

## APSF Workshop Engages Audience in Communication Skills and Drills

by Jeffrey B. Cooper, PhD, Robert A. Caplan, MD, and David M. Gaba, MD

If you are confronted with a situation where you need to speak your mind about a possible patient safety situation, will you be able to do it effectively? This question was posed to the audience by Dr. Jeffrey Cooper, the organizer of this year's annual APSF Board of Directors workshop. Although there are not empirical data to confirm how often such situations occur, Dr. Cooper reminded the audience about 2 tragic accidents in which a failure to speak up at all or to speak up effectively clearly contributed to these events. He and the 2 other workshop faculty, Drs. David Gaba and Robert Caplan, went on to lead a highly interactive workshop, unusual in the way this important patient safety topic was presented.

The audience was introduced to an example of a challenging situation. A surgeon and an anesthesiologist, played by Drs. Robert Morell and Casey Blitt, respectively, appeared on the stage and enacted a scripted "mini-play" that illustrated an event that is similar to what most anesthesia professionals encounter periodically in the course of caring for their patients. The case involved an otherwise healthy 62-year-old, hypertensive male scheduled for 4 level spinal fusion in the prone position with an estimated OR time of 8 hours. The scenario began with the anesthesiologist placing a telephone call to the surgeon on the Friday preceding the case scheduled for Monday.

During their first conversation, the anesthesiologist tried to raise his concerns about the surgeon's request for deliberate hypotension. The anesthesiologist wanted to advise the patient of the risk of postoperative vision loss. The surgeon pushed back, without clearly explaining why. The anesthesiologist gave in, dropping further discussion of the perceived need for deliberate hypotension or the rationale for discussing the risks and benefits of deliberate hypotension with the patient.

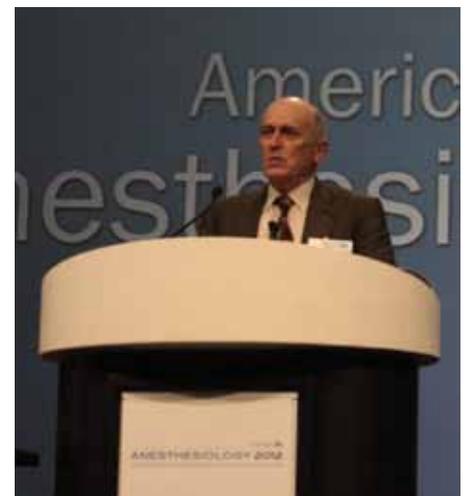
After this first play, audience members had a chance to share their own experiences with these kinds of situations and how they deal with them.

Next, the scenario was repeated, but this time the spoken conversation was supplemented with "asides" to the audience. These "asides" were the private thoughts of the surgeon and anesthesiologist in this simulated drama. For example, the anesthesiologist, who hadn't worked with this surgeon before, had heard from others that he was not one to accept disagreement. The anesthesiologist was concerned about avoiding conflict. The surgeon, in his private thoughts, felt that the anesthesiologist was being overly cautious and might unintentionally scare the patient from having the surgery, which he felt was strongly indicated.

Dr. Caplan next presented to the audience 3 brief stories that illustrated the speaking-up paradigm. The first involved what became a much-publicized case in which a patient died after injection of chlorhexidine in place of contrast media. Retrospectively, all members of the care team learned that they had opportunities to break the chain of error and prevent the mistaken injection, just by speaking up.

In another story, an anesthesiologist used effective advocacy to convince the surgeon to change his practice of shaving the surgical site and use the new protocol, which is known to have a lower infection rate.

In the third example, a nurse spoke up and voiced her concern about an inappropriate order for chemotherapy from an oncologist. When he rebuffed the nurse's concern, she asked for advice from the



Dr. Jeffrey Cooper, organizer of the APSF Workshop, opens this highly interactive session at the 2012 ASA meeting in Washington, DC.

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**ANESTHESIA PATIENT SAFETY FOUNDATION (APSF)  
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See [www.apsf.org](http://www.apsf.org) for grant guidelines and other information.

**APSF Newsletter**

*guide for authors*



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**NEWSLETTER**

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# Techniques for Effective “Speaking Up” Introduced, Modeled, and Discussed

## “Speaking Up,” From Page 45

department chair, who instructed the oncologist to use the correct protocol. The oncologist then berated the nurse for her intervention. The nurse was backed up by the Department Chair, and the oncologist was reprimanded, placed in a performance improvement program, and later gave an apology to the nurse.

These stories set the stage for learning how to effectively speak up in the kinds of situations that might arise in the life of an anesthesia professional. Dr. Gaba spoke about why it’s so hard to speak up and how to overcome the inertia. Some examples of the reasons for not speaking up are listed in the box.

- Natural reluctance to interrupt
- Fear of embarrassment (self or others)
- Concern about being misjudged / conflict
- Fear of being wrong and concern for reputation
- Fear of outright retribution
- Don’t know what to say or how to say it

One additional influence is the phenomena of “social shirking” or the “bystander effect”—the expectation that someone else will take action so that yours isn’t needed. Dr. Gaba also discussed production pressure, the pressure to cut corners in order to maintain throughput, and how this can be a barrier to speaking up.

There are different types of approaches to using effective speech to help overcome these barriers and to get others to share your concern without becoming defensive. One such approach that was suggested is using “advocacy/inquiry.” This involves maintaining curiosity and trying to learn the other person’s “frame” or point of view. This takes a lot of practice, but it can be very useful in many life situations once it’s mastered.

The two-challenge rule was developed in aviation in response to accidents in which co-pilots did not successfully challenge a pilot’s errors or misjudgments. It involves raising a concern twice, more forcefully each time; and, if the concern isn’t recognized, either taking control or calling in a higher authority in the chain of command.

### Techniques for Effective Speaking Up

#### Advocacy/Inquiry:

(deliberate practice is required to achieve useful skill levels)

- State your observation (facts)
- Express and own your concerns
- Be **curious** about their “frame”: There’s a chance they are right!

#### Two-Challenge rule:

(needs to be adopted as policy of the organization)

- Raise the concern in a non-confrontational tone.
- If the concern is not acknowledged, repeat with more emphasis.
- If the second challenge is not acknowledged, refer the issue to another person, e.g., supervisor with authority to intervene, trusted colleague.

The common objective of these techniques is to get the team to focus on what’s right for the patient, not *who* is right (a slogan learned from an American Airlines’ Crew Resource Management course).

The surgeon and anesthesiologist actors returned to the stage and repeated their conversation, this time using forms of advocacy/inquiry. When that wasn’t entirely effective they invoked an aspect of the two-challenge rule and agreed to get another opinion from a mutually trusted colleague, which likely led to a satisfactory outcome.

Then it was the audience’s turn to try out the techniques. Everyone had been given 1 of 2 different envelopes. Each paired up with a partner with the opposite color dot on the envelope. One became the surgeon and the other the anesthesiologist in a new case that created some conflict. This case involved the choice of antibiotic. The surgeon had ordered cefazolin, but the anesthesiologist had learned that the patient had a prior allergic reaction to penicillin. The patient already had received 2 doses of cefazolin during this hospital admission and with no untoward

effect. The anesthesiologist was still concerned and wished to avoid the potential for problems. The surgeon had his own reasons for wanting to stick with his original order. Each role player privately received more information in their written instructions about their perceptions of the issues and about the other person (each had some commentary the other did not have).

The role-playing ensued with much vigor. The room noise level increased. After about 5 minutes, Dr. Cooper, with some difficulty, managed to get the energized players to stop to discuss the techniques they had used to get the agreement they needed.

Because speaking up can be difficult for all the reasons articulated in this Workshop, no one exercise will succeed in “fixing” this serious problem. The Workshop was quite successful in articulating the problem more fully, and in exploring practical ways to mitigate it. The APSF hopes to continue to search for ways to help anesthesia professionals to protect their patients from harm by becoming better able to prudently challenge others when necessary, regardless of the many factors that inhibit action.

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*Dr. Gaba is Associate Dean for Immersive & Simulation-based Learning, Professor of Anesthesia at Stanford University, and Staff Anesthesiologist and Co-Director at the Patient Simulation Center of Innovation, VA Palo Alto Health Care System, Palo Alto, CA.*

#### Reference

1. Pian-Smith MC, Simon R, Minehart RD, et al. Teaching residents the two-challenge rule: A simulation-based approach to improve education and patient safety. *Simul Healthc* 2009;4(2):84-91.

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# President's Report Highlights Accomplishments of 2012

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

A highlight of the annual meeting of the American Society of Anesthesiologists in Washington, DC, in October 2012 was the inaugural Ellison C. Pierce, Jr., MD Patient Safety Memorial lecture delivered by Donald M. Berwick, MD. This named lectureship will continue to be part of the annual ASA meeting, thus providing sustained recognition for the vision and contributions to anesthesia patient safety made by Dr. Pierce as the founding president of the APSF. The annual APSF Board of Directors Workshop held on October 13, 2012, was moderated by Jeffrey B. Cooper, PhD, APSF executive vice president on the topic "When and how to challenge the hierarchy: Speaking up for patient safety."

The APSF is pleased to congratulate Jeffrey B. Cooper, PhD, for his well-deserved selection as the 2014 recipient of the prestigious ASA Distinguished Service Award. Dr. Cooper was a founding member of the APSF Executive Committee in 1985 and has continued to lead anesthesia patient safety efforts during his illustrious career.

## Perioperative Visual Loss (POVL)

The report of this multispecialty conference held on September 11, 2012, may be viewed on page 52 and on the APSF website ([www.apsf.org](http://www.apsf.org)). The consensus of the 87 attendees was the need for an informed consent process for patients considered to be at risk for POVL. The informed consent process should include known risk factors for POVL and interventions that may reduce the risk of POVL caused by ischemic optic neuropathy.

## Residual Muscle Relaxant-Induced Weakness in the Postoperative Period: Is It a Patient Safety Issue?

An APSF-sponsored panel at the NYPGA annual meeting on December 17, 2012, was moderated by Drs. Brull and Stoelting and included Drs. Eriksson, Kopman, and Murphy. There was general agreement regarding the need to recognize residual postoperative weakness from neuromuscular blocking drugs as a patient safety concern and the importance of objective monitoring to confirm recovery from the effects of these drugs.

## Anesthesia Professionals and the Use of Advanced Medical Technologies: Recommendations for Education, Training, and Documentation

The APSF will sponsor a conference on Wednesday, September 18, 2013 (Royal Palms Resort and Spa, Phoenix, AZ), to address the safe use of advanced medical technology by anesthesia professionals. The goals of this conference will be to engage all stakeholders (anesthesia professionals, technology manufacturers, accrediting and regulatory agencies, professional technology organizations, insurers, hospital administrators, risk managers) to discuss and refine the existing APSF Committee on Technology's ADVANCED MEDICAL TECHNOLOGY TRAINING document (see page 50 and [www.apsf.org](http://www.apsf.org)).

All those interested in this topic are encouraged to attend this APSF-sponsored conference. Please contact [stoelting@apsf.org](mailto:stoelting@apsf.org) for registration information.

## Research

The APSF Committee on Scientific Evaluation chaired by Sorin J. Brull, MD, received 23 grant applications in 2012. In October 2012, the committee recommended funding 4 research awards totaling \$596,000 to begin in January 2013.

In addition, the APSF is partially supporting the MOCA GRANT and has announced the APSF/ASA Safety Scientist Career Development Award (SSCDA) (\$150,000 over 2 years) beginning in July 2012. The next SSCDA will be funded beginning July 2014 and the application deadline is November 1, 2013 (contact [Stoelting@apsf.org](mailto:Stoelting@apsf.org) for grant guidelines and application).

The APSF is the largest private funding source for anesthesia patient safety research in the world. Since the inception of the APSF grant program, 545 grant applications have been received by the APSF. When the first grants were funded in 1987, funding for anesthesia patient safety was virtually unknown. Since 1987, the APSF has awarded 98 grants for a total of more than \$7,670,000. The impact of these research grants is more far-reaching than the absolute number of grants and total dollars, as APSF-sponsored

research has led to other investigations and the development of a cadre of anesthesia patient safety investigators.

