed commercial solutions to anesthesia medication errors. He cited numerous traditional medication labeling safety hazards and cited the alternative benefits of pharmacy-prepared syringes of anesthetic medications (preferably filled by robots)

marked with distinctive (print layout and lettering, color coding by drug class, and bar coded) labels. Such labels can have a “peel-off” duplicate to go on a traditional paper anesthesia record. The pre-filled syringes can be dispensed by OR pharmacies or computerized automated cabinets (centralized or, preferably, one in each OR). Standardization is critical. The 15 different available preparations of heparin and the highly-publicized recent accidents with infants were cited as dramatic examples of the need for agreed-upon standard concentrations and infusions, which becomes especially important during transfers from the OR to PACU or an ICU. Citing the significant potential for medication errors associated with inexperienced practitioners attempting to use unfamiliar infusion pumps, he noted the expected benefit of “smart pumps” that recognize the codes for drug and concentration on the syringe inserted in a pump to reduce errors. He also commented that target-controlled infusion technology has not yet been approved in the US.

One home-grown proprietary system to help address potential anesthesia drug errors in the OR is in use at Boston’s Massachusetts General Hospital (MGH), and this system was presented by Wilton Levine, MD, clinical director of that Department of Anesthesia and Critical Care. Each equipped anesthetizing location has a computerized anesthesia information management system and also a small color printer that prints unique colored waterproof labels for medication syringes. A scanner reads the bar code on each ampule or vial of medication and prints a syringe label with another bar code that is read again (with visual and audio read-back) and recorded as the medication is administered from the syringe to the patient. Time savings is more than 50% per administration and practitioners there have been enthusiastic about the system. Plans are in place to install the system in every OR at MGH with future consideration for the same in all sedating locations as well.

The final speaker for the formal presentations was Jerry Cohen, MD, long-time safety/quality researcher from the University of Florida and chair of the ASA Section on Professional Standards. He addressed “cultural and practical barriers to medication safety in the OR.” Again the idea of complex pathways and the “Swiss cheese” model introduced the concept of the multifactorial causes of drug errors. Errors involve “look-alike/sound-alike drugs,” incorrect doses, incorrect injection sites (arterial or epidural), contamination of drugs, and administration of contraindicated drugs (e.g., allergy). The list of causes of drug errors was familiar, but the key emphasis was on the lack of standardization of all aspects of medication use causing “chaos and distraction.” Barriers to improvement include egos, lack of agreement on best practices, communication limi-

tation into silos (anesthesia providers vs. surgeon vs. OR staff), communication failure during hand-offs, lack of protocols/too much individual discretion, rapidity of impact (anesthesia – seconds, internists – next month), and production pressures. Interestingly, Dr. Cohen highlighted how computerized medication order entry and computerized information systems can, in many circumstances, actually increase the risk of anesthesia drug error in the OR because OR conditions are so unusual. Accordingly, benefits from such systems will require intense anesthesia input and compatibility testing. Likewise, Dr. Cohen made a plea for OR-specific medication protocols and rules that are hammered out by users who actually have to live with and in the systems they create. This, he maintained, should help overcome resistance to adoption, particularly of the required standardization of the entire anesthesia medication process. Hand-offs and also the availability of critical medications during transports were cited as other key issues. Adoption of technology to administer and record medications will be an iterative process requiring engineers to learn a great deal about anesthesia care. An associated issue is the need for one common unified automated medication administration record for the entire institution, including the OR. Encouraging a blame-free environment for error reporting and analysis as well as focusing on the role of fatigue in medication errors will contribute to an honest global process engaging all involved—administrators, regulators, and clinicians—to “drive out fear” associated with drug errors and reform the drug administration process once and for all.

The second phase of the workshop consisted of break-out sessions into four small groups to help formulate specific strategies in different areas to improve anesthesia medication safety. The session asking the question: “What research still needs to be performed?” was led by David Gaba, MD, human factors expert from Stanford and member of the APSF Executive Committee. The group produced a long list of potential research projects and the top ones, in order of priority, were 1) (recognizing the difficulty and expense of organizing such studies) randomized controlled trials of the various proposed technologies and systems and their impact on actual patient outcome; 2) bench and simulation research into the details of the human factors involved in all phases of anesthetic medication administration in the OR—particularly because many of the proposed interventions being touted have never been rigorously tested for relevancy to what actually occurs in the process; 3) expansion of studies and consideration, using both simulation and real-life observation, to include fast-paced, life-critical situations in which multiple providers may be injecting multiple medications via various access routes; 4) a confidential independent reporting system to collect and analyze anesthesia

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## Joint Commission and College of Surgeons Endorse Message

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drug error incidents; 5) investigation of the relationship between medication administration practices in the OR and nosocomial infections; and 6) long-term observational studies by knowledgeable observers (uninvolved anesthesia practitioners?) who can provide background data on actual practice, performance-shaping factors, and the associated vulnerabilities and constraints.

The group led by Lorri Lee, MD, closed claims safety researcher from the University of Washington and member of the APSF Executive Committee, addressed the question: “What can industry do to make a difference?” The resounding loud answer started with “standardization.” Considering how this standardization would be achieved was a more complex matter. The group generated an alphabet-soup list of relevant professional and technical organizations with a challenge to industry to try to bring all these involved parties together to hammer out a cost-effective, technology friendly, standardized system that would supersede corporate competition and profit motive. Initial efforts could focus on standardized containers, peel-off labels for drugs drawn up in the OR, prefilled syringes, and a volume sensor on the IV line in addition to the associated bar code reader so the computerized information system would know the exact dose administered and could react in real time (clamp the IV tubing?) to medication errors as they are happening.

“What are the current best medication safety practices?” was the question approached by the group led by Matt Weinger, MD, human factors and quality researcher from Vanderbilt University and secretary of the APSF. The group addressed many aspects, starting with communication. Discussion of medication plans, what medications will be needed, and the specific location of any high-risk drugs in the room should help reduce confusion and intention errors. Thorough communication during hand-offs is critical. Read-back of any requests for medication is essential. Packaging

suggestions included eliminating multi-dose containers, glass ampules, latex stoppers, and sulfite preservatives. Also, the familiar labeling standardization suggestions were repeated with the addition of the idea that containers of different classes of medications should have different shapes and feel, adding touch to the senses involved in discriminating among drugs. Standardization of concentrations and infusions was considered essential and, likewise, standardization of the storage and dispensing facility in the OR. Standardization of administration should involve some type of double-check immediately before any medication is injected. This might involve people, processes, and/or technology. Documentation of drugs given should be “seamless” and all empty containers should be kept until the case is over in order to facilitate checking exactly what was given. Drug disposal after an anesthetic also should be “seamless.”

The final group, led by Dr. Caplan, outlined what the APSF should do as the next steps in this campaign for anesthesia medication safety. An initial step would be to educate regulators about the unique issues of anesthesia drug administration so that they could shape more relevant regulations. Also, the APSF is in a unique position both to lobby for and to fund research into cultural, behavioral, and human factor issues that have chronically contributed to OR medication errors. A key APSF feature should be assisting in the development of educational programs that start at the beginning of medical or nursing school to instill in students specific medication safety behaviors as a foundation that would then be expanded during anesthesia training and later even more in continuing education programs for practicing clinicians. It was suggested that the APSF support universal installation of OR pharmacies, including a unique partnership between pharmacists and anesthesia professionals at the actual site and moment of medication delivery (which would also be executed under a standardized uniform protocol within each institution, which the APSF can help promote via encouraging national standards). The APSF should

support and promote technologies and systems that address the complexities of the anesthetizing location and reduce error potential through standardization and reduction of complexity. Finally, the APSF has the means and motivation to promote practitioners and investigators to be leaders and innovators in anesthesia medication safety.

The summation of the day’s efforts was presented by Drs. Stoelting and Cooper. Many of the concepts had been highlighted by the “APSF action” group. Emphasis again was placed on the reality that the OR is unique and poorly understood as far as workflow dynamics, complexity, and human factors. Standardization seems to be the first remedial strategy cited by essentially everyone addressing the problem of anesthesia medication errors in the OR. This and related messages were received and endorsed by TJC and also William Schecter, MD, the APSF director from the American College of Surgeons, who fully agreed, enthusiastically endorsing interdisciplinary involvement and cooperation. From a practical standpoint, the leaders continued, however logical the value of the “forcing function” of using all pre-filled syringes for anesthesia care in the OR, the cost is an institutional barrier likely to persist for now. Also, it is true that there is, to date, no clearly conclusive evidence that this strategy would significantly reduce anesthesia drug errors. Accordingly, the parting thought was that, if possible, the APSF should organize a comprehensive study to evaluate the efficacy of using exclusively pre-filled syringes and pre-mixed infusions in the OR as well as other related proposed strategies to reduce drug errors and enhance anesthesia medication safety.