## APSF Newsletter

The APSF Newsletter continues its role as a vehicle for rapid dissemination of anesthesia patient safety information with Robert C. Morell, MD, and Lorri A. Lee, MD, as co-editors. The circulation of the APSF Newsletter exceeds 107,500 recipients and is provided as a member benefit by the ASA, American Association of Nurse Anesthetists (AANA), American Association of Anesthesiologists Assistants (AAAA), American Society of Anesthesia Technologists and Technicians (ASATT), American Society of PeriAnesthesia Nurses (ASPAN), American Society of Dentist Anesthesiologists (ASDA), American Dental Society of Anesthesia (ASDA) and the American Association of Oral Maxillofacial Surgeons (AAOMS). In addition to the electronic version of the APSF Newsletter, a hardcopy is mailed to all members of the ASA, AANA, AAAA, ASPAN, and ASDA.

The "Question 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. A. William Paulsen (chair, APSF Committee on Technology) and Robert C. Morell (co-editor, APSF Newsletter). The value of industry to anesthesia patient safety is reflected by these columns.

## Communication

The APSF website design and appearance ([www.apsf.org](http://www.apsf.org)) continues under the direction of APSF executive vice president, George A. Schapiro. The APSF website includes a monthly poll question related to anesthesia patient safety issues. The poll question is coordinated by Timothy N. Harwood, MD, a member of the APSF Committee on Education and Training, chaired by Richard C. Prielipp, MD. Online donations to the APSF are possible via the website.

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

APSF sponsored a panel on *Operating Room Medication Safety: Mishaps, Missteps and (Mis) Management* at the May 2012 annual congress of the International Anesthesia Research Society. The panel was moderated by Richard C. Prielipp, MD, chair, APSF Committee on Education and Training.

See "President's Report," Next Page

# APSF Creates Patient Safety DVDs for Prevention of OR Fires and Medication Safety

## “President’s Report,” From Preceding Page Prevention and Management of Operating Room Fires

The APSF conducted a survey of the 542 anesthesia professionals who requested a complimentary copy of the *Prevention and Management of Operating Room Fires* DVD ([http://www.apsf.org/resources\\_video.php](http://www.apsf.org/resources_video.php)) between its introduction in April 2010 and October 2011. The goal of the survey was to evaluate the impact of this educational video on how anesthesia professionals approach the administration of supplemental oxygen to “patients at risk for operating room fires.” Survey responses (30% response rate) indicated the DVD increased recognition by anesthesia professionals of “at risk patients” and changed practice related to supplemental oxygen via open delivery systems (see Spring/Summer 2012 *APSF Newsletter*, <http://www.apsf.org/announcements.php?id=7>). For example, before viewing the APSF fire safety video, 37.8% of the respondents indicated they would “provide open delivery of 100% oxygen via a nasal cannula or face mask” to at risk patients requiring supplemental oxygen to maintain an acceptable arterial oxygen concentration. After viewing the fire safety video, this percentage decreased to 1.8%.

The Food and Drug Administration (FDA) Safe Use Initiative has undertaken a fire safety initiative based on the initial role of APSF and ECRI Institute in bringing this safety issue to the forefront. Between April 1, 2010, and June 1, 2012, the APSF had received more than 5,000 individual requests for the complimentary fire safety DVD ([http://www.apsf.org/resources\\_video.php](http://www.apsf.org/resources_video.php)).

## Fire Prevention Algorithm

Prevention of surgical fires is a team effort including communication among all the caregivers, prudent use of supplemental oxygen by the anesthesia provider, proper use of alcohol-based disinfectants by nursing and surgery, and appropriate use of ignition sources by the surgeon. In an effort to increase awareness for the potential of surgical fires in at risk patients, the APSF published a *Fire Prevention Algorithm* in the Winter 2012 issue of the *APSF Newsletter* (<http://www.apsf.org/newsletters/html/2012/winter/index.htm>). The goal of the *APSF Fire Prevention Algorithm* to increase awareness of the risk of operating room fires was endorsed by ASA, AAAA, AANA, ASATT, American College of Surgeons, ASPAN, Association of periOperative Registered Nurses, ECRI Institute, Food and Drug Administration Safe Use Initiative, National Patient Safety Foundation, and The Joint Commission.

## Medication Safety in the Operating Room

On January 1, 2012, the APSF announced the availability of a complimentary 18-minute educational DVD entitled, *Medication Safety in the Operating Room: Time for a New Paradigm* ([http://www.apsf.org/resources\\_video2.php](http://www.apsf.org/resources_video2.php)). The APSF had received more than 1800 individual requests to receive the complimentary medication safety DVD ([http://www.apsf.org/resources\\_video2.php](http://www.apsf.org/resources_video2.php)).

## Pre-Anesthetic Induction Patient Safety (Pips) Checklist

The APSF conducted a survey among 2229 anesthesia professionals to determine the support for a checklist and the recommended content. A total of 739 respondents completed the online survey, and the results will be presented in a subsequent issue of the *APSF Newsletter*. The next step will be a RFA to study the implementation and performance of the proposed checklist template.

## Financial Support

Financial support to the APSF from individuals, specialty and component societies, and corporate partners in 2012 has been most gratifying. This sustained level of financial support makes possible the undertaking of new safety initiatives, the continuation of existing safety initiatives, and funding for anesthesia patient safety research. The level of research support is particularly dependent on the level of financial support received.

## Online Donations

The APSF website permits “online” credit card contributions. Go to “Donate” on the APSF home page and follow the prompts.

## Concluding Thoughts

The APSF wishes to thank retiring Board of Directors members Nassib G. Chamoun (APSF vice president) and Sally T. Trombly, JD (long-time member of the APSF Scientific Evaluation Committee). We are pleased to welcome Jason R. Byrd, JD, to the APSF Board of Directors. Robert J. White, Covidien, was elected from the Board to a Member at Large position on the APSF Executive Committee.

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

Best wishes for a prosperous and rewarding year 2013.  
*Robert K. Stoelting, MD*  
*APSF President*



*Robert K. Stoelting, MD*  
*APSF President*

## Vision

*The vision of the Anesthesia Patient Safety Foundation is to ensure that no patient shall be harmed by anesthesia.*



## Mission

The APSF’s Mission is to improve continually the safety of patients during anesthesia care by encouraging and conducting:

- safety research and education;
- patient safety programs and campaigns;
- national and international exchange of information and ideas.

# Training Anesthesia Professionals to Use Advanced Medical Technology

by the APSF Committee on Technology

The Anesthesia Patient Safety Foundation (www.apsf.org) believes that anesthesia professionals should be competent to use advanced medical technology to provide safe patient care. The APSF includes practicing anesthesia professionals, representatives from the medical device industry and other relevant stakeholders. The APSF, through its Committee on Technology (COT), has been considering the current state of medical device training for anesthesia professionals for many years and developed recommendations for **Advanced Medical Technology Training**. This document provides a framework for learning, assessment, and documenting of competency in the use of advanced medical technology (see **Appendix** for definition and examples).

Anesthesia professionals have not generally been required to demonstrate their competence to use anesthesia technology to care for patients. In contrast, mandatory user training and/or demonstration of competence are currently required for clinicians who use some devices including lasers, radiation emitting devices (e.g., fluoroscopy), some technology-based surgical procedures (e.g., carotid stents), and point-of-care laboratory devices. Demonstrating competency to use medical devices is consistent with safe patient care, and the requirements for anesthesia professionals should be consistent with other similarly complex and risky medical devices.

## Background

Industry members of the APSF COT reported a consistently low rate (as low as 20%) of anesthesia professional participation in training programs associated with the introduction of new technology into clinical practice. A number of obstacles to participation have been articulated:

- Absence of recommendations from an anesthesia professional organization to demonstrate competence before using a device to care for a patient.
- Limited time in an already busy workday to attend and complete technology training.
- A general lack of training programs that are easily accessible and can be completed in a realistic time frame.
- Regulations that prohibit offering CME/CEU credits when industry representatives deliver the training content despite the manufacturer's expertise and incentives to provide quality training.
- Those who enter a practice or facility after a new technology has been introduced typically do not have ready access to a formal training program.

Anesthesia professionals widely agree that they should be able to safely use advanced medical technology to care for their patients. The APSF recognizes

that the diversity of clinical practice models precludes a single framework for accomplishing this goal. Nevertheless, the APSF encourages relevant health care organizations to develop policies and procedures that promote adequate training and confirm continuing competence of anesthesia professionals to use advanced medical technology safely. It is anticipated that educational programs will be tailored to the unique needs of the organization and be compatible with available resources.

**The following considerations are intended to guide anesthesia professionals, anesthesia technicians, health care organizations and technology manufacturers as they develop educational programs to train and confirm anesthesia professionals' continued competence to use advanced medical technology.** These educational programs may be developed in conjunction with anesthesia professionals, anesthesia departments, the medical device industry, health care institutions and other patient safety organizations.

## Considerations for Anesthesia Professionals

Anesthesia professionals should participate in an educational program to become competent to use advanced medical technology before using that equipment to care for a patient. A quality educational program will not only include training, but also a means to assess and document competence.

Competence to use advanced medical technology includes the following skills:

- Understand the setup, function, operation, and information necessary to provide safe and effective patient care when using the device.
- Consistently use the device safely and effectively.
- Consistently use a device's safety features and take appropriate measures to avoid known potential for patient harm.
- Identify when each device is not functioning as intended and be able to perform basic troubleshooting and respond appropriately to maintain the highest level of patient safety.
- Have competence assessed by various mechanisms, including but not limited to, written or oral examinations, demonstrating safe use to a skilled observer, and using the device in simulations of relevant clinical situations.

## Considerations for Health Care Institutions

- Require appropriate advanced medical technology training and demonstrated competence before an anesthesia professional is permitted to use a (new or existing) device to care

for patients unless a person with demonstrated competence is present throughout the procedure.

- Provide formal advanced medical technology training programs for every anesthesia professional including a mechanism to ensure that anesthesia professionals who are new to the institution receive this training before they begin delivering patient care.
- Document an individual's participation in technology training, education, and assessment.
- Create a mechanism to ensure that the advanced medical technology training program is meeting its goals.
- Establish a schedule for periodic reassessment of anesthesia professionals' continued competence.
- Allocate time for training and assessment within the regular workday.

## Consideration for the Technology Manufacturer

- Utilize a rigorous, user-centered, human factors design process to create devices that are easy to learn to use, easy to use, easy to remember how to use, and that fail safely and gracefully.
- Develop effective training materials and instructions for use (IFU) using the same rigorous engineering processes applied to other aspects of the device.
- Create standardized user training and recommended competency assessment materials, based on user-centered design and validation methods, which can be used by institutions to comply with these recommendations.
- Assist customers in the implementation of user training and competency assessment materials and procedures.

*Disclaimer (Approved by APSF Executive Committee on October 16, 2009)*

*Recommendations developed and promulgated by APSF are intended to assist professionals who are responsible for making health care decisions. APSF's mission is to assure that no patient is harmed by anesthesia care. Thus, our recommendations focus on minimizing the risk to individual patients for rare adverse events rather than necessarily on practices that balance all aspects of population health quality and cost. APSF does not intend for these recommendations to be standards, guidelines, practice parameters, or clinical requirements, nor does application of these recommendations guarantee any specific outcome. Furthermore, these recommendations may be adopted, modified, or rejected according to clinical needs and restraints. APSF recognizes that these recommendations are subject to revision as warranted by the evolution of medical knowledge, technology, and practice.*

**See "Training," Next Page**

# Advanced Medical Technology Defined

“Training,” From Preceding Page

## APPENDIX

### Definition and Examples of Advanced Medical Technology

We define Advanced Medical Technology as medical devices and software systems that are complex, provide critical patient data, or that directly implement pharmacologic or life-support processes whereby inadvertent misuse or use error could present a known probability of patient harm.

AMT for which these recommendations could apply include, but are not limited to, the following examples:

- Anesthesia workstations (traditionally known as “anesthesia machines”) and mechanical ventilators
- Patient monitoring systems that could include cardiovascular, respiratory, neuromuscular, and electrophysiological monitoring
- Complex diagnostic imaging systems including doppler velocity and ultrasonic imaging
- Medication delivery systems including infusion pumps
- Energy delivery systems including defibrillators and pacemakers
- Cardiovascular support devices including intraaortic balloon pumps
- Point-of-care diagnostic/laboratory devices
- Anesthesia and other health care documentation or informatics systems if they include medication ordering, clinical decision support, or diagnostic components on which an acute life-affecting diagnosis or therapy will be based.

*Dr. William Paulsen is chair of the Committee on Technology for the APSF and is AA-C, Chair, Hamden, CT. For a full list of the committee members, please refer to Page 59 of this issue.*

### New Scientific Evaluation Committee Members

Annually, the APSF Scientific Evaluation Committee (SEC) considers the addition of new members to participate in the review of clinical and educational patient safety grants. Applicants for SEC membership should be experienced patient safety researchers with a track record of funding and peer-reviewed publication. The SEC is particularly interested in applicants with safety-related expertise in informatics, simulation, or the responsible conduct of research. Interested applicants should submit their curriculum vitae and a cover letter explaining interest and qualifications to Dr. Sorin Brull at [brull@apsf.org](mailto:brull@apsf.org).



## FDA and IARS Hold SmartTots Workshop

Over the last decade, studies in rodents and non-human primates have found that exposure to anesthetic agents during sensitive periods of brain development results in widespread neuronal apoptosis and functional deficits later in life. Population-based birth cohort studies have suggested there may be adverse effects on brain development in humans. Although the anesthesia community and the FDA agree there are insufficient data to demonstrate a causal link between the use of anesthetics and neurotoxicity in the human pediatric population, the need has grown to communicate accurately to practitioners and parents the current understanding of the risks.

On September 10, 2012, the International Anesthesia Research Society (IARS) and the U.S. Food and Drug Administration (FDA) held a SmartTots Scientific Workshop at the FDA White Oak Campus in Silver Spring, Maryland, with the goal of developing a consensus statement regarding the safety of anesthetic and sedative drugs administered to infants and young children. Attendees included over 60 experts in pediatric medicine and patient safety. The Anesthesia Patient Safety Foundation, along with other stakeholder organizations including the American Society of Anesthesiologists and the American Academy of Pediatrics, were represented.

Workshop participants were charged with reviewing and discussing the available data; assessing the medical, ethical and legal implications of communicating this information broadly; and formulating a consensus statement that defines the problem and addresses the concern surrounding the risks and benefits associated with sedation and anesthesia in children. Workshop participants agreed the key elements of the statement should include the following:

- Infants and young children often need surgery and other procedures requiring anesthetic and

sedative drugs—agents that are used to ensure patient comfort, safety, and health.

- Data from animal studies indicate harm and raise concerns about the use of these drugs, but the applicability of the results to humans is unclear and many scientific unknowns still remain. Data from human studies are unclear with mixed results; until we have more data, we must proceed with caution.
- There is a clear and urgent need for more research in this area. To inform clinical decisions, we need to understand key questions such as the mechanism of harm, how to prevent harm, agents in question, and which populations are most vulnerable.
- Health care providers, including primary practitioners, surgeons, and anesthesia professionals, need to be educated and informed about the potential risks and benefits associated with anesthetic and sedative drugs in children in order to convey the necessary information and conduct the proper dialogue with parents.
- Until more is known, parents should be made aware of the current data and proceed with necessary surgeries and treatments that require anesthetic and sedative drugs.
- The IARS, with assistance from a professional marketing and communications firm, is drafting a formal statement including these key elements for review and ratification by the FDA and stakeholder groups.

*For more information, contact IARS Executive Director Tom Cooper: [tcooper@iars.org](mailto:tcooper@iars.org), (415) 296-6915.*

# APSF-Sponsored Conference on Perioperative Visual Loss Develops Consensus Conclusions

by Lorri A. Lee, MD, and Robert K. Stoelting, MD

On September 12, 2012, the APSF sponsored a multidisciplinary conference, *Perioperative Visual Loss: Who is at risk, What should we tell patients preoperatively, and How should we manage their intraoperative care?*

The goals of this Perioperative Visual Loss (POVL) conference were to

- Assure that current management reflects evolving information and understanding of “best practices” for patients at risk for POVL.
- Create a “participant-developed, moderator-led statement of safety recommendations (“best practices”) for managing patients considered at risk for POVL.

The 87 attendees included

- Anesthesia professionals (n-74) (anesthesiologists, CRNAs, AAs)
- Other physicians (n-4) (orthopedic surgeon, neurosurgeon, neuro-ophthalmologist, robotic surgeon)
- Non-physicians (n-8) (2 risk managers, an anesthesia researcher, professional liability insurer, practice administrator, pharmacist, Veterans Administration Hospitals and APSF staff)
- Industry (n-1).

The anesthesia professionals included 13 attendees who had participated in the *Postoperative Visual Loss Study Group* (*Anesthesiology* 2012;116:15-24). Several of the other attendees participated in or represented organizations that supported the most recent American Society of Anesthesiologists *Practice Advisory for Perioperative Visual Loss Associated with Spine Surgery* (*Anesthesiology* 2012;116:274-285).

The POVL conference included podium presentations, panel discussions, small group breakout sessions, and completion near the end of the conference (following all podiums presentations and panel discussions) of a questionnaire/survey (<http://www.apsf.org/announcements.php?id=12>).

For the initial organizational purposes of the conference, POVL was assumed to be due to ischemic optic neuropathy (ION) or central retinal artery occlusion (CRAO). High-risk patients for ION were defined as those undergoing spine procedures while positioned prone and who had prolonged procedures (exceeding an average of 6.5 hours) and experienced substantial blood loss (an average of 44.7% of the estimated blood volume), or both (*Anesthesiology* 2012;116:274-282). A similar definition with regard to operative duration was arbitrarily applied by the



Dr. Stoelting (APSF president and conference co-moderator) welcomes attendees to the multidisciplinary APSF-Sponsored POVL Conference.



Dr. Mark A. Warner moderates panel: panelists are Ronney Abaza, MD (urologic robotic surgeon), Nancy J. Newman, MD (neuro-ophthalmologist), Teo Forch Dagi, MD (neurosurgeon), and Michael A. Olympio, MD (anesthesiologist).

APSF to head-down (degree of head-down not definable) robotic/laparoscopic surgeries.

An overwhelming theme of the conference presentations, panel discussions, and small group breakout sessions as well as the questionnaire/survey was the importance of including the risk of POVL caused by ION in the informed consent process. For patients considered to be at risk of POVL caused by ION, anesthesia professionals and surgeons should include discussion of the remote risk of visual impairment, ranging from partial vision loss to complete blindness in both eyes, during the informed consent process. POVL from CRAO caused by external globe compression was felt by the attendees to be largely preventable with the use of appropriate positioning aids and monitoring of the external globes (eye checks) during the intraoperative period. Discussion of the rare

adverse event of CRAO during the informed consent process should be left to the discretion of the anesthesia professional and surgeon.

**It was further recognized that the informed consent process should include a discussion of**

- The current state of understanding as to risk factors for POVL due to ION.
- The interventions that may reduce the risk of POVL due to ION.

**Indeed, the value of the informed consent process to the patient is dependent on those responsible for the perioperative care to be cognizant of evolving information and strategies designed to reduce the risk of POVL caused by ION.**

**See “POVL Conference,” Next Page**

## Informed Consent Process Emphasized at APSF-Sponsored POVL Conference

### “POVL Conference,” From Preceding Page

It was recognized that POVL is a rare event that, based on its incidence (less than 0.2% of spine surgeries), might not be considered for inclusion in an informed consent by anesthesia professionals and surgeons. However, the rare occurrence of POVL caused by ION is negated by the “**extreme value that patients place on vision**”) as demonstrated by patients’ willingness (>80% surveyed) to accept risks of stroke or death to save some vestige of vision (Ophthalmology 1996;103:691-696). When patients who had undergone prior spine surgery were asked if they would want to be consented for the risk of POVL with prone spine surgery, more than 80% reported that they would prefer full disclosure of the risk of POVL by the surgeon in a face-to-face discussion prior to the day of surgery (*Mayo Clinic Proc* 2011;86:865-868).

A total of 67 questionnaire/surveys out of a possible 74 were returned by attendees at the conference who designated their affiliation as “anesthesia professionals” (<http://www.apsf.org/announcements.php?id=12>). Their responses to the survey questions are discussed below. The questionnaire/surveys available from the other professional affiliations were considered too few (n=12) to analyze but were recognized to be supportive of the consensus of the anesthesia professionals with respect to the need for inclusion of the risk of POVL during the informed consent process.

Of anesthesia professionals, 23.9% (16 of 27) had cared for one or more patients who had experienced ION, whereas another 46.8% (30 of 67) were aware of this complication occurring in their hospital/practice group. CRAO was infrequent with 95.5% (64 of 67) of the anesthesia professionals indicating they had not cared for a patient who experienced blindness due to this mechanism, and only 22.3% (15 of 67) were aware of this complication occurring in their hospital/practice group. **Thus, for the purposes of this report, POVL will be considered to be due to ION in the subsequent sections.**

The vast majority of anesthesia professionals, (86.6%) responding to the questionnaire felt that “most surgeons do not recognize the risk of ION in the susceptible patient population, whereas 52.2% felt the same was true for anesthesia professionals. Of respondents, 85.9% felt that “risk factors for ION” could be modified or eliminated by both the anesthesia professional and surgeon.

When asked if “ION should be discussed during the informed consent process” the majority of participants believed it should be included in the “informed consent form,” either as a single document for surgeons and anesthesia professionals or as a separate consent form from each specialty. The information to be included in the informed consent process can be

inferred from responses to specific questions and was supported by the podium presentations, panel discussions, and small group breakout sessions. For example 60 of 67 anesthesia professionals (89.6%) agreed that the “best option available for patients and those responsible for their care is to create and adopt universal best practices management guidelines and recommendations (based on current knowledge and understanding) at their institution and to apply it to the intraoperative management of all patients considered to be at risk for ION.”

Of anesthesia professionals, 85.1% agreed that best practices management guidelines to decrease the risk of ION should be based on steps to decrease the likelihood of venous congestion and edema formation in the periorbital area/head. There was agreement among 63 of 67 anesthesia professionals that male gender, obesity, decreased percent colloid administration of nonblood replacement, and use of the Wilson frame should be added to the risk factors for developing ION following spine surgery. A need to balance colloid and crystalloid administration was supported by 58 of 67 attendees (86.6%). Most anesthesia professionals (97%) agreed that “during spine surgery, the patient’s head should be positioned level with or higher than the heart” in patients considered to be at risk for ION.

Although controlled hypotension has not been identified as an independent risk factor for ION, 57 of 67 anesthesia professionals (85.1%) agreed that “controlled hypotension should not be used routinely in patients considered to be at risk for ION.”

There was agreement among 55 of 67 anesthesia professionals (82.1%) that “consideration should be given to the use of staged spine procedures” when the duration of spine surgery is anticipated to be prolonged (preoperatively) or becomes prolonged (intraoperatively).

The need to periodically monitor hemoglobin or hematocrit to detect anemia in patients considered to be at risk for ION was supported by 60 of 67 anesthesia professionals (92.3%), while 86.6% agreed that a specific “transfusion threshold that would reduce the risk of ION related to anemia was not known.” Further, 89.6% of the anesthesia professionals agreed there is no proven treatment for ION when it manifests postoperatively.

**In conclusion, the consensus of the attendees at the APSF-sponsored POVL conference may be summarized as follows:**

- During the informed consent process, anesthesia professionals and surgeons should include discussion of the remote risk of visual impairment ranging from partial vision loss to complete blindness in both eyes for patients considered to be at risk for POVL from ION.