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

### Five-Point Checklist for Avoiding Medication Errors

1. Read the labels.
2. Check the labels with a second person or a device before drawing up or giving a drug.
3. Labels must be legible.
4. Syringes must be labeled.
5. Workspaces should be formally organized, particularly to separate or even remove dangerous drugs (e.g., KCl).

# Implications of a Mislabeled Vaporizer and the Importance of Color Coding

Gregory L. Rose, MD; John Eichhorn, MD; Amy DiLorenzo, MA

## Introduction

Vaporizers have long been color-coded for ease in identification of the different anesthetic inhalational agents. In addition, vaporizers are text-labeled with the specific drug name to identify the agent. We present a case of a mislabeled vaporizer and discuss the importance of color recognition as a human factor in vaporizer design and use.

The vaporizer in question was part of an anesthesia work station incorporating a relatively new anesthesia machine for our institution (Apollo, North American Drager). The body of the vaporizer was clearly marked from the factory as "Sevoflurane." However, the control dial on top was purple, and the purple filler port accepted the purple key for isoflurane; the vaporizer was seated between a blue desflurane vaporizer and a yellow sevoflurane vaporizer. It was unclear exactly how long this vaporizer had been in service with us (Figures 1 and 2).

Our initial concern was determining exactly which agent the vaporizer contained. Was it an isoflurane vaporizer with the wrong name stenciled on it or a sevoflurane vaporizer assembled incorrectly with the purple plastic parts designating isoflurane? The second point of interest to us was how long it was used before the mislabeling was noticed. The third question was how the vaporizer came to be mislabeled.

Analysis of the agents by gas monitoring showed that the vaporizer in question was indeed an isoflurane vaporizer containing isoflurane with correct purple trim but with an incorrect factory-stenciled label.

Our assumption concerning how the vaporizer became mislabeled is that the plastic front panel of the vaporizer was switched accidentally when the unit was being factory-reconditioned.

## Implications

This episode demonstrates vividly just how much humans rely on other cues (in this case, color) besides words in a printed label.

Over the years, there have been many reports of incorrect medication administration from misreading drug vials and ampules or mislabeled syringes.<sup>1</sup> Efforts to decrease drug administration errors continue to this day.<sup>2</sup> However, the difference here is that it is likely no one administered isoflurane when they thought they were delivering sevoflurane, because anesthesia professionals are so accustomed to recognizing inhalational agents from the color of the vaporizer trim, instead of reading the printed label on the front of the vaporizer. This incident confirms the importance of crosschecking labels with other identi-



Figure 1: Photo showing mislabeled isoflurane vaporizer located between properly labeled desflurane and sevoflurane vaporizers

fying features prior to administration. But, unlike the case of similarly colored drug vials or ampules, reliance on color for vaporizers, in our case at least, was a more reliable way to avoid administration of the wrong drug. The human propensity to follow color rather than printed labeling for vaporizer identification was significant in our situation.

Color coding is a well-known and powerful tool for aiding quick recognition. There is pervasive use of color coding in medicine in general—not exclusively anesthesiology.<sup>3</sup> One ubiquitous example is the fact that blood collection tubes are color coded according to the kind of preservative in the tube (and universally referred to as "red top," "purple top," etc.). Color coding for medical gases and their tanks and hoses is another example (although the colors may vary around the world).

There is a classic psychology experiment that relates to the concept of color and identification called the Stroop Test, based upon the work of John Ridley Stroop, first published in the 1930s. There are many variations, but the basic message is that when people are accustomed to seeing things one way, and something unfamiliar is added, the brain has a more



Figure 2: Mislabeled isoflurane vaporizer incorrectly labeled as sevoflurane

difficult time processing it. So for example, if one can say correctly these: **Green Red Blue Yellow Blue Yellow** much more quickly than these, **Blue Yellow Red Green Yellow Green**, this is called the Stroop Effect<sup>4</sup> (Figure 3). Our vaporizer in question produced a variation of the Stroop effect in showing how significantly we were relying on color instead of the printed labeling.

Green	Red	Blue	Yellow	Blue	Yellow
Blue	Yellow	Red	Green	Yellow	Green

Figure 3: Stroop Test matrix in which one finds it easier to read the correct color/word combinations across the top row than the mismatched color/word combinations across the bottom row.

# Scientific Papers on Patient Safety Presented at the 2008 Annual Meeting of the American Society of Anesthesiologists

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

Over 1,700 abstracts were presented at the 2008 American Society of Anesthesiologists annual meeting in Orlando, FL. 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.

## Patient Databases and Anesthesia Morbidity & Mortality

Hospitals often seek information regarding risk factors for morbidity and mortality from their own patient databases. One study (A845) at Columbia University utilized the International Classification of Diseases (ICD) codes to report that anesthesia complications were documented as the underlying cause of death in 11% of cases. Forty-seven percent of deaths were related to anesthetic overdoses, and another 42% of adverse effects were noted when anesthetics were being utilized in the therapeutic range. Men were twice as likely to die when compared to women, and this mortality rate increased substantially after age 65 (A845). Another study (A378) analyzed national estimates of anesthetic complications in 2005 by utilizing the Healthcare Cost and Utilization Project's (HCUP) Nationwide Inpatient Sample (NIS). A total of 39,506 hospitalizations had at least 1 anesthetic complication in 2005, resulting in an incidence of 1 case per 1000 admissions. Labor and delivery was associated with approximately half of all complications. Women and patients between 25-34 years of age were associated with a higher risk of anesthetic complications. Litz et al. (A428) from Dresden, Germany, reviewed a 10-year survey of 20,000 patients undergoing spinal anesthesia and discovered that 13 cardiac arrests occurred without warning signs in healthy patients undergoing elective surgery (incidence=0.6%). All patients underwent successful cardiopulmonary resuscitation and recovered without neurologic sequelae. Further analyses such as the ones above may allow for the creation of preventative measures to reduce morbidity and mortality rates.

One abstract reported predictors of impossible mask ventilation in a large patient sample size. Data from Kheterpal et al. (A1243) prospectively reported 70 cases of impossible mask ventilation (IMV) in a sample of approximately 47,000 over a 4-year period (incidence=0.15%). Independent risk factors for IMV included: male sex, history of sleep apnea, Mallampati III or IV, and a history of neck radiation. Twenty-six percent of these patients were difficult to intubate.

Abstract A803 retrospectively analyzed the American College of Surgeons National Surgical Quality Improvement Program (ACS NSQIP) database to generate a list of potential predictors of post-operative acute renal failure (ARF). Acute renal failure developed in 1% of the 69,000 patients evaluated. A logistic regression full model fit revealed the following predictors of ARF: age  $\geq 58$ , male sex, diabetes mellitus, congestive heart failure, myocardial infarction within the prior 6 months, ascites, hypertension, previous cardiac procedure, emergency surgery, preoperative renal insufficiency, and high-risk surgery. By revealing these predictors through large database analyses, risk reduction may be addressed.

Three other abstracts examined morbidity and mortality associated with the use of perioperative statins, beta blockers, and morphine patient controlled analgesia (PCA). Huffmyer et al. (A804) analyzed 2,657 patients undergoing CABG surgery from 1998-2007. Patients who received a preoperative statin had a reduction in perioperative mortality of 45%. In addition, preoperative statin use was associated with a reduction in the need for hemodialysis by 42%. Another study examined 5,000 patients undergoing non-cardiac surgery between 2004-2006 (A846). Multiple logistic regression revealed that both beta blockers and acute perioperative anemia were independent predictors for death and myocardial infarction (MI). For every 10% decrease in hemoglobin, the odds of death and MI were 1.33. The probability of mortality or MI was progressively more likely for patients who received beta blockers in the setting of a reduction of hemoglobin by <30%. In a large retrospective cohort (A31) of nearly 700,000 patients who received intravenous morphine PCA, 5.5% required naloxone for opioid overdose. Naloxone use was associated with an increased hospital length of stay, a higher rate of intensive care use, a higher total hospital cost, and a higher rate of in-hospital death. Further prospective data should address all of these associations.

## Medical Errors

Iatrogenic errors continue to be an important issue facing hospitals worldwide. Sandnes et al. (A770) from the University of Washington reviewed the ASA Closed Claims Project to assess liability associated with medication errors during anesthesia. Medication errors accounted for 3% of claims between 1990-2001. Incorrect dosing accounted for 44% of claims made, while 30% of claims involved substituting one drug for an intended drug. A higher proportion of pediatric medication errors existed. These claims were often found to be preventable and contributed to a higher proportion of permanent

brain damage when compared to other claims made. Another study (A765) from Fukuoka, Japan, retrospectively analyzed 64,285 in hospital anesthetics and discovered 50 cases associated with drug errors (incidence=0.078%). None of these led to serious sequelae. Giving the wrong medication and overdosing contributed to nearly 90% of all medication errors.

Several abstracts investigated tools to reduce medical errors. Wassef et al. (A758) observed practices of 18 anesthesiologists, nurses, and residents when drawing up and labeling medications at Penn State. The authors found that peel off labels were associated with fewer errors and improved time efficiency when compared to black and white labels. Levine et al. (A759) discussed their development of a new system that reliably reads vial barcodes and creates labels at the point of care. This system was developed to reduce drug errors and improve efficiency over time. Abstract (A767) discusses the development of a standard (IEC 62366) to assist manufacturers in improving the safety and usability of medical devices. This standard generates an engineering process for locating, assessing, and reducing risks. Further studies are required to validate the above technological processes to reduce medication errors.

## Perioperative Glucose Control

Perioperative glycemic control continues to be an area of active investigation. Abstract (A233) examined whether blood glucoses of  $\geq 140$  mg/dl alter expression of HLA-DR and the function of monocytes that are integral in fighting infection. Among 152 ASA III and IV patients studied, those patients with a glucose  $\geq 140$  mg/dl had a significantly higher infection rate (26.4% vs. 11.1%) than those with a glucose <140 mg/dl. No significant difference was found in relation to HLA-DR expression of monocytes or *ex vivo* secretion of TNF-alpha and IL-10 when comparing patients with glucoses  $\geq 140$  mg/dl versus patients with glucoses <140 mg/dl. Abdelmalak et al. (A234) examined the safety and feasibility of intensive insulin therapy (glucose goal=80-100mg/dl) versus conventional therapy (glucose goal=180-200 mg/dl) in major non-cardiac surgery. Among the 54 patients studied, no hypoglycemic episodes occurred in either group. However, the conventional group was associated with both higher glucoses and greater glucose variability. Data (A473) from the University of Virginia, retrospectively reviewed 1,359 patients admitted with subarachnoid hemorrhage and the effects of an intensive insulin treatment protocol on outcomes. Survivors had a statistically lower mean admission and mean average glucose when compared to non-survivors. However, implementation of the protocol had no effect on over-

See "Abstracts," Page 64

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# Abstracts Probe Deep Sedation & Deep Hypnotic Time

## “Abstracts,” From Page 61

all mortality. In fact, a subgroup of patients maintained between 120-180 mg/dl per protocol had a statistically significant increase in mortality from 19.4% to 27.6%. Further prospective studies will need to validate these results.

## Anesthetic Depth and Monitoring

The effect of the depth of anesthesia monitoring on outcomes remains controversial. Abstract A192 performed at Duke University enrolled 595 patients undergoing sedation primarily for colonoscopies monitored by bispectral analysis (BIS) outside the operating room. The average BIS value during the procedures was  $49 \pm 17$ . Seventy-eight percent of patients had a BIS  $< 60$  for greater than 5 minutes. Adverse events occurred in 6% of the patients and included: oxygen desaturation, pain, hypertension, hypotension, restlessness, difficulty in arousal, and tachycardia. Deep sedation correlating with BIS values associated with general anesthesia may lead to adverse events. Sieber et al. (A445) prospectively observed 40 patients undergoing procedures with spinal anesthesia and propofol sedation with BIS monitoring. Patients were divided into a standard care group (usual clinical routine) and a targeted sedation group (sedation was adjusted based on response to verbal questions). Average BIS levels and time spent at BIS levels consistent with general anesthesia were less in the titration group. A third abstract (A1) evaluated 1,941 patients undergoing major surgery for the possible association between deep hypnotic time (DHT) (or time a patient spends below a BIS  $< 45$ ) and mortality. Cardiac surgery patients who died within a year of surgery had a median 50.7 minute longer DHT ( $p = 0.004$ ), while non-cardiac surgery patients who died within a year of surgery had a median 5.7 minute longer DHT ( $p = 0.21$ ). Therefore, the authors demonstrated an association between DHT and mortality in the subset of cardiac surgical patients.

While deep sedation may correlate with an increase in adverse events, lighter levels of general anesthesia may result in awareness. Divan and Mathews (A985) performed a systematic review of 25 studies that adopted awareness risk reduction strategies and noted that risk reduction strategies were associated with a significant decrease in anesthesia awareness when compared to historical controls (high-risk patients: 0.16% vs. 0.96%). Another study (A1347) from Beijing, China, analyzed nearly 11,000 patients and discovered 45 cases of awareness (incidence=0.41%). Factors associated with awareness included female sex, increased ASA status, anesthesia history, anesthesia methods, and type of operations.

## Miscellaneous

An abstract (A30) from Dartmouth Medical Center, examined the institution of the Masimo Patient Safety Net system, which consists of a Radical 7 oximeter and radio transmitter per bed, a pager per nurse, and a central station for admission/discharge. This monitoring system was placed in a 36 bed surgical unit. At the end of 3 months, mortality and rescue activations were decreased when compared to the prior 11 months without this system. Another prospective observational study (A384) examined patients taking proton pump inhibitors (PPI) prior to surgery. Those on PPIs had increased levels of TNF-alpha perioperatively. In addition, patients who were taking PPIs had a higher rate of infection and a longer hospital length of stay. Further randomized studies need to validate these results.

Other abstracts investigated perioperative management techniques and associated adverse events. Abstract (A1589) reported a post-hoc analysis of data from the ECLIPSE trial comparing intravenous antihypertensives for cardiac surgical patients. The authors observed that increases in blood pressure

labiality were associated with increased rates of 30-day death, stroke, myocardial infarction, and renal dysfunction. Another study (A841) randomly assigned 49 patients with primary breast cancer to either propofol/paravertebral anesthesia or sevoflurane/opioid anesthesia. Propofol/paravertebral anesthesia was associated with a reduced level of IL-1B and IL-8 and an increase in IL-10 when compared to the sevoflurane/opioid group. The favorable response with propofol/paravertebral anesthesia may lead to resistance of tumor progression, metastasis, and recurrence. Larger studies need to investigate this further.

This brief review summarized only a small number of the important abstracts on patient safety presented at the 2008 annual meeting. To view other abstracts on patient safety, or to obtain further information on the abstracts discussed in this review, please visit the *Anesthesiology* website at [www.anesthesiology.org](http://www.anesthesiology.org).

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

## Steven B. Greenberg, MD, Appointed to Editorial Board



Steven Greenberg has been practicing anesthesiology and intensive care medicine at North Shore University HealthSystems in Evanston, IL, since 2006. He serves as assistant professor in the Department of Anesthesiology at Northwestern University Feinberg School of Medicine and associate director of Surgical Critical Care at North Shore University HealthSystems in Illinois. He graduated from the University of Wisconsin-Madison Medical School and continued his medical training at Northwestern University Feinberg School of Medicine in the field of anesthesiology. There, he served as chief resident of anesthesiology. After his residency, Dr. Greenberg completed his training at Massachusetts General Hospital in Boston, MA, as a critical care fellow. He is developing expertise in hemodynamic monitoring and goal directed therapy, and is presently participating in the revisions of the chapter *Monitoring the Anesthetized Patient*, in the upcoming 6th edition of the textbook *Clinical Anesthesia*. He is also lecturing both nationally and internationally on the topic of *Perioperative Goal-Directed Therapy*. The APSF is pleased to welcome Dr. Greenberg to the editorial board and appreciates his contributions.

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# ASA Meeting Exhibits Showcase Patient Safety Efforts

by John H. Eichhorn, MD

Both the Scientific and the Technical Exhibits at the ASA annual meeting in Orlando in October had significant patient safety elements that demonstrated ongoing and new patient safety concerns as well as safety improvement strategies.