- If the risk of POVL from ION is not part of a combined anesthetic and surgical informed consent process, or part of a separate surgical informed consent process, it should be part of the anesthetic informed consent process.
- The informed consent process may include a discussion of risk factors (prolonged spine surgery in the prone position or prolonged robotic surgery in the head down position, increased blood loss, male gender, obesity, use of Wilson surgical frame) and the current understanding of interventions that may reduce the likelihood of POVL caused by ION (minimize duration of surgery, consider staged spine procedures, keep head at or above the level of the heart, minimize use of surgical frames that place the head lower than the heart, include colloid in nonblood replacement). Discussion may include the concept that this complication is difficult to study because of its low incidence. Preventive measures are based on our best educated guess from what we know of the risk factors but have not been tested.
- Use of controlled hypotension in patients at risk for POVL caused by ION, although not documented to be an independent risk factor, is not recommended on a routine basis.
- POVL from CRAO caused by globe compression should be preventable with the use of appropriate positioning aids and monitoring of the external globes (eye checks) during the intraoperative period.

### Supporting Literature

1. Practice advisory for perioperative visual loss associated with spine surgery: An updated report by the American Society of Anesthesiologists Task Force on Perioperative Visual Loss. *Anesthesiology* 2012;116:274-285.
2. Risk factors associated with ischemic optic neuropathy and spinal fusion surgery. The Postoperative Visual Loss Study Group. *Anesthesiology* 2012;116:15-24.
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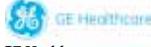
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In memory of Gordon O. Stafford, MD (Texas Society of Anesthesiologists)

# APSF Awards Four Grants for 2013

by Sorin Brull, MD

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

The application process continues with an electronic, online submission format that was introduced in 2005. The applications, as well as all the required attachments, are uploaded to the new 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 responses to queries, and facilitates transmission of reviewer feedback to the applicants. The Scientific Evaluation Committee members continue to modify and perfect the electronic application and review process.

The Scientific Evaluation Committee is very pleased to report that the APSF Executive Committee developed last year a Request for Application (RFA) for a Patient Safety Investigator Career Development Award (see: [www.apsf.org](http://www.apsf.org)) that seeks to develop the next generation of patient safety scientists. Additionally, APSF is proud to announce the continued funding of named awards, including the **APSF/American Society of Anesthesiologists (ASA) Endowed Research Award** (\$150,000), utilizing funds from the APSF endowment account that was made possible by the generous financial support from ASA over the past 25 years; the **APSF/ASA President's Research Award** (\$150,000); the **APSF/Masimo Foundation Research Award**, supported by a generous (\$150,000) grant from the Masimo Foundation; and the **APSF/Covidien Research Award**, supported by a generous (\$150,000) grant from Covidien.

In addition to the *Clinical Research and Education and Training* content that is the major focus of the funding program, the APSF continues to recognize the patriarch of what has become a patient safety culture in the United States and internationally, and one of the founding members of the foundation—Ellison C. “Jeep” Pierce Jr., MD. The APSF Scientific Evaluation Committee continues to designate each year one of the funded proposals as the recipient of this prestigious nomination, the **Ellison C. “Jeep” Pierce Jr., MD, Merit Award**. The selected nomination carries with it an additional, unrestricted award of \$5,000.

The APSF also has awarded **The Doctors Company Foundation Ann S. Lofsky, MD, Research Award**. This award is made possible by a \$5,000 grant from The Doctors Company Foundation that will be awarded annually for a total of 5 years to a research project deemed worthy of the ideals and dedication exemplified by Dr. Ann S. Lofsky. Dr. Lofsky was a regular contributor to the *APSF Newsletter*, a special consultant to

the APSF Executive Committee, and a member of the APSF Board of Directors. Her untimely passing cut short a much-valued and meaningful career as an anesthesiologist and as a dedicated contributor to anesthesia patient safety. It is the hope of the APSF that this award will inspire others toward her ideals and honor her memory.

For the year 2012 (projects to be funded starting January 1, 2013), 4 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 23 applications in the first round, 12 of which were selected for final review at the American Society of Anesthesiologists' (ASA) Annual Meeting in Washington, DC. As in previous years, the grant submissions addressed areas of high priority in clinical anesthesia. The major goal of APSF funding is to stimulate the performance of studies that lead to prevention of mortality and morbidity due to anesthesia mishaps. A particular priority continues to be given to studies that address anesthetic problems in healthy patients, and to those studies that are broadly applicable and promise improved methods of patient safety with a defined and direct path to implementation into clinical care. Additionally, the APSF is encouraging the study of innovative methods of education and training to improve patient safety, and methods for the detection and prevention of medication errors.

The APSF Scientific Evaluation Committee convened during the ASA Annual Meeting on October 13, 2012, in Washington, DC, for evaluation and final selection of the proposals. Of the 12 finalists, the members of the APSF Scientific Evaluation Committee selected the following applications:



**Leanne Groban, MS, MD**

*Professor of Anesthesiology, Section of Cardiothoracic Anesthesia, Wake Forest School of Medicine, Winston-Salem, NC.*

Dr. Groban's Clinical Research submission is entitled *“Does Preoperative Assessment of Nutritional Status, Mobility, and Frailty Among Geriatric Patients Predict Early Postoperative Morbid Events?”*

**Background:** Traditional risk assessment tools for preoperative evaluation have a focus on single organ systems. Consequently, it is unknown whether general health status—including nutritional status, muscle strength, and mobility—can predict early postoperative outcomes in older patients who are undergoing elective, non-cardiac surgery. This project is designed to address this gap in knowledge. The authors propose an observational cohort study of 200 patients aged 70 years and older who are undergoing elective non-cardiac surgical procedures.

**Aims:** The primary outcome of interest, determined by chart review, will be 1 or more morbid events within 30 days of the operation, including cardiac complications (e.g., myocardial infarctions, heart failure, and dysrhythmia), pulmonary complications (e.g., respiratory failure, pneumonia), infection, renal complications, gastrointestinal complications, neurologic complications (e.g., delirium, CVA) and re-operation. The relative frequency of various postoperative adverse events, length of hospital stay, and discharge disposition (e.g., home, extended-care facility) will also be determined. The aims of the study are 1) to assess nutritional status and prevalence of malnutrition or “risk of malnutrition” among older patients (≥70 years of age) who are undergoing elective non-cardiac surgery; 2) to measure the mobility status of this patient population; 3) to determine if nutritional status, strength, and mobility are either independently or jointly predictive of early postoperative complications; and 4) to compare the results from Aim #3 with the Fried Frailty score, to assess the relative value of these tools.

**Implications:** Dr. Groban and colleagues hypothesize that the information obtained from these simple, yet comprehensive, measures of patients' general health status can better predict early morbid events in older surgical patients than currently available organ-based systems, or measurement methods that are time-consuming and impractical in preoperative settings. It is feasible to incorporate these measures into a busy preoperative clinic; thus, the model, if validated, will be widely reproducible. Adequate screening of physiologic reserves in older patients scheduled for elective surgery could identify at-risk patients and enable proactive perioperative management plans (e.g., physical “prehabilitation” procedures, preoperative diets, or vitamin/nutrient supplementation) to reduce adverse postoperative outcomes in this large segment of the American population.

**See “2013 Grant Recipients,” Next Page**

## APSF Awards 2013 Grant for Monitoring Postoperative Ventilatory Depression

### “2013 Grant Recipients,” From Preceding Page

In addition to receiving the requested funding of \$149,382 for her project, Dr. Groban’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 Anesthesia Patient Safety Foundation.

Dr. Groban is also the recipient of the **Ellison C. “Jeep” Pierce, Jr., MD Merit Award**, which consists of an additional, unrestricted amount of \$5,000.



**Noa Segall, PhD**

*Assistant Professor, Department of Anesthesiology, Human Simulation and Patient Safety Center, Duke University Medical Center, Durham, NC.*

Dr. Segall’s Clinical Research project is entitled *“Forgetting to Remember: Prospective Memory Error as an Unexplored Patient Safety Risk.”*

**Background:** Prospective memory is the human ability to remember to perform an intended action following some delay. Failures of prospective memory may be the most common form of human fallibility. They have been found to be a significant source of error in aviation and other work domains, but have received little attention in the anesthesia literature. Demanding perioperative work conditions, which often require multitasking and are fraught with interruptions and delays, place a heavy burden on the prospective memory of anesthesia providers. For example, distractions—one source of prospective memory errors—account for 6.5% of critical anesthesia incidents. There is an urgent need to examine the effect of prospective memory and its failures on patient safety and the care delivery process in the perioperative environment.

**Aims:** The first objective of this project is to systematically quantify prospective memory errors of anesthesia providers. An additional goal is to determine to what extent failures of prospective

memory contribute to medical errors in this domain. The authors plan to interview anesthesia providers in order to understand situations and conditions that are conducive to forgetting to perform clinical tasks. Interview questions will also probe task types that were more likely to be deferred or omitted and cueing strategies, i.e., methods for recalling tasks at the right time. Dr. Segall and colleagues will analyze interview transcripts to categorize prospective memory failures along several axes, such as cue source (self-initiated or external), causes for task deferrals (disruptions, delays, etc.), and mechanisms for dealing with them. They will use these categories to guide observations and queries of anesthesia providers in the operating room in order to quantify and classify prospective memory failures and distractions that may cause them. The investigators will also analyze databases of anesthesia-related adverse events both retrospectively and prospectively to determine the extent to which prospective memory errors and near-misses affect patient safety in the perioperative environment.

**Implications:** The proposed work will have significant impact on our understanding of prospective memory as a source of errors in the operating room and will advance our ability to support clinicians’ cognitive work in this complex, busy environment.

In addition to receiving the requested funding of \$149,999 for the project, Dr. Segall’s application was designated as the **APSF/American Society of Anesthesiologists (ASA) President’s Research Award**, made possible by an unrestricted, \$150,000 grant from the American Society of Anesthesiologists.

Dr. Segall 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.



**Richard R. McNeer, MD, PhD**

*Assistant Professor, Department of Anesthesiology, University of Miami Miller School of Medicine, Miami, FL.*

Dr. McNeer’s Clinical Research project is entitled *“Investigation into the Reduction of Alarm/Listener Fatigue.”*

**Background:** Alarm/Listener Fatigue has been repeatedly identified as a major culprit in clinician dissatisfaction and impaired performance. Numerous factors in the auditory environment contribute to the generation of fatigue, including background noise, numerous false alarms, and lack of quality control over acoustic aspects of critical care settings. At a recent medical device alarm summit, a resounding directive to initiate research and develop methods for mitigating fatigue was issued. Although there is anecdotal evidence suggesting a link between fatigue and clinician dissatisfaction and impaired performance, this link has not been rigorously tested. These studies are difficult to conduct because, despite many recent efforts, there currently is no metric to quantify fatigue levels in controlled experiments.

**Aims:** The investigators plan to develop and validate a tool for assessing and predicting levels of fatigue, using an innovative combination of principles and techniques from the biomedical and music engineering domains. The investigators will record the auditory environment in critical care settings and decompose the recordings into features that can be characterized for contribution to fatigue. These data will then be used to develop a predictive model for fatigue that will be validated against physiologic and psychometric assessments of fatigue in a realistic, simulated critical care setting. Finally, they will utilize this predictive model in conjunction with difficult anesthesia cases in a simulated operating room, in order to correlate levels of fatigue with anesthesiologist performance and satisfaction. Since no methods currently exist for assessing and predicting fatigue of clinicians, efforts to reduce fatigue are difficult to evaluate; as an outcome of these studies, Dr. McNeer and colleagues plan to develop such a tool. Furthermore, this tool will elucidate the salient auditory components of the clinical environment that contribute significantly to anesthesiologist fatigue.

**Implications:** These findings could serve as a means of quality control monitoring, or as real-time feedback, which could be utilized by critical care appointees to detect and take steps to mitigate hazardous levels of fatigue. Importantly, the impact of this research could help reduce one of the causes of medical error, thus improving patient safety.