In the Scientific Exhibits, airway concerns did not dominate as much as in recent years, but there were several relevant entries. A protocol developed at the University of Pennsylvania identifies and labels, both at the bedside and throughout all hospital care, patients with known difficulty airways (including historical details and tips about both prior unsuccessful and successful airway management techniques for that patient). Teaching laryngoscopy and intubation to students, particularly stressing non-OR settings, using video-assisted laryngoscopes of various brand and types was the topic of presentations from the Universities of Oregon and Nebraska. Predictably, both learning and performance were improved after video-assisted teaching. An exhibit from Belgium showed a new specially shaped inflatable pillow for optimizing patient position for airway management, catheter insertions, or even surgical procedures. Beneficial application in morbidly obese patients was stressed in the demonstration. An exhibit from a Chicago group outlined complex multidisciplinary management of obstructive sleep apnea patients, especially for corrective airway surgery.

Again this year several exhibits involved the safety of regional anesthesia and nerve blocks with particular emphasis on ultrasound needle guidance as a way to avoid complications and untoward outcomes.

## Exhibits Stress Education

A series of exhibits from various sources focused on educational issues, always with the implication that better educated practitioners are safer practitioners. Following up on the APSF "technology training initiative," an exhibit from Milwaukee outlined a program for a computerized anesthesia machine training protocol while the well-known team from the University of Florida introduced a new technical approach called "mixed reality," in which computerized virtual anesthesia machines are shown side-by-side with real machines that students can (and do) manipulate to learn practical concrete skills. On a more comprehensive level, a combined team from Ohio and Texas demonstrated a "core" anesthesia patient safety curriculum for new anesthesia trainees, with special emphasis on critical incidents and crisis management. Also, a program from Harvard based on a 2006 ASA Panel Discussion focused on ensuring maximum safety of office-based anesthetics was exhibited and featured many ASA publications, including the key 2008 update on a "safe office anesthesia environment." Further, a multimodal training protocol to enhance compliance by anesthesia personnel with infection-control measures was exhibited by a team from Milwaukee.

From a large New Jersey group, an updated and more elaborate version of a "technically simple and effective" face tent fashioned essentially from a plastic bag was presented demonstrating the transformation of basic nasal cannula administration of oxygen into a much higher concentration (40-60%) delivery device. This also facilitates CO<sub>2</sub> sampling for ventilation monitoring and is intended for use during MAC or TIVA cases in virtually any patient position.

The Mass General in Boston provided 2 comparatively elaborate exhibits. In keeping with the APSF 2008 theme stressing the prevention of OR medication errors and their potentially lethal consequences, there was an impressive exhibit of their proprietary "smart label" system for syringes of medications drawn up by anesthesia personnel into syringes marked with a specific unique patient label printed right on the anesthesia machine. Finally, the importance of medical device free interoperability that facilitates the assemblage and coordinated function—essentially "plug and play"—of equipment in the OR (e.g., the ability to take an OR table x-ray without turning off the ventilator because the anesthesia machine and the x-ray tube are compatible and can "talk to each other") provoked an exhibit featuring ideas that promote this "Integrated Clinical Environment."

## Airway Management

Airway management issues remained prominent. As often stated in this report, the induction of deep unconsciousness and muscle relaxation before genuine confirmation that a patient's airway can be comfortably managed and accessed is still one of the least improved and most dangerous things anesthesia professionals do. Accordingly, new variants of "laryngeal mask" devices were exhibited, some of which are intended specifically to help facilitate placement of an oral endotracheal tube into the larynx, including with special extra channels and novel shapes all to help direct blind passage of a tube. Other new laryngeal devices were without an inflatable cuff or with a built-in insertion handle. An "intra-oral mask" with an attached oropharyngeal airway was advertised as a "solution for ventilatory emergencies." Many versions of optical and video laryngoscopes were displayed, one in particular with an internal fiberoptic system for illumination and viewing the larynx on a 1-inch screen (that will also accept a video camera to project the image) in a basic handle onto which can be affixed 1 of 7 different disposable plastic blades for different sizes and purposes. Again featured this year was the video teaching system consisting of a camera on a head band worn by a resident attempting airway manipulation and aimed so that others, particularly the supervising faculty, see on the monitor exactly what the resident is seeing down the airway.

Other airway-related devices featured in exhibits included an intubating stylet to facilitate passage of a regular endotracheal tube that, on the stylet itself, has

a soft inflatable dilating balloon and a flexible tapered tip, all intended to guide an endotracheal tube smoothly into a larynx "when anatomical challenges are encountered." To help prepare for an awake fiberoptic approach to the larynx, another device was displayed that sprays atomized local anesthetic into the airway. It consists of a curved rigid blade that at the proximal handle end holds a syringe of local that connects via internal tubing to an atomizer at the distal end, which is started over the tongue and slowly advanced down to the vallecula, spraying local all the way.

Another type of airway-related device that seemed to attract significant attention on the exhibit floor was a plastic head-rest device that administers and holds a "jaw-thrust" maneuver for the practitioner. Intended for patients breathing spontaneously under sedation or general anesthesia, getting positive pressure mask ventilation, fiber optic intubation, or even during post-op transport, the "jaw elevation device" has a plastic support pillow that creates the "sniffing position" and a plastic cradle-like support on either side that is adjustable. These supports are positioned to hold and elevate the angles of the patient's jaw and then are locked in place, maintaining that "jaw-thrust" position hands-free. It is advertised to be applicable in any circumstance where a jaw thrust is beneficial.

One other positioning issue addressed in various similar ways by different manufacturers involved pillow systems, foam or inflatable, of varying shapes and sizes all intended to optimize patient upper body and head position for direct airway access, particularly in morbidly obese patients. Somewhat related were the several various systems and services prominently displayed and touted that are intended to screen outpatients preoperatively at home for obstructive sleep apnea in a manner that will prospectively alert the involved anesthesia (and surgery) professionals to be prepared to deal with a patient's airway obstruction at the time of surgery and after.

A device potentially useful for an emerging or sedated patient at risk for airway obstruction is a small non-rebreathing bag with tubing for connection to an oxygen flowmeter (and also with a side port for connection of capnograph tubing if desired) that is part of a plastic mask-shaped device that can either be connected directly to an LMA or unfolded to make a small face mask with an elastic head strap. The visible excursion of the small non-rebreathing bag with each breath is intended to function as a surrogate ventilation monitor for the observant anesthesia professional presiding over the sedation, emergence, or transport. Another "sedation mask" intended for monitored anesthesia care appeared to be a fairly standard plastic anesthesia mask with an inflatable cuff and a rubber head strap and connected to an anesthesia machine breathing circuit, but also with a new

See "Exhibits," Next Page

# Ultrasound and Normothermia Are Subjects of Exhibits

## “Exhibits,” From Preceding Page

“CO<sub>2</sub> monitoring port” in the mask to sample gas directly from the patient’s mouth/nose area.

## Vascular Access

Ultrasound guidance devices, both for vascular access and placement of nerve blocks, were again very prominently displayed and heavily advertised in the exhibit hall. One quite different approach to situations of difficult intravascular access at the time of an acute need for fluid and/or medication infusion was the device that very quickly and easily establishes interosseous access via a surprisingly simple insertion of a cannula into the tibia or proximal humerus that is then connected to IV tubing and a bag of fluid. Often now used on ambulances or in emergency departments, the device, according to the manufacturer, facilitates administration of medication and fluid (even large volumes) essentially as fast as an IV. Until now it has not been widely used in ORs, and it is being offered as an alternative to establish necessary primary or supplemental “vascular access” when IV puncture (peripheral or central) would be time-consuming, difficult, or even impossible.

Continuous cardiac output measurements were advanced as enhanced patient safety features in unstable patients. One manufacturer offers a device for continuous output measurements determined from only a “standard central venous catheter” that is advertised as “less invasive” than a pulmonary artery catheter. Another device billed as “non-inva-

sive” is a continuous cardiac output device incorporated into an endotracheal tube that would be used in a standard manner for general anesthesia. It measures changes in electrical impedance resulting from pulsatile blood flow in the aorta.

## Normothermia Remains Hot Topic

Patient warming in the OR received renewed attention due to the federal performance measure involving a requirement for normothermia at the end of extensive colorectal surgery. The usual array of devices had this new specific purpose added to their advertising. One new device was a “forced air warming gown” intended for the patient to wear preoperatively in order to enter the OR with a maximal reservoir of body heat. Application of this heat preoperatively was shown in an abstract from Northwestern to be more effective in achieving normothermia at PACU admission than without, and this pre-op warmed group had fewer infections and a shorter average hospital stay. Possibly more to the direct point was a new device for “intravascular temperature management.” A variety of central venous catheters have been crafted incorporating small bore tubing carrying circulating saline, creating functionally an internal heat exchanger when connected to the external pump on which the temperature of the circulating fluid can be varied to add or remove patient heat “from the inside out.” The device is advocated for active warming of surgical patients to

treat or prevent hypothermia or active cooling of surgical or ICU patients for any appropriate indication.

Last but not far from least was a new device intended to address the issue of bacterial contamination of the anesthesia work space and the specific risk of spread of infection by anesthesia personnel through manipulation of IV lines, injection ports, and stopcocks during administration of anesthesia. The “personal sanitizer dispenser” delivers metered doses of alcohol-based hand antiseptic with a gentle squeeze, fits in the palm of the hand, and is intended to be clipped to the scrub suit (usually at the beltline on the side of the dominant hand) of an anesthesia professional in the OR. A study at Dartmouth documented a 27-fold increase in hand decontamination events and a more than 80% reduction in bacteria cultured from IV tubing in the cases where the device was used correctly. Further study to correlate with postoperative nosocomial infections was intended.

Overall, patient safety persisted as a focus among both types of exhibits at the ASA annual meeting. This emphasizes 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 editor until 2002. He remains on the Editorial Board and serves as a senior consultant to the APSF Executive Committee.*

## “Color Coding,” From Page 60

Between 5-8% of the general male population is color blind.<sup>5,6</sup> Even those not affected will acquire functional color blindness when wearing some kinds of laser-protective goggles.<sup>7</sup> Little study has been done on color blindness in anesthesiology,<sup>8</sup> especially recently since the introduction of monitoring screens with variable colors for the different parameters displayed. One colleague who has color blindness reports that he cannot differentiate blue and purple; he therefore relies on not only the label to choose between isoflurane and desflurane, but also the shape of the vaporizer and the range of percentages on the dial.

How is vaporizer recognition taught in residency programs? Are residents instructed to cross-check colors with labels? Or are only the colors emphasized? It is paradoxical that we are concerned with the potential for dangerous medication errors from relying mainly on color or shape with drug vials but seemingly much more casual about reading vaporizer labels. One explanation may be that there is relatively little risk when isoflurane is adminis-

tered instead of sevoflurane, compared to mistaking epinephrine for ephedrine, or substituting an epinephrine ampule for one of oxytocin when caring for a parturient.

## Conclusion

In conclusion, we reiterate the importance of reading labels in addition to also crosschecking using other identifying features such as color and placement. Labels on syringes and vaporizers do little good if they are not read. We observed that for many anesthesia professionals, color may be the more habitual method of vaporizer identification, rather than labeling. It is interesting to consider if distinctive agent-specific changes in vaporizer shape would be of benefit to incorporate in future vaporizer designs, in addition to color-coding and proper labeling.

*The coauthors are affiliated with the Department of Anesthesiology at the University of Kentucky in Lexington. Dr. Rose is an Assistant Professor, Dr. Eichhorn a Professor, and Ms. DiLorenzo an Education Specialist.*

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**Editor's Note:** The following article is a response to the APSF's request for manufacturer's feedback on technology training initiatives (See Fall 2006 and Winter 2007-2008 issues of this Newsletter for background information.

## Covidien Provides Feedback on Technology Training Initiative

Covidien's patient monitoring business recognizes that effective product training promotes staff efficiency and ultimately affects patient care. Covidien field representatives responsible for training their accounts on Nellcor™ pulse oximetry systems institute a number of strategies to promote a successful transfer of knowledge and skills to those people who will be using the products daily.

Gaining commitment and participation in training sessions was recognized as a key challenge by APSF. After a new product installation, scheduling the inservice training sessions is the first step. To bolster attendance, it is important to offer training that covers a variety of shifts. Ideally sessions are scheduled for day shift, evening shift, and even weekends in order to reach as many staff members as possible. Scheduling training around staff meetings and other structured events helps encourage attendance, as clinicians are already in a specific gathering place and away from their daily duties. In addition, participating in a Skills Day or other special training event sponsored by the hospital is a great way to take advantage of a "captive" audience.

Once the training is scheduled, making clinicians aware of the sessions is crucial. The hospital plays an integral role in advertising the training, and it may employ different media such as posters, email, and announcements at staff meetings to get the word out.

Erich, a Covidien field representative, said, "When the customer does a good job of marketing our availability, that's when I see my greatest success."

From the manufacturer's side, a lack of time to adequately cover content can be addressed by paying attention to logistics. The trainer should allow ample time for the training session itself, and block off time before and after the actual session to catch stragglers and be able to answer individual questions. During the training session, it helps to have a sign-in sheet, which lets the staff know they are expected to attend.

To address the issue of increasing complexity of medical technology, Covidien believes strongly in follow-up training. The basic functionality of the Nellcor™ patient monitor can be covered in the initial inservice session. Then, in follow-up training—typically conducted a week to a few weeks later—the trainer provides more in-depth instruction on new or advanced features of the product.

For more complex technology, training is covered in multiple phases. It's important to not overwhelm the staff with more information than they can remember in a single session. "They need to feel successful with it right away," said Michelle, a Covidien field representative, "or they won't want to use the product or continue with training."

Another successful training strategy is to conduct an individual train-the-trainer session with a "super user." This key user can help collect questions from other staff members for follow-up training and also serve as an internal resource to help others understand the Nellcor™ equipment better. Equipping these key users with company-produced materials such as training videos, competency checklists, and quick guides helps them provide guidance to their colleagues that is consistent with the company's training.

Even when training is not formally evaluated, the representatives delivering it have their own ways to measure its effectiveness. During follow-up training, they get a good sense of how successful the first training was, based on their interactions with the clinicians and the types of questions they ask. Good trainers know that if they inservice right the first time, they have a lot fewer headaches down the road. As Carrie, another Covidien field representative put it, "Success is measured by how few phone calls I get afterward!"



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## Dear SIRS

# Isoflurane Damages Apollo Water Trap

## 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.

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### Dear SIRS:

Anesthesia personnel have come to rely heavily upon end-tidal carbon dioxide concentration to confirm correct endotracheal tube placement and adequate ventilation. We report a case of sudden loss of end-tidal carbon dioxide during a prone-positioned case due to a substantial leak in the breathing circuit caused by failure of the sidestream capnography measurement system. This failure was a result of a crack in the water trap for the gas analyzer on a Dräger Apollo anesthesia machine that occurred from accidental spillage of isoflurane.

A healthy, 75-year-old woman for a left L5-S1 minimally invasive discectomy was induced with propofol, intubated, and maintained using a mixture of oxygen, nitrous oxide, isoflurane, and remifentanyl. The patient was positioned onto an Andrew's frame and equal breath sounds confirmed. Approximately 1 hour after the start of the procedure, the isoflurane fill level on the viewing glass was noted to be nearing empty, and the vaporizer was refilled. Due to difficulty with the key-fill block mechanism on the Dräger Vapor 2000 vaporizer (Telford, PA, USA), some anesthetic agent inadvertently leaked out of the canister during the refilling process. Less than a minute later, a sudden loss of end-tidal carbon dioxide was noted. The patient was switched from a volume-control mode to manual ventilation as troubleshooting began, including examining the patient's endotracheal tube and breathing circuit and listening for breath sounds to evaluate for tube dislodgement.



Figure 1: Close-up of cracked water trap.