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

**See “2013 Grant Recipients,” Next Page**

# APSF Grants Develop the Next Generation of Patient Safety Scientists

“2013 Grant Recipients,”  
From Preceding Page



**Lara Brewer, PhD**

*Research Assistant Professor, Department of Anesthesiology, University of Utah, Salt Lake City, UT.*

Dr. Brewer's Clinical Research project is entitled “Reducing Postoperative Adverse Respiratory Events through Low-Cost Detection and Prompting for Patient Self-Rescue.”

**Background:** Two of the three most common patterns of unintended hospital deaths are caused by hypoventilation. In the postoperative period, the risk for hypoventilation leading to death is increased markedly by the administration of sedatives and opioids for the management of pain. The risk of opioid-induced respiratory depression in the postoperative period is greatest in the first 24 hours after initiation of opioids, and that risk is not correlated with the dose of administered opioid. Yet, postoperative patients are often monitored with pulse oximetry alone. State-of-the-art pulse oximetry monitoring is sufficient for tracking oxygenation, but is not a direct measure of ventilation. As an adjunct to pulse oximetry, monitoring the adequacy of ventilation in a cost-effective manner may be particularly useful when supplemental oxygen is needed to maintain acceptable oxygen saturation. In the event of drug-induced respiratory depression, a monitoring system should request a patient to breathe, inform the clinician of the observed pattern of respiratory depression, and warn of possible unintended, progressive over-sedation.

**Aims:** The objective of this research plan is to use low-cost sensors in a volunteer study to improve detection of drug-induced respiratory depression (defined as partial to complete airway obstruction, ventilatory depression, or both) and to verbally

prompt patient (volunteer) self-rescue to reduce the frequency of adverse respiratory events and increase patient safety.

**Implications:** The information from the low-cost sensors will be combined to reject motion artifact of the pulse oximetry signal and to discern between airway obstruction and ventilatory depression. With positive findings at completion of the proposed research, drug-induced problems with both oxygenation and ventilation can be accurately identified before they result in serious adverse respiratory events. If this APSF program is successful, missed postoperative drug-induced respiratory compromise events will be reduced, and patient safety will improve.

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

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

*Sorin J. Brull, MD, FCARCSI (Hon)  
Chair, APSF Scientific Evaluation Committee*



*Request for Applications (RFA) for the*

## **SAFETY SCIENTIST CAREER DEVELOPMENT AWARD (SSCDA)**

**Application deadline:  
November 1, 2013**

APSF is soliciting applications for training grants to develop the next generation of patient safety scientists.

In this initial, proof of concept RFA, we intend to fund one (\$150,000 over 2 years) Safety Scientist Career Development Award to the sponsoring institution of a highly promising new safety scientist. The award will be scheduled for funding to begin July 1, 2014.

Please contact [Stoelting@apsf.org](mailto:Stoelting@apsf.org) to request the SSCDA GRANT GUIDELINES AND APPLICATION.

## Letter to the Editor:

# Communicating and Managing the Difficult Airway: One Health Care System's Story

### **To the Editor:**

When we installed our Perioperative EMR, we created a category of “allergies” called Special Alerts. This includes items we felt would otherwise be difficult to find in the record, but had significant impact on ongoing and future care episodes. In addition to Difficult Intubation, we included Pseudocholinesterase Deficiency, Malignant Hyperthermia, Difficult Crossmatch, and Refuses Transfusion.

We selected the “allergy” option because it is patient specific, as opposed to event (encounter) specific, and as such will flow forward into each subsequent care event. We did have some pushback from

the IT folks implementing our house-wide EMR, because “nobody else does that.” So I'm happy to see someone else has done the same sort of thing.

I hadn't thought about the wristbands, and I will probably take that to my nursing executives.

*Christine A. Doyle, MD  
President, Coast Anesthesia Medical Group  
Vice-Speaker, California Society of Anesthesiologists  
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# Scientific Papers Highlight Patient Safety at the 2012 ASA Annual Meeting

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

Over 1,500 abstracts were presented at the 2012 American Society of Anesthesiologists Annual Meeting in Washington, DC. As in previous years, a number of these abstracts examined issues directly related to patient safety. This brief review will highlight several abstracts discussed at the meeting.

## Database Studies and Perioperative Complications

Several investigator groups utilized database information to determine factors associated with perioperative morbidity and mortality. Bauer et al. from the University of Michigan attempted to define the incidence and risk factors associated with severe maternal sepsis by reviewing a cohort of 2,758 deliveries complicated by maternal sepsis (BOCO8). Over the 10-year study period, the incidence of severe sepsis increased significantly from 17.1% to 30.3%. In addition, mortality increased during the same time period from 2.2% to 4.9%. Factors associated with severe sepsis included chronic renal insufficiency, chronic liver disease, stillbirth, retained products of conception, cesarean delivery, hypertensive diseases of pregnancy, chronic heart failure, cerclage during pregnancy, and preterm delivery (<37 weeks) (BOCO8). Investigators from the Cleveland Clinic (A015) reviewed electronic records from 31,148 ASA 3-4 adults undergoing non-cardiac surgery under general anesthesia to investigate the effect of etomidate induction on mortality and hospital length of stay. Propensity scoring was used to account for some confounding factors (i.e., ASA status, Charlson comorbidity score, and emergency surgery) between 2,143 patients given etomidate and 5,231 patients given propofol. Using multivariable logistic or Cox proportional hazard regression, the authors reported a 2.3-fold increase in 30-day mortality postoperatively in patients given etomidate compared with those administered propofol. Furthermore, patients who received etomidate were 18% less likely to be discharged at anytime in the postoperative period (A015). Sampat et al. from the University of Chicago (A1173) used the Nationwide Inpatient Sample (NIS) to examine the incidences of postoperative visual loss (POVL) and corneal abrasions in patients undergoing either robotic assisted (RAP) or open radical prostatectomy (OP). A total of 136,711 surgical cases were reviewed over a 10-year period; the overall incidences of POVL and corneal abrasions were 0.22% and 0.15%, respectively. Rates of POVL and corneal abrasions increased nearly 10-fold during the years of 2000-2009, which corresponded to the period of time when the robotic approach became the predominant surgical technique. The rate of total POVL and corneal abrasions increased with RAP when compared to OP (A1173).

Two database studies focused on outcomes associated with duration of red blood cell (RBC) storage. Gazmuri et al. from the Cleveland Clinic reviewed data from 86,483 patients undergoing a variety of general surgery cases. These investigators found no increased risk of postoperative mortality due to increased mean storage duration of RBCs (A073). Contrary to this study, other investigators from the same institution examined the effect of prolonged RBC storage on clinical outcomes in patients undergoing orthotopic liver transplantation (OLT) (A505). In a sample of 915 patients, those OLT recipients who received older blood ( $\geq 15$  days) had an increased risk of either graft failure or mortality (HR (95% CI): 1.47 (1.02, 2.11), when compared to those patients receiving younger blood (<15 days) (A505). The age of blood may affect different populations in different manners.

## Closed Claims Database

Several studies used the Closed Claims database to investigate the incidence and risk factors for perioperative complications. Mehta et al. from the University of Washington reviewed 9,536 closed claims to examine patient injuries from anesthesia gas delivery equipment (A1072). Anesthesia gas delivery claims decreased from 4% of claims in the 1970s to 1% from 2000-2010. The specific claims in the later era included vaporizer problems (N-13), breathing circuit problems (N-10), anesthesia machine problems (N-7), ventilator problems (N-5), and supplemental oxygen line events (N-4). Payments in the later era also went down substantially (approximately a \$600,000 reduction in median payment). The same group used the closed claims database (N-9,536) to compare burn injuries from warming devices during 1995-2010 vs. those that occurred during 1970-1994 (A1079). Both periods had the same 1% incidence of burn injuries from warming devices. The most common cause of burn injury from forced air warming devices was use of the hose without the appropriate blanket attachment (A1079). The buttocks, legs, and axilla were the most common areas burned by warming devices or materials. Payments for new burns were higher in the newer era when compared to the older era ( $p < 0.01$ ). Esmail et al. from the University of Washington reviewed the closed claims for airway injuries that occurred in 1995 or later (A1081). The most common airway injury was esophageal perforation, which accounted for 24% of airway injury claims. Other sites reported included vocal cord or laryngeal injury, tracheal tear, and pharyngeal injury. The primary causes of esophageal injury were due to difficult intubation or esophageal equipment (e.g., transesophageal echocardiography probe or esophageal dilators/anvils for gastric surgery). Forty-three percent of patients with esophageal perforation had preexisting esophageal pathology. Similar to

previous analyses, death from esophageal perforation occurred in 19% of cases. Esophageal injury related payments were significantly higher than payments for other airway injury claims (median payment-\$117,900). The same institution used the closed claims database to compare central venous catheter (CVC) injuries between 1995-2009 and 1970-1994 (A1075). Fifty-nine percent of CVC injury related claims resulted in either death or permanent brain damage and this incidence did not differ between time periods. Complications related to access increased significantly over time (63% in 1970-1994 vs. 87% in 1995-2009). Carotid cannulation/puncture was the most common complication in both time periods and increased in the later time period to 24% from 14% in the earlier period. During 1995-2009, 50% of CVC claims were evaluated to be potentially preventable by using ultrasound and 41% of the claims could have been prevented by using pressure wave form monitoring. Sixty-one percent of CVC claims resulted in payment, but there was no difference in payment amounts between the 2 time periods (A1075).

## Anesthesia Type and Outcomes

Two abstracts focused on whether anesthesia type affects perioperative outcomes. Fiscaro et al. from Jefferson Medical College investigated the decision making process involved in selecting general anesthesia (GA) or monitored anesthesia care (MAC) for patients undergoing endoscopic retrograde cholangiopancreatography (ERCP) (A502). Of the 4,727 ERCP cases evaluated, 38% of patients received GA. Factors associated with patients undergoing GA for ERCP were increasing BMI ( $> 30$  kg/m<sup>2</sup>), emergency case status, higher ASA physical status, increasing anesthesia experience for ERCPs by the supervising anesthesiologist, and cases started after 12 pm. There was a 1.7% conversion rate from MAC to GA. Airway events accounted for 50% of the changes in anesthetic technique, and full stomach considerations accounted for 30% of the changes in anesthetic technique (A502). Case duration was significantly longer with the GA technique when compared to MAC. Cata et al. from MD Anderson Cancer Center investigated anesthesia factors that may contribute to longer term survival and recurrence free survival (RFS) in patients undergoing surgery for non-small cell lung cancer (A743). Among the 204-patient cohort, the long-term survival was 63% and the RFS was 53%. Anesthesia time longer than 270 minutes was significantly associated with a lower RFS. Other variables associated with poor long term survival or RFS included age  $> 65$  years, BMI  $< 25$  kg/m<sup>2</sup>, ASA 3 & 4, Stage II-III cancer, current smoking status, and COPD. Perioperative

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# Patient Safety Abstracts Prominent at 2012 ASA

## “Abstracts,” From Preceding Page

blood transfusion was not associated with poor oncological outcomes (A743). Further studies are warranted to validate this association of prolonged anesthesia time and poor RFS.

## DeLiT Trial Results

The DeLiT trial is a clinical investigation examining the impact of glycemic control, steroid use, and depth of anesthesia on major outcomes after non-cardiac surgery. Abdelmalak et al. at the Cleveland Clinic enrolled 381 patients in a study utilizing a 3-way factorial design to investigate 3 important interventions (intravenous dexamethasone vs. placebo, intensive (80-110 mg/dl) vs. conventional glucose (180-200 mg/dl) control, and lighter vs. deeper anesthesia) on major morbidity (BOC05). In an abstract presenting data on glycemic control, the authors reported that patients randomized to receive intensive control did not have a reduction in major morbidity. In addition, no severe hypoglycemic episodes (<40 mg/dl) were noted. The authors also reported their findings from the study regarding the effect of corticosteroids and depth of anesthesia on acute postoperative pain (A510). In this trial, neither light anesthesia nor dexamethasone was associated with improved pain scores or a reduction in opioid consumption (A510). Data from the DeLiT trial examining the effect of steroids on perioperative inflammation (assessed by measuring plasma hsCRP levels) and clinical outcomes after non-cardiac surgery were also presented (A745). Both the mean hsCRP and change in hsCRP levels were significantly lower in patients receiving dexamethasone versus placebo on postoperative days 1 and 2 (A745). While steroid administration did not have a direct effect on major morbidity, changes in hsCRP from baseline to the maximum value on postoperative days 1 and 2 were associated with an increase in major morbidity. Another arm of the DeLiT trial reported the effect of depth of anesthesia on outcomes following non-cardiac surgery (A1200). The median BIS values were greater in the lighter anesthesia group when compared to the deeper anesthesia group (51 vs. 43, respectively). The anesthetic depth had no effect on major morbidity. There was also no association between the incidence of any major morbidity and median patient BIS or percent of time spent under deep anesthesia. Overall, the DeLiT trial did not show significant outcome benefits with the use of tight intraoperative glycemic control, steroid use, and lighter anesthesia.

## Monitoring For Consciousness and Respiratory Function

Several abstracts this year focused on appropriate monitoring strategies for patients undergoing sedation procedures or recovering in the PACU. Authors from the University Medical Center, Utrecht, Netherlands, performed an open, stratified, randomized controlled

trial in 427 healthy adult women during outpatient gynecological procedures (A584). Patients undergoing propofol sedation were randomized to standard respiratory monitoring or standard monitoring plus capnography. Results suggested that there was no difference in the incidence of hypoxic episodes between the 2 groups. However, the number of airway interventions (authors did not specify the types of interventions) performed was significantly increased in the capnography cohort (A584). Another study (A768) examined whether a TSE mask (face tent mask) was more efficient than high nasal cannula oxygen flow in reducing severe desaturation events in patients undergoing deep propofol sedation during upper GI endoscopy. Two cohorts of patients were evaluated, those with a TSE mask (N=171) and those with a nasal cannula only (N=64). The data demonstrated that the TSE mask was more effective than nasal cannula high oxygen flow in reducing severe desaturation events requiring bag-mask ventilation (A768). Mestek et al. from Boulder, Colorado, developed an algorithm (RRoxi) to derive respiratory rate from the photoplethysmogram signal (i.e., pulse oximetry) and compared the accuracy of this modality with a reference measurement of respiratory rate from capnography in 12 patients in the PACU that underwent a variety of elective surgeries (A094). The agreement between RRoxi and the reference was  $R^2=0.89$ . Pulse oximetry derived respiratory rate provided continuous measurements during 97% of the monitoring period. Further studies are required to investigate alternative methods to reduce critical desaturation events during and after anesthesia sedation cases.

## Factors Related to Nosocomial Infections

Punj et al. from the All India Institute of Medical Sciences screened a total of 325 mobile phones of health care workers (HCWs) for bacteria (A593). This study showed that 94.5% of the mobile phones screened had evidence of bacterial contamination. Gram negative strains were isolated from 31.3% of the mobile phones, while 52% of the mobile phones were found to have staph aureus. This study also reported that only 6% of HCWs disinfected their phones. Another study implemented a program to improve the compliance of hand washing among HCWs in a pediatric operating room (A592). Preliminary data were collected and a subsequent education presentation was provided on recommendations from the Centers for Disease Control (CDC) and the World Health Organization (WHO). There was a significant increase in hand washing compliance in the post-education era from 61% to 73%. The authors suggest that further steps are required in order to achieve a targeted compliance of 90%, such as increasing the number of alcohol dispensers in the operating room and auditing the functionality of the dispensers on a regular basis.

## Vasopressors and Cerebral Oxygenation

Two abstracts investigated the effect of using vasopressors on cerebral oxygenation measured by cerebral oximetry. Kalmer et al. from the University Medical Centre Groningen, Groningen, Netherlands, performed a double-blinded, randomized controlled trial of 60 patients undergoing general anesthesia for ophthalmic surgeries to investigate the effect of atropine, norepinephrine, and phenylephrine on mean arterial pressure (MAP), heart rate (HR), cardiac output (CO), and cerebral tissue oxygenation (SctO<sub>2</sub>) (A840). When the MAP dropped below 90 mmHg, either norepinephrine or phenylephrine was administered randomly. When the HR dropped below 60 bpm, patients were treated with atropine. Results suggested that while both phenylephrine and norepinephrine increased MAP, phenylephrine decreased both CO and SctO<sub>2</sub>. Norepinephrine preserved CO, but did decrease SctO<sub>2</sub> to a lesser degree than phenylephrine. Lastly, atropine administration was associated with an increase in MAP, CO, and SctO<sub>2</sub> (A840). Allen et al. from Duke University performed an observational study in 14 parturients undergoing spinal anesthesia for cesarean delivery (A134). The authors compared the effects of a phenylephrine bolus versus a prophylactic infusion of phenylephrine for the treatment of hypotension (to maintain MAP within 20% of baseline values) on cerebral tissue oxygenation (SctO<sub>2</sub>). Cerebral tissue oxygenation decreased significantly in both groups over time. The phenylephrine infusion group experienced a greater reduction in SctO<sub>2</sub> measurements than the bolus group, presumably due to the higher doses used and the longer administration time (A134). These findings suggest that, although phenylephrine increases systemic blood pressure, cerebral oxygenation may be compromised by this therapy.

## Miscellaneous

Several abstracts addressed issues related to thrombosis and embolism. Glick et al. from the University of Chicago investigated the incidence of postoperative deep venous thrombosis (DVT) in the lower extremities following elective surgery and the associated perioperative risk factors (A597). The DVT incidence was 1.3% among all 231 patients included and 4.5% among patients undergoing orthopedic surgeries. The authors suggested that the following risk factors may increase DVT incidence: longer hospital stays, periods of immobility after surgery and orthopedic procedures. The low overall DVT incidence may reflect the implementation of perioperative measures to reduce DVTs, although DVT prophylaxis was given to only 54% of patients (A597). Ono et al. from Fukuyama City Hospital, Fukuyama, Japan, investigated the effects of continuing and discontinuing aspirin on hemorrhagic and thrombotic risks in 498 patients who underwent open urological cancer

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## Difficult Airway and Videolaryngoscopy Studies Presented at ASA Abstract Session

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surgery (A495). The main finding was that the risk of perioperative transfusion was not increased by preoperative aspirin continuation. However, the incidence of thromboembolic events increased by more than 10-fold in those patients who discontinued aspirin preoperatively. Jun Kim et al. examined the incidence of venous air embolism (VAE) in 100 ASA I parturients undergoing cesarean section under general anesthesia (A130). The presence of air emboli was evaluated by 2 cardiac anesthesiologists who used intraoperative transesophageal echocardiography. The observed incidence of VAE was 94%. Those women who received uterus externalization had a higher grade VAE than those without uterine manipulation.

Another study investigated the relationship between the length of oral intake restriction and circulating blood volume by using the stroke volume variation (SVV) method (A367). Ninety-seven patients undergoing either otolaryngological or breast surgery were enrolled. Patients were randomly assigned to either restriction of clear liquid intake for 2 (short period group, SPG) or 4 (long period group, LPG) hours prior to surgery. There was no significant difference in the amount of clear liquid intake between groups. Both groups had dehydration as indicated by the estimated SVV. However, the degree of dehydration was significantly greater in the LPG when compared to the SPG. This study suggests that even a 2-hour clear liquid restriction is associated with dehydration.

As in previous years, a series of abstracts discussed trends in techniques for intubation and extubation. Bellmore et al. from the Mayo Clinic investigated the impact of the introduction of video laryngoscopy (VL) on the utilization of fiberoptic bronchoscopy (FOI) to secure airways (A306). The authors utilized the Mayo Clinic database to compare pre-VL airway management techniques (N-10,176) with post-VL ones (N-12,617). During the 5-year study period, VL use increased significantly from 0% to 8.65%, while FOI decreased from 2.79% to 0.97%. The use of direct laryngoscopy also decreased significantly (from 82.24% to 72.88%), while the use of LMAs increased significantly from 9.59% to 11.52%. Another observational study of 44 patients with difficult airways described experiences with extubating this patient population with an airway exchange catheter (AEC) combined with the cuff leak test (A770). With this technique, there were no reintubations required. Oxygen saturations were  $\geq 95\%$  in all patients post-extubation. The AEC remained in all patients <4 hours post-extubation. Thirty-eight out of 48 patients tolerated the AEC without cough or discomfort, while the other 10 patients experienced a mild cough or discomfort. Of the 44 patients who

received a cuff leak test, the test was positive in all patients. The authors concluded that the AEC coupled with the cuff leak test may enhance the safety of extubation of the difficult airway (A770).

This brief review summarized only a small number of abstracts on patient safety presented at the 2012 Annual Meeting. This is not an endorsement of the methods, results, or conclusions of any particular abstract. 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).

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*The Anesthesia Patient Safety Foundation (APSF) announces the availability of the 18-minute educational video:*

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### Letter to the Editor:

## A Critical Incident in Anesthetic Machines:

### Remember Different Countries Have Different Electrical Standards

#### To the Editor:

Over a period of 2 weeks, in 4 different operating rooms, 4 monitors attached to 4 different Aisys Datex-Ohmeda anesthesia machines (General Electric, USA) went blank while in use. A burning smell was noticed in each case by the attending anesthesiologist. A portable monitor was hastily replaced in each case. Fortunately, no harm came to the patients.

The Aisys machines, 7 in total, were bought from General Electric, USA, 2 1/2 years previously. Unfortunately, the supplied transformers had an incorrect rating. The 3 ampere fitted transformer was unable to power the larger 15-inch screen and burned out.

All 7 machines had the faulty 3 ampere transformers removed and replaced with new 5 ampere transformers. The machines have worked well ever since.

There are over 100 Aisys machines in South Africa that have not presented any problems. These machines use a smaller 12-inch screen that is powered by the patient monitor rack via the on-board UPS. battery supply back up. No external supply is used.

We bring these cases to your readers' attention for the following reasons:

1. It is imperative that new machines coming from "overseas" are up to the electrical standards of the recipient country. Both the supplier and the local hospital bioengineering department have a responsibility regarding this. As far as we know this is the first documented case of this problem.
2. This may not be an isolated incident. It may have happened before and may not have been reported.

*Alan Hold, MB, FFA  
Durban, South Africa*

*John G Brock-Utne, MD, PhD  
Stanford University Medical Center  
Stanford, California, USA*

*Check out the APSF website at*

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*The Anesthesia Patient Safety Foundation (APSF)  
announces a Request for Proposals (RFP) to study the  
implementation and performance of the*

## **APSF Pre-anesthetic Induction Patient Safety Checklist (PIPS)**

The deadline for receipt of a proposal is November 1, 2013 for a grant scheduled for funding to begin May 1, 2014.

- APSF intends to provide up to \$200,000 for a period not to exceed 2 years.
- The proposed study should be a prospective observational clinical trial utilizing the APSF PIPS checklist with a matched and/or parallel control group not cared for with the utilization of the checklist.
- The proposals will be evaluated by a scientific review committee selected by APSF.
- Proposals will be assessed for merit based primarily on their likelihood of meeting the contractual objectives outlined in the RFP as well as the proposed study's scientific rigor, innovation, and cost-effectiveness.
- The principal investigator must be an experienced scientist from a North American institution.
- A contract mechanism will be used and funds will be awarded to a single institution.
- Funding will be contingent upon acceptable modifications to the proposal based on feedback from the APSF review committee as well as appropriate IRB and institutional approvals.

*Please contact [Stoelting@apsf.org](mailto:Stoelting@apsf.org) to request grant guidelines and an application.*

### **A Statement by the Executive Committee of the APSF**

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

## ANESTHESIA PATIENT SAFETY FOUNDATION

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## Letter to the Editor:

# Exchanging a CLIC Absorber in the Middle of the Surgery

### To the Editor:

We report here that the ventilator of the Fabius\_R GS premium anesthesia workstation (Dräger Medical Inc., Lübeck, Germany) worked adequately with a defective Drägersobe\_R CLIC 800+ Disposable Absorber (Dräger Medical), which was replaced during surgery.