The nitrous oxide was discontinued, and oxygen flow was turned to 10 L/min. A substantial leak was apparent on manual ventilation, and the capnogram tracing was absent, despite connection of the sampling tubing. The patient was switched from the anesthesia circuit to a self-inflating bag valve system. Despite apparent loss of end-tidal carbon dioxide, blood pressure and heart rate remained stable, and the pulse oximeter read 100% with a nominal plethysmogram. Anesthesia was maintained by increasing the remifentanyl drip and intermittent boluses of propofol. Although no evidence of a change in the endotracheal tube was apparent clinically, a stretcher was brought in the room and the surgery team was made aware of the possible need to turn the patient to the supine position for repeat laryngoscopy to confirm tube placement. We attempted to change out the sample line of the capnograph and were in search of an auxiliary capnograph when we discovered a large crack on the posterior side of the Apollo capnography water trap (Figure 1). We switched the patient back to a volume-controlled mode of ventilation with high flows to overcome the substantial leak until a new water trap could be found, and the case proceeded uneventfully. The patient emerged from anesthesia with no apparent ill effects. We considered this incident to be a unique and chance occurrence until a similar experience happened to another anesthesia provider. The journal *Anesthesiology* declined publication of this report but subsequently published another report of this same problem.<sup>1</sup>

### Discussion

We are concerned about the placement of the water trap beneath the anesthetic vaporizers (see Figure 2.) Avidan et al.<sup>2</sup> demonstrated the deleterious effects of spillage of enflurane and isoflurane on polycarbonates present in the venous outlet of membrane oxygenators from cardiopulmonary bypass machines. In their laboratory tests, a few drops of enflurane and isoflurane that trickled onto the base of the venous reservoirs led to cracks within seconds of contact. Our case, and now others, clearly demonstrates that spillage can irreparably damage the water trap and aspiration capnography system on the Dräger Apollo machine with potentially dangerous consequences. Personal correspondence with a Dräger representative indicates that the water trap is made of polymethyl methacrylate, also known as Plexiglas. We are unaware of any literature describing the specific effects of etheric volatile anesthetics on polymethyl methacrylate, but we suspect that volatile agents may

See "Dear SIRS," Next Page

# Manufacturer Solves Problem With New System

## “Dear SIRS,” From Preceding Page

lead to cracking of many different thermoplastics. The cracks in the water trap may not be readily visible, and the substantial leak in the breathing circuit could inhibit positive-pressure ventilation and delivery of anesthetic vapors and oxygen while awaiting a new trap. We further wonder whether or not the water trap plastic might gradually decay with routine exposure to sampling volatile anesthetics. We believe that anesthesia personnel should become more aware of the potential interaction between volatile anesthetic agents and thermoplastics associated with the anesthetic machine and ask Dear SIRS to assist in dialog with the manufacturer, requesting a response. Pursuant to the *Winter 2007/2008 APSF Newsletter* Dear SIRS recommendations for reporting such incidents, we have submitted this report to ECRI. Perhaps the following should be considered

- A label cautioning users about the effects of accidental spillage
- A modification in the machine component arrangements to prevent future occurrences. For example, at our institution, the position of the isoflurane and desflurane vaporizers has been switched
- An upgrade to the DrägerFill® (Dräger Medical, Inc., Telford, PA.) plunger-type system with O-ring, that is seemingly less likely to spill
- Extra water traps readily accessible in the storage drawer of the anesthetic machine.

Finally, we appreciate the response and cooperation of the manufacturer in reducing the likelihood of this problem affecting the safety of any other patients.

*Sincerely,*

*Ashley M. Tonidandel, MD, MS*

*Scott A. Miller, MD*

*Winston-Salem, North Carolina*

## In Response:

Dräger welcomes the opportunity to respond to this letter. Dräger became aware of this potential failure mode after the release of the Apollo anesthesia machine in 2006. This failure mode requires that liquid anesthetic agent fall onto the water trap, and is not considered normal operation of the machine or vaporizer. In order to minimize the risk of this reoccurring, internal documentation was developed and released to the sales and clinical applications teams for installation training to advise the customers not to place the isoflurane vaporizer above the water trap.

The author reports a substantial leak as a result of the water trap cracking. Dräger has not been able to



Figure 2: The original position of the isoflurane vaporizer was directly above the water trap. The desflurane and isoflurane vaporizer positions were subsequently interchanged. Note the problematic key-filling system prior to the DrägerFill, plunger-type upgrade.

reproduce this finding, and suspects that this may not have been related to the cracking of the water trap. The water trap is connected to the breathing system by the sample line. A standard sample line has an internal diameter of 1-2 mm, and a length of 4-6 feet. The maximum flow of gas at normal ventilation pressures is no more than 200-300 mL/min.

In addition to the revised training documentation, Draeger has subsequently replaced the key filling system on the vaporizers, with the new DrägerFill system which has significantly reduced the risk of spillage of anesthetic agent during the filling process. For customers that are concerned about the potential for leakage of liquid isoflurane during vaporizer filling, Dräger has developed a field upgrade kit for existing Vapor 2000 vaporizers to the new DrägerFill design. Please contact your Dräger representative for more details.

The vaporizers at Wake Forest University School of Medicine have been upgraded to the new DrägerFill design.

*Robert Clark*  
*Director, Perioperative Care*  
*Dräger Medical, Inc.*  
*Telford, PA*

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**Anesthesia Patient Safety Foundation (APSF)**

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Letter to the Editor:

# Reader is Poised to Rethink Ischemic Optic Neuropathy in Light of "POISE" Study

**To the Editor:**

Several authors presented significant pertinent information in the Spring 2008 *APSF Newsletter*, which deserve consideration together as very significant interrelated themes regarding patient safety. Dr. Lehner described the impact and course of his personal battle with posterior ischemic optic neuropathy (PION).<sup>1</sup> Dr. Lee summarized contemporary recommendations for management in avoiding PION, while pointing to the only 2 identified associated factors: long and sanguine surgery.<sup>2</sup> I was particularly surprised that Dr. Lee failed to reference or discuss her recently published findings from May 2008, incriminating hypovolemic deliberate hypotension using beta blockade (labetalol) and anemia as specific liabilities to optic nerve metabolism in a porcine model.<sup>3</sup> While deliberate hypotension and hemodilution are anesthetic procedures per se, they are typically also performed at surgical request/direction and thus may be more rationally events requiring surgical rather than anesthetic consent. The recently published PeriOperative Ischemic Evaluation (POISE) study results deserve mention here and did clearly confirm the cardioprotective effects of perioperative beta blockade (PBB)—a message not to be ignored. However, the cost was that of increased morbidity and mortality from stroke in the metoprolol treated group. Clearly, the doses of metoprolol used in POISE were fixed and quite aggressive (100 mg oral bid or 15 mg q 6 hr iv), with metoprolol held only when systolic blood pressures or heart rate remained <100 mmHg or 50 bpm, respectively.<sup>4</sup> An atherosclerotic patient presenting preoperatively with untreated hypertension of 170/95 (mean of 120 mmHg), heart rate of 95 bpm, and a known LV ejection fraction of 30% might well be expected to have an adverse outcome, when allowed to remain at 100/35 (mean 56 mmHg) at 45 bpm, and with a, now, unknown acute drug-induced depression of ejection fraction. Under this prescribed significant dosing regimen, it may be surprising that POISE could be completed, and the increased morbidity documented may well be that of drug overdose. Thus, Drs. Kleinman and Corey's observations regarding perioperative hemodynamics, goals, and consequence of drug administration are especially pertinent and timely, raising the serious question of just what goals we should accept in light of these very recent studies.<sup>5,6</sup> While contemporary patients have become increasingly polymorbid, and while the anesthetic ability to manipulate hemodynamic parameters has been increasing to extreme degrees, the continued use of "historic hemodynamic guidelines" (when patients were healthier and surgeries shorter) may be a significant liability. The custom of accepting mean pressures of 60 (or worse 50) mmHg under modern anesthesia appears questionable for short periods in the polymorbid, and apparently can become disas-

trous even in "otherwise typically normal" individuals. With normally 120/80 and mean pressures of 90-100 mmHg, the historic acceptance of 60 mmHg mean values under anesthesia (derived from healthy animal studies demonstrating autoregulation and minimal urine production) also becomes suspect, especially in the comorbid and geriatric patient.<sup>7</sup> A 20% deviation from the "usual or normal" baseline (i.e., to a mean of 70-80 mmHg?) may prove a much more rational, safe, and physiologic intraoperative goal. Introducing acute beta blockade will reduce cardiac output as well as blood pressure, while modern PBB recommendations promote judicious introduction over weeks to adequately monitor for side effects and facilitate remodeling of the cardiovascular system. In spite of the availability of multiple modern methods to quantify cardiac output, they are typically not utilized in spine surgery, with this important parameter remaining "unknown." Support of blood pressure with alpha agonists is also commonplace to prevent tachycardia and may further compromise overall substrate delivery to important, marginal tissues, by increasing systemic vascular resistance or reducing systemic venous capacitance/compliance at any measured CVP.<sup>8</sup> Should striving for "normal" intraoperative hemodynamics perhaps receive renewed interest as a factor to eliminate PION? Anesthetists must now decide if participation in induced hypotension or anemia, and to what degree, is really in the patient's best interests.

Imperative questions arise:

- 1) Who has the obligation for discussions regarding perioperative visual loss?
- 2) Is the planned use of hypotension or hemodilution desirable, and to what degree? Does this also require specific informed consent?
- 3) Can the use of CVP vs. pulmonary catheter monitoring to avoid hypovolemia become an effective standard measure to prevent hypovolemia and blindness, particularly given perturbations in intrathoracic pressures? How does morbid obesity or beta blockade affect these variables?
- 4) Will vasopressor support, the choice of vasopressor, and the target blood pressure be protective or merely shift morbidity to other organ systems?
- 5) How does liability relate to the allowed degree of anemia and what is the minimal sampling interval to determine intraoperative hematocrit?
- 6) Just how long should a prone procedure be allowed to persist and will "staging" of surgical procedures only increase cost, infection, morbidity, and mortality by methods of repeated insult?
- 7) Have hypotension and clinical anemia remained unidentified as important factors because of a

widespread acceptance of marginally low values as a false definition?

- 8) Given the frequent discordance of oscillometric vs. transduced arterial blood pressures in many patients, does the arterial trace represent a consistently reliable measure or must interval correlation to non-invasive blood pressure (NIBP) measured values become an important standard to accurately assess blood pressure over prolonged periods?

Modern banked blood and conservation/cell salvage techniques are quite safe and effective. Perhaps it is time to define and stress "normal" or "optimal" over "acceptable" and "desired" induced hemodynamic parameters intraoperatively. Are the surgical requests to suppress patient hemodynamic parameters to extreme margins, creating significant stresses with only questionable benefit in reducing blood loss, really acceptable? Does this approach only serve to promote the prolonged, more extensive, and sanguine surgical trespass, in which PION is promoted? Should such prolonged/extensive surgeries be reserved for senior and efficient surgeons, rather than relegated to trainees under limited supervision? While hemodilution can be safely maintained when adequate filling pressures are insured, hypovolemia is often the nature of such surgical bleeding and can compromise systemic oxygen delivery. Perhaps the historical optimum hemoglobin level of 10 gm may be more appropriate in sanguine situations with sudden, episodic loss.

- 9) Would maintenance of (more) normal hemodynamic parameters eliminate PION? We as professionals stress a preoperative evaluation to insure patients are optimized for surgery, recognizing the cardiovascular depressant effects of anesthetic agents. Should we then actively strive for marginal hemodynamic states intraoperatively, and if so, why, to what degree, and with what goals? Are iatrogenic blindness and stroke acceptable alternatives to transfusion risks and myocardial infarction, respectively? Are we asking the right questions? Should patients be asking more? Research may not readily yield an answer on PION, with the rarity of occurrence.

Paul M Kempen, MD, PhD  
Wexford, PA

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## In Reply:

Dr. Kempen provides some very thoughtful and astute comments regarding perioperative management of complex surgical spine procedures. He asks the numerous salient questions in the minds of most anesthesiologists and anesthesiologists who care for these patients with respect to ischemic optic neuropathy (ION). Numerous specialized anesthetic management techniques such as deliberate hypotension, hemodilution, and fluid restriction with resultant hypovolemia have converged in spine surgery. As spine operations have become much longer in duration and with larger blood loss, anesthesiologists must be clinically astute to assess whether or not their patient is an appropriate candidate for any of these techniques. Combinations of these techniques, or use of a single technique for a prolonged duration in the prone position may exhaust compensatory mechanisms designed to maintain adequate perfusion to end organs.

However, the lack of any randomized controlled trial or other clinical study demonstrating an association between hypotension, anemia, and perioperative ION limits the ability of any guideline or advisory-setting group to rationally devise any evidence-based parameters for hemodynamic management and transfusion threshold. Seventeen percent of patients with ION in the ASA POVL Registry had their nadir hematocrit  $\geq 30\%$ .<sup>1</sup> Choosing a transfusion threshold  $> 30\%$  would require speculation with significant potential for increased risk and without any guarantee of benefit. Using non-primate animal studies as the sole supporting evidence when differences in vascular anatomy exist is less than ideal. The effects of anemia and hypotension on porcine optic nerve oxygen delivery may only apply to a small subset of patients with similar blood supply to their optic nerve, and perhaps only under these very severe physiologic stresses.<sup>2</sup> Though the benefit of using deliberate hypotension is dubious, and is not a technique that this author advocates, condemnation of the practice in association with perioperative ION is also not supported by the literature.<sup>3</sup> There are many anesthesiologists and anesthesiologists who have utilized deliberate hypotension in prone spine surgery for decades, reportedly without significant complications—albeit without adequate power to detect an influence on ischemic optic neuropathy. Making changes in clinical care without evidence-based medicine can cause harm in 2 ways. First, harm can occur because of the intervention itself—e.g., maintaining a higher mean arterial pressure with phenylephrine could mask hypovolemia and result in other end organ ischemia to the kidneys or heart as Dr. Kempen notes in his letter. The immunosuppressive and infectious risks of blood transfusion are well known. Second, it may divert attention away from the actual cause of the problem. Recall that most anesthesia professionals,

surgeons, and ophthalmologists were undeniably certain that pressure on the globe was responsible for all POVL after spine surgery without cortical strokes. It was perfectly logical—made perfect sense. However, it took a very long time to collect enough data to refute this misperception, and then continue the search for the actual cause of ischemic optic neuropathy (ION). In the meantime, many anesthesia professionals were wrongly accused of being negligent in protecting the eyes in the prone position.

Dr. Kempen is correct that randomized clinical trials for perioperative ION are unlikely to be accomplished soon, because they would require an enrollment of an extremely large number of subjects for sufficient power. The ongoing multicenter case control study matching cases from the ASA POVL Registry to controls who underwent similar procedures, but did not develop ION, may identify specific risk factors. One hopes that results from this study will be able to determine whether maintenance of a specific blood pressure or hematocrit decreases the risk of developing ischemic optic neuropathy. Dr. Kempen and many other anesthesia professionals may well be proven correct.

Lorri A. Lee, MD  
Seattle, WA

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## Letter to the Editor:

# Look-alike Drugs Cause Near Miss

## To the Editor:

I would like to report two look-alike medications and make other anesthesia professionals aware of them. The medications are dexamethasone and glycopyrrolate (see figure).

Last month I worked at a surgicenter and administered anesthesia to a 4-year-old, 15-kg girl. The procedure was tonsillectomy and adenoidectomy. Because of the size of the tonsils and adenoids, the surgeon requested 20 mg of dexamethasone IV. However, glycopyrrolate was also in the same drug tray and placed in close proximity to the dexamethasone vial. I was to give

5 vials of dexamethasone (4 mg/vial), and luckily I checked the label. Otherwise, if I had given 5 vials of glycopyrrolate (0.4 mg/vial), I would have administered a total of 2 mg of glycopyrrolate, which would have been at least 10 times more than the maximal allowable dose of glycopyrrolate for the patient!

I think this "look-alike" is something important and that every anesthesiologist and anesthesiologist should be aware of this similarity.

Ge Li, MD, PhD  
Elgin, IL



Photo showing similarity between dexamethasone and glycopyrrolate.

# Anesthesia Patient Safety Foundation (APSF) 2010 GRANT PROGRAM

## Guidelines for Grant Applications to Be Selected in October 2009, and Scheduled for Funding Starting January 1, 2010

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

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

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

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

### NAMED AWARDS IN 2009

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

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

APSF/Anesthesia Healthcare Partners (AHP) Research Award (\$150,000)

APSF/Cardinal Health Foundation Research Award (\$150,000)

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

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

### PRIORITIES

The APSF accepts applications in one of two categories of identified need: **CLINICAL RESEARCH** and **EDUCATION AND TRAINING**. Each year, at least one grant in each of the two categories will be funded. 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.

### AREAS OF RESEARCH

Areas of research interest include, but are not limited to

- New clinical methods for prevention and/or early diagnosis of mishaps.
- Evaluation of new and/or re-evaluation of old technologies for prevention and diagnosis of mishaps.

- Identification of predictors of negative patient outcomes and/or anesthesiologist/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.
- Development, implementation, and validation of educational content or methods of relevance to patient safety; and
- Development of innovative methods for prevention of medication errors.