The Fabius\_R GS premium anesthesia workstation passed the built-in automated check-out. The patient was scheduled for gynecological laparoscopic surgery. General anesthesia was administered with no difficulty and was maintained with air, oxygen, and sevoflurane. Total fresh gas flow was 41/min with 1.5% sevoflurane. The gas analyzer at the Y-piece showed that  $\text{FiO}_2$  was 38%, and the inspired and expired concentrations of sevoflurane were 1.4% and 1.1%, respectively. The ventilator setting was in pressure-controlled mode. Because of an elevation of inspired carbon dioxide fraction during surgery, we replaced the device with another Drägersobe\_R CLIC 800+ Disposable Absorber with the ventilator. The disposable absorber was replaced, but a decrease in  $\text{FiO}_2$  to 34% was noted subsequently; the inspired and expired sevoflurane concentrations were decreased to 1.1% and 1.0%, respectively; a slight increase in the bispectral index score was observed; and a slight smell was noted, which was suspected to be the inhaled anesthetic. A leak from the absorber was inferred. However, no obvious change was noticed in the performance of the ventilator, including tidal volume and end-tidal carbon dioxide level, and no alarm rang. We turned

up the vaporizer dial but did not inspect the absorber. Sevoflurane administration was terminated after surgery, the patient's spontaneous breathing resumed, and the ventilator was switched to manual ventilation mode. We noticed that the breathing bag had collapsed, and sufficient fresh gas was not delivered from the inspiratory port of the breathing system in spite of increasing the total fresh gas flow and oxygen flush. The patient's tracheal tube was disconnected from the anesthesia circuit. An external oxygen supply and a manual ventilation bag were promptly obtained, and oxygen was supplied to the patient. Extubation was performed after spontaneous breathing was fully restored. No hazardous effects were observed. A later inspection of the absorber revealed a defect of approximately 2 cm in diameter at the edge of the attachment lid (Figure 1).

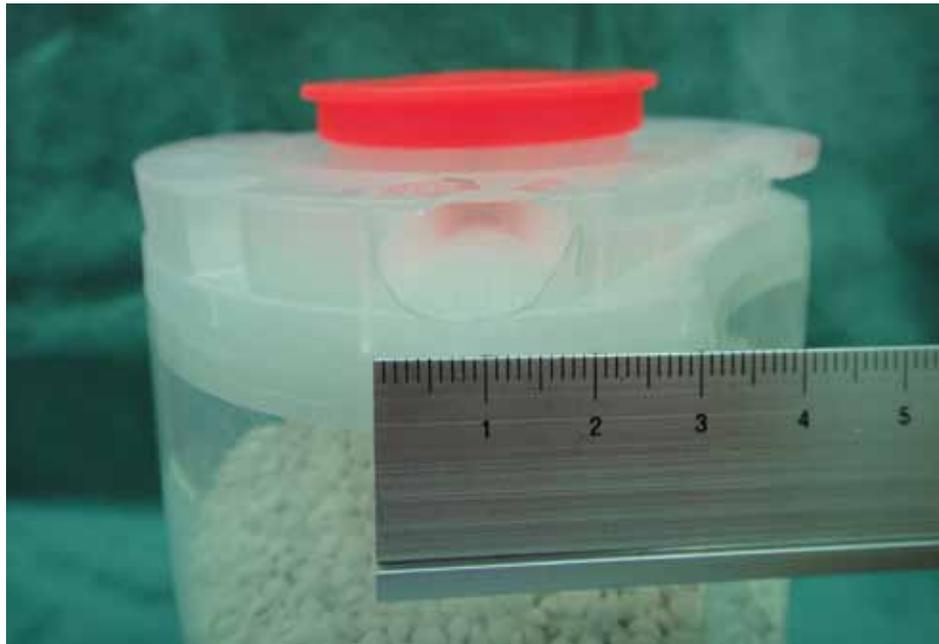
The Fabius\_R GS premium anesthesia workstation has a piston-type ventilator and a fresh gas decoupling (FGD) valve, which is located between the fresh gas inlet and the ventilator circuit<sup>1</sup> (Figure 2). The carbon dioxide absorber with the CLIC adapter, which is designed to enable the canister to be exchanged during surgery<sup>2</sup>, is located between the fresh gas inlet and the breathing bag. During the inspiratory phase of mechanical ventilation, the FGD valve shuts off fresh gas flow to the ventilator, and part of the excess gas moves to the breathing bag through the absorber. During the expiratory phase, the FGD valve opens and the piston-type ventilator creates slight negative pressure to allow fresh gas and gas contained in the breathing bag to

refill the ventilator.<sup>3</sup> In our case, the anesthesia machine with the defective disposable absorber operated adequately except for the changes in  $\text{FiO}_2$  and inspired and expired concentrations of the inhaled anesthetic. We considered that the FGD valve spared the anesthesia circuit on the patient side from the leakage site on the absorber during the inspiration phase of mechanical ventilation; thus, a low pressure alarm did not sound. During the expiratory phase, ambient air was drawn from the hole in the defective absorber into the anesthesia circuit; therefore, a low fresh gas alarm did not sound.

A system leak test with the defective CLIC absorber was performed later, but the built-in system leak test could not be started, because the internal pressure in the circuit with closing of the Y-piece was not raised to the required level. A trial operation of the ventilator with the defective absorber revealed that positive pressure ventilation could be provided with breathing bag collapsed due to entrainment of room air through the hole in the canister. The defect in the canister may be detected during visual inspection and during a leak test of the breathing circuit.

As stated in a previous report,<sup>4</sup> any part of an anesthesia machine and circuit that passes a leak check should not be replaced. The Fabius\_R GS and the other Dräger anesthesia machines with the CLIC system allow replacement of the disposable absorber without interrupting the ventilation and the anesthesia delivery. The disadvantage of the CLIC absorber when a leaking absorber canister is exchanged for an

**See "Line Leak" Next Page**



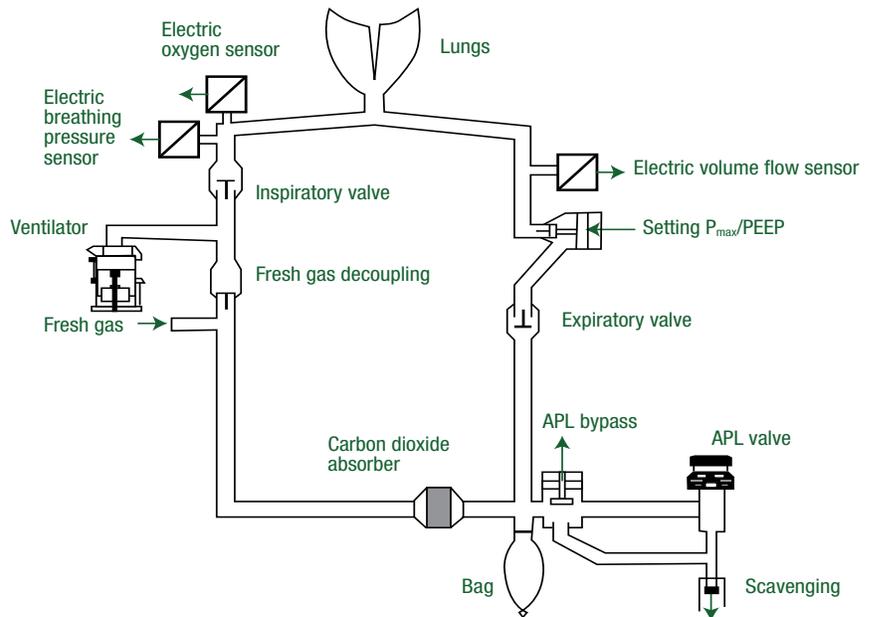
**Figure 1:** The defective CLIC absorber. A) The canister in place on the machine. The black arrow points to the defect. B) A close-up of the hole.

# Visual Check of the CLIC Absorber Itself is Crucial to the Integrity of the Circuit

## “Line Leak” From Preceding Page

exhausted non-leaking canister during surgery has been presented.<sup>2</sup> In our case, the aspects indicating the defect in the absorber were decreased FiO<sub>2</sub>, decreased inhaled anesthetic concentration, the smell of the inhaled anesthetic, and the collapsed breathing bag, which were derived from entrainment of room air and leaking exhaled gas. Neither visible nor audible alarms were activated. If these signs are missed, a hazardous situation may result during spontaneous ventilation, depending upon the resistance of the hole in the canister. In an adult the inspiratory flow rate may be as great as 15 liters/minute, which cannot be satisfied by only the fresh gas inflow. The remaining inspired gas must then come from either the hole in the CLIC absorber (entraining room air) or the breathing bag if it is distended resulting from a small leak in the absorber. If the hole in the canister creates a large leak, spontaneous ventilation cannot be assisted by squeezing the breathing bag. The visual check of the replacement canister is essential since a leak test cannot be performed during surgery. Future design changes should incorporate some methodology for alarming or alerting the clinician of a leak in the CLIC canister.

Yuki Kuruma, MD, Yuya Kita, CE, Shigehisa Fujii, CE, Department of Anesthesiology, Department of Clinical Engineering, Saiseikai Matsusaka General Hospital.



**Figure 2:** Gas flow diagram. Fabius\_R GS premium anesthesia workstation. Modified from an original figure, according to the Instructions for Use: Fabius\_R GS premium Anesthesia Workstation Software 3.n.2. Information furnished courtesy of Dräger Medical Inc. APL, adjustable pressure limitation; PEEP, positive end-expiratory pressure; Pmax, pressure limitation in volume mode.

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## APSF 2012 Award Winner for Best Scientific Display



Members of the APSF Committee on Education and Training present the Ellison C. ("Jeep") Pierce, MD, Best Scientific Exhibit in Patient Safety at the ASA meeting on Sunday, October 14, 2012, in Washington, DC.

Photo displays award recipients Franco Resta-Flarer, MD, and Jonathan B. Lesser, MD, Robert B. Bolash, MD, and Keith Haller DO, from the Dept of Anesthesiology, St. Luke's-Roosevelt Hospital, New York, NY.

Also pictured are APSF Education Committee members: Maria Magro, CRNA; Richard Prielipp, MD, FCCM; Sem Lampotang; Tricia Meyer, Pharm D; Deb Lawson, Certified Anesthesia Assistant; John O'Donnell, CRNA.

The authors displayed a hands-on exhibit noting the extreme airway challenge of infants with vascular abnormalities of the airway. The authors demonstrated effective algorithms using video laryngoscopes and other advanced airway devices, and also provided parents with medical documents that summarized the most practical strategies.

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**Letter to the Editor:**

**The Joint Commission Sentinel Event Alert #49 Motivates Monitoring Strategies**

**To the Editor:**

The Joint Commission (JC) Sentinel Event Alert #49 on the safe inpatient use of opioids (issued August 2012) has motivated many hospital administrators and medical staff to explore monitoring strategies that are aligned with its recommendations.<sup>1</sup> The APSF has been a catalyst in driving awareness on the dangers of parenteral opioids, convening 2 conferences and numerous articles in its *Newsletter* to this serious patient safety issue since 2006. The JC Sentinel

Event Alert specifically calls out inadequate monitoring as the root cause of many opioid-related adverse events and references the 2012 APSF recommendations for improved monitoring of patients receiving opioids on medical/surgical wards.<sup>2</sup> The following table reconciles the monitoring recommendations from the JC Sentinel Event Alert with those from the APSF as they relate to patient monitoring in an effort to highlight similarities and differences, and guide electronic monitoring “best practice.”

*Frank Overdyk, MSEE, MD  
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Professor, Hofstra North Shore-LIJ School of Medicine  
Melville, New York*

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2. <http://www.apsf.org/announcements.php?id=7>. Accessed 12/31/2012.

JC Sentinel Event #49 Clinical Monitoring Recommendations		APSF 2011 Essential Monitoring Strategies		Consensus/Comment
DOs	DON'Ts	DOs	DON'Ts	
Serial clinical assessments of: <ul style="list-style-type: none"> <li>• quality/adequacy of respiration</li> <li>• depth of sedation</li> </ul> Serial assessments should: <ul style="list-style-type: none"> <li>• occur often enough to observe <i>trends</i></li> <li>• be increased in frequency after dosage changes</li> </ul>		Structured clinical assessment of sedation and level of consciousness is vital to early detection of respiratory depression.	Do not use continuous electronic monitoring in place of nursing assessments of ventilation, oxygenation, and level of consciousness.	1) Do not substitute monitors for clinical assessments. 2) Observation of <i>trends</i> in vital signs is key to early detection of respiratory depression.
Pulse oximetry (SpO <sub>2</sub> ) can be used to monitor oxygenation.	Do not rely on SpO <sub>2</sub> alone, especially on patients receiving supplemental oxygen.	All patients should have SpO <sub>2</sub> monitored continuously (see below).		
Capnography can be used to monitor ventilation and provides added value when supplemental oxygen is being used.		Capnography/modalities that measure ventilation/airflow are indicated when supplemental oxygen is used.		Pulse oximetry's effectiveness as a monitor is impaired by supplemental O <sub>2</sub> .
When using pulse oximetry or capnography, it should be used continuously.	Do not rely on "Spot Checks" of SpO <sub>2</sub> or ventilation.		Do not rely on "Spot Checks" of SpO <sub>2</sub> or ventilation.	"Spot Checks" SpO <sub>2</sub> values are misleading as patient is stimulated.
Screen patients for risk of over sedation/respiratory depression. Risk Factors: <ul style="list-style-type: none"> <li>• Sleep apnea/sleep disorder</li> <li>• Morbid obesity</li> <li>• Snoring</li> <li>• Old age: OR increases &gt; 61 yo</li> <li>• Opioid naive/ dependent</li> <li>• Co-admin of sedatives</li> <li>• Long duration of anesthesia</li> <li>• Preexisting major organ dysfunction</li> <li>• Smoking</li> </ul>		Continuous electronic monitoring of oxygenation and ventilation should be available and considered for ALL patients.	Risk stratification by screening criteria are likely to miss life threatening respiratory depression.	The risk factors identified by JC are inclusive of the vast majority of inpatients. Risk stratification places patients at risk for undetected life threatening respiratory depression.
		Monitor continuous oxygenation and ventilation from central location/ provide electronic notification to caregivers.		Telemetry and provider notification are critical elements in the detection and rescue "loop."
		Monitors should incorporate multiple physiologic parameters and smart alarms to improve specificity.	Single threshold alarms; major cause alarm fatigue.	Alarm fatigue is a great impediment to adoption of continuous electronic monitoring.

Letters to the Editor:

# Reader Calls for Standard Label Colors

**To the Editor:**

Inadvertent administration (“syringe swapping”) of anesthetic drugs can be a cause of morbidity and mortality.<sup>1,2</sup> In addition to the basic but essential need to read medication labels, a color coding system of common anesthetic drug classes to decrease medication errors was established by the American Society for Testing and Materials International (ASTM International) and the International Organization for Standardization (ISO).<sup>3</sup> Most of us should be familiar with the standard colors, e.g., light blue for narcotics, red for muscle relaxants, grey for local anesthetics, and so forth.

Recently we discovered a supply of drug labels in our holding room area that did not follow the ASTM color guidelines. The label for morphine was the same color as the ASTM guideline for benzodiazepines, the midazolam label was the same blue color reserved for narcotics, and the label for fentanyl was pink. It turns out that someone in the pharmacy who was not familiar with anesthetic drug label standards ordered these labels for the holding room. The labels were pulled, and replaced with labels of standard color recommendations.

While label color should not be used in lieu of label reading, undoubtedly anesthesia practitioners rely on color of labels, vaporizers, and so forth to a great degree—perhaps more than we should.<sup>4</sup> But certainly the use of nonstandard label colors is a recipe for disaster. Anesthesia providers should be active in scouting their work environment for such items, and discard them immediately when found.

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# Spinal Cord May Be Vulnerable to Ischemia in Beach Chair Position

**To the Editor:**

I would like to add yet another factor in considering the potential problems resulting from the “Beach Chair” position, namely, that like the brain, the spinal cord is a structure that autoregulates its blood flow in a similar fashion, normally between mean arterial blood pressures of 60 and 120 mmHg.<sup>1</sup> Below the lower and above the upper limit of autoregulation, flow becomes pressure dependent and spinal cord ischemia may be exacerbated if the spinal cord perfusion pressure is sustained below the lower limits of autoregulation. The adequacy of spinal cord blood flow has important structural components associated with arterial input, and a number of authors have shown a paucity of radicular arteries in the cervical spinal cord in autopsy material.<sup>2,3</sup> Thus, Manners<sup>4</sup> noted in a post mortem review of 215 spinal cords, that 45 had only 1 radicular cervical artery. In addition, the lower cervical spinal cord is a vulnerable “watershed” area as it is farthest from collateral pathways.<sup>5</sup>

Confirmation of the clinical response can be seen in Jellinger’s analysis of the distribution of chronic, ischemic cord lesions in 60 cases of advanced arteriosclerosis.<sup>6</sup> In the Manners postmortem review just mentioned, he described 25 spinal cord infarctions in

geriatric cases in which the selective site for small softening was at the C5-C8 levels, with the greatest numbers of infarcts being at the C6 segment. In essence we are dealing with a region of the spinal cord, the cervical area, having the highest functional metabolic demand with a very marginal blood flow. With our large geriatric population coming to surgery, these spinal cord vascular-rheological considerations are critical in the management of these patients and the utmost care should be manifest in the use of deliberate hypotension as emphasized by the Letters to the Editor by Cullen and Kirby<sup>7</sup> and Munis<sup>8</sup> in prior issues of the *APSF Newsletter*. While we may think that the cerebral perfusion pressure in a given patient may be adequate for the brain, the same perfusion pressure may be inadequate for the metabolic requirements of the spinal cord and cause an ischemic state which, if prolonged, could lead to dire neurological consequences. A more complete review of the factors concerning autoregulation and spinal cord perfusion pressure can be seen in the paper by Albin and coworkers.<sup>9</sup>

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## Coring and Fragmentation May Occur With Rubber Cap and Blunt Needles

A 45-year-old female was being prepared for induction of general anesthesia for a total thyroidectomy. An induction dose of propofol was drawn through a disposable syringe attached to a blunt plastic needle to pierce the rubber stopper. After the needle was withdrawn, a dark object was seen at the bottom of the propofol vial. Upon close inspection, a cored piece of rubber from the vial's rubber stopper was identified (Figure).

The issue of coring, the shearing off of a portion of the rubber stopper from a medication vial as it is pierced has been described in the past. The frequency of such incidents seems to be rising as the use of blunt plastic tips increases. Per one study, the incidence of coring was 29% with blunt plastic needles as opposed to only 4% with acutely beveled sharp steel needles.<sup>1</sup> The cored fragments can be difficult to visualize because of their small size, the masking effect of the vial labels, or the medication opacity.

Exposure to the macro and microscopic rubber fragments has been linked to latex allergy as well as embolization into small vessels causing ischemia.<sup>2</sup> Aspiration of a cylinder shaped rubber core back into the syringe followed by introduction into a patient's blood stream might seem an unlikely combination of events. A case of near-embolization of the rubber core from a propofol vial that lodged itself into the 24-gauge angiocath interrupting the propofol infusion and setting off the high-pressure pump alarm during a rigid bronchoscopy has been reported.<sup>3</sup>

Microscopic rubber particles can contaminate the medication and upon systemic administration may cause latex allergy. Isolated cases of systemic reactions to latex allergens have been reported and often associated with the use of multidose vials.<sup>4</sup>

The amount of latex protein in the multidose vials was determined to be extremely low in 1 study after the rubber stopper was punctured 40 times.<sup>5</sup> As



A cored piece of propofol rubber cap after the cap was pierced with a blunt tip plastic needle to draw the medication. Such contamination has been linked to latex sensitivity and fragment embolization.

we try to protect personnel and patients from the dangers of needle sticks, we may be increasing exposure of our patients to unintended risks.

The use of blunt needles with filters may prevent aspiration of the macro rubber particles. Removing the rubber stopper from the vial altogether addresses the macro or microscopic particle contamination concerns but may increase the potential for errors in dosage, dilution, contamination, and waste.<sup>6</sup> Each health care institution should therefore formulate management guidelines for the use of multidose vials in the care of latex-sensitive patients.

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### Letter to the Editor:

## Coring Observed With Large Bore Beveled Needle

### To the Editor:

I am an anesthesiology resident at the Mayo Clinic in Rochester, MN. I had an experience I would like to submit, should your staff feel it is worth including in the *Newsletter*.

Reconstituting powdered medications (such as cefazolin or vecuronium) into solution for intravenous injection is part of every anesthesia provider's daily practice. Utilizing large bore needles allows for quicker and easier mixing. However, a known hazard with this practice can easily go unnoticed—that of



coring out a portion of a rubber-topped vial. This has been reported with the use of blunt safety tip needles by Riess et al.<sup>1</sup> I had a similar case with a 15-gauge beveled needle. These particular needles are used by many in our operating rooms, and in this case one was used to reconstitute a vial of cefazolin. As a new anesthesia resident I was working with your call team during this weekend call case. After mixing up the

vial and drawing the solution back into the syringe, one of the team members spotted a dark particle floating inside. On closer inspection, this turned out to be a portion of the rubber top.

This case suggests that large-bore beveled tip needles, as with blunt tip needles, are prone to coring and that vigilance should always be applied when drawing up and mixing medications. It may be wise, as an additional precaution, to employ anti-coring plastic cannulas with side eyelets rather than hollow bores.

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## Q &amp; A

# Colors for ECG Tracings, SpO<sub>2</sub> Pulse Oximetry on Patient Monitors in the OR and ICU

## Q Dear Q&A,

Are there any established guidelines regarding the colors designated for ECG tracings, SpO<sub>2</sub> pulse oximetry on patient monitors in the OR and the ICU?

Ranga P. Venna, MD  
Cleveland, Ohio

## A Dear Reader,

There are no agreed upon standards. Various groups from clinicians to industry have discussed this issue, without resolution. Many clinicians like to customize their screens and create specific configurations, including color, for each type of surgery, and the monitor manufacturers are quite accommodating. Clinical practice illustrates different color schemes are the norm not just between institutions but also within institutions.

The first issue is how to link numerics to waveforms, assuming the patient is treated based upon numerics and the waveform is used to validate the data. This is commonly done with color. The second issue is how to distinguish one set of numerics from another, since not all numerics are associated with waveforms, and this is where standardizing color may be helpful, but not practical. If heart rate is always green and arterial pressure is always red, pulse oximetry is always yellow, carbon dioxide is always white, and temperature is always cyan, then the most basic form of patient monitoring can be achieved unambiguously. An anesthesiologist supervising multiple rooms has the advantage of looking at the data they are interested in with only a glance, and in a crisis could gather the important physiologic data very quickly.

Problems arise when multiple measurements of a single parameter appear on the screen. For example, a patient has an arterial line and an automated blood pressure cuff. The arterial waveform and both sets of numerics will be in red. This raises the question as to which numerics are which; which ones will be used to treat the patient? Upon careful inspection the NIBP numerics contain information about the cycle time and the age of the data, which will not be found on the arterial line. Two ECG waveforms with ST segment depression from multiple leads along with one impedance plethysmography waveform with numerics for respiratory rate, all come from the ECG module. Are they all colored green?

Goggles worn during cases employing lasers present another problem by filtering out certain wavelengths or colors of light.

One significant problem concerning standardizing colors is that color is limited as a display feature for many people due to the prevalence of color blindness. Red green is much more common in men with an occurrence of approximately 10% in the population. If color becomes a standard