### 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 healthcare adoption.
- Clinical significance of the area of research and likelihood of the studies to produce quantifiable improvements in patient outcome such as increased life-span, physical functionality, or ability to function independently, potential for reductions in procedural risks such as mortality or morbidity, or significant improvements in recovery time.
- Ability of research proposals to maximize benefits while minimizing risks to individual human research participants. Each proposal should prospectively enunciate the criteria for instituting rescue therapy whenever there is the remotest possibility of an untoward adverse event to a human research volunteer. In some instances, the rescue therapy may be triggered by more than one variable (e.g., duration of apnea [in seconds], oxygen saturation <90%, etc.). Additionally, the protocol should specify the nature of the rescue procedure(s), including the rescue therapy and dosages, and the

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# Grant Application Submission Date—June 1, 2009

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personnel responsible for oversight. If other departments are involved in the rescue process, the application should specify if such departments are to be informed when a new volunteer is participating in the trial.

- 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 or 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.

## EDUCATIONAL and TECHNOLOGY PROJECTS

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

## BUDGET

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

## ELIGIBILITY

Awards are made to a sponsoring institution, not to individuals or to departments. Any qualified member of a sponsoring institution (hospital, university, clinic, etc.) in the United States or Canada may apply. Only one person may be listed as the principal investigator. All co-investigators, collaborators, and consultants must be listed. Applications will not be accepted from a principal investigator currently funded by the APSF. Re-applications from investigators who were funded by the APSF in pre-

vious years, however, will be accepted without prejudice.

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

**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 all applicants within 8 weeks after grant selection.**

## AWARDS

**Awards for projects to begin January 1, 2010, will be announced at the annual meeting of the APSF Board of Directors (2-3:30 PM) on Saturday, October 17, 2009 (New Orleans, LA).**

**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, 2009.**

## PAPERLESS APPLICATIONS

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

- Application
- Budget justification
- Applicant's curriculum vitae
- Departmental chair's letter of support
- Applicant's "Acceptance of Grant Conditions" form; and
- Institutional Review Board approval or copy of submission letter.

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

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

Please name the IRB Approval Letter file as Lastname.Firstname-IRB-2009 (example: Smith.John-IRB-2009).

The complete Application Packet (application, applicant's CV, Acceptance of Grant Conditions Form, chair's letter of support, budget justification, and IRB approval or submission letter) **must be uploaded to the APSF website:** (<http://www.apsf.org/grants/application/applicant/login.aspx>).

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

## APPLICATION PACKET

### A. APPLICATION

#### I. Cover Page

- Title of research project
- Designation of proposal as "Clinical Research" or "Education and Training"
- Name of applicant with academic degrees, office address, phone number, fax number, and e-mail address
- Names and affiliations of all investigators and consultants
- Name, office address, and phone number of departmental chairperson
- Sponsoring institution and name, office address, phone number, and e-mail address of the responsible institutional financial officer
- Amount of funding requested
- Start and end dates of proposed project
- Number all pages (bottom right corner) sequentially, starting with the cover page.

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

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

#### a. Introduction

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

ii. 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.

iii. 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?

iv. Significance and applicability: briefly describe the historical prevalence and severity of the morbidity and mortality of the studied anesthesia mishaps.

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# Grant Application Due June 1, 2009

## “Grant Guidelines,” From Preceding Page

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.

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

### b. Methods to be employed

- i. Describe data collection procedure, specific techniques, and number of observations, subjects or experiments. For educational projects, describe how the effects of the intervention program will be assessed. Qualitative methodologies are acceptable. Provide a justification for sample size (power analysis).
- ii. Describe types of data to be obtained and their treatment, including statistical and power analyses, if indicated.
- iii. Point out and discuss potential problems and limitations of project.
- iv. 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. Discussion**—Format: maximum of 2 double-spaced pages; 1- inch margins; Times New Roman font; font size 12.

- a. Describe the impact of the proposed study on patient safety and the applicability of the expected results to clinical care or education in patient safety.

**B. BUDGET JUSTIFICATION**— include all proposed expenditures. Indicate under each category the amount requested or provided from other sources.

- I. Personnel (limit salaries of individuals to NIH Guidelines)
- II. Consultant costs
- III. Equipment costs
- IV. Supplies
- V. Patient costs
- VI. Other costs
- VII. Total funds requested
- VIII. 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.

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

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

**C. ABBREVIATED CV** (maximum of 4 pages) of the principal investigator and any co-investigators.

**D. LETTER OF SUPPORT** from the departmental chairperson indicating:

I. 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.

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

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

**E. SIGN AND DATE THE ACCEPTANCE OF GRANT CONDITIONS** form and upload this form to the website as part of the complete Application Packet (see above).

**F. APPROVAL LETTER** from the Investigational Review Board (IRB) or Animal Care and Use Committee (ACUC) or copy of submitted application to IRB or ACUC.

**The original application must be submitted electronically to the website no later than Monday, June 1, 2009. Once the completed application is uploaded, an automatic confirmatory email will be sent to the applicant and to the Chair of the Scientific Evaluation Committee.**

Sorin J. Brull, MD  
Chairman, APSF Scientific Evaluation Committee  
Professor of Anesthesiology  
Mayo Clinic College of Medicine  
4500 San Pablo Road  
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**Further information about the Grant Program and applicant eligibility may be found at "Frequently Asked Questions," under the "Grants" tab on the APSF website.**

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# APSF Highlights



The APSF Committee on Education & Training awards the **Ellison C. Pierce Research Award for Best Scientific Exhibit** at the ASA 2008 annual meeting in Orlando, FL. Dr. Richard Prielipp, APSF Committee chair, presents the award to Dr. Wilton Levine, MD, for the exhibit **"SMART LABELS"—Improving Medication Safety in the Perioperative Environment**, sponsored by the Massachusetts General Hospital Boston, MA.

Pictured in photo (left to right) are: Dr. Alan Harvey; Dr. Jeff Cooper; Maria Magro, CRNA; Kevin Cardinal, CRNA; Kim Donovan; Gayle Fishman, RN; William Driscoll, M.A.; Dr. Wilton Levine; Dr. Ken Abrams; Tricia Meyer, PharmD; Dr. Tim Harwood; and Dr. Richard Prielipp.



Your APSF was well represented at the AANA meeting in Minneapolis, August 2008. A large poster (background), highlighting the history and contributions of the APSF to patient safety, is reviewed by APSF Education Committee chair, Richard Prielipp, MD, MBA, FCCM, and 2008 AANA President, Wanda Wilson, CRNA, PhD. Also pictured from left to right are Alfred E. Lupien, CRNA, PhD; John O'Donnell, CRNA, MSN; Rodney Lester, CRNA, PhD, MSN, MBA; Ken Plitt, CRNA, MBA; Maria Magro, CRNA, MS, MSN; Kevin Cardinal, CRNA, MS. Not featured but present at the exhibit was Patty Mullen Reilly, CRNA, BSN.



Jeff Cooper and Nassib Chamoun join Ellison C. Pierce, Jr., MD, (Jeep), APSF co-founder and former APSF Executive Director, to celebrate his 80th birthday.

## Recent Losses to the APSF Community



### Dr. J.S. Gravenstein

Dr J. S. "Nik" Gravenstein was a pioneer in anesthesia and patient safety. Nik served on the APSF Board of Directors and the Executive Committee from 1986 to 1995 and remained an advisor and role model for many years after. Dr. Gravenstein was an innovator in patient simulation and a founding member and former chair of the Department of Anesthesiology at the University of Florida. Nik passed away on January 16, 2009 and will be missed by all who knew him. The APSF extends its condolences to his family, friends and colleagues.



### Dr. Robert J. McQuillan

The APSF family recently lost another contributor to the cause of patient safety, Dr. Robert J. McQuillan, age 47. Bob was an associate professor of Anesthesiology and Clinical Ethics at Creighton University and former chairman of the Department of Anesthesiology at Creighton. In addition to his anesthesia practice and extensive leadership efforts, Bob joined the APSF Committee on Education and Training in 2006, and was involved in training and research in patient safety, teamwork development (Team-STEPPS) in the perioperative arena, and human factors. Bob is survived by his wife, Colleen M. McQuillan; daughters, Bridget and Erin; and his son, Gavin. He was a friend of APSF and an enthusiastic advocate of its vision that no patient be harmed by anesthesia. He will be missed. The APSF extends its condolences to Dr. McQuillan's family, friends and colleagues.



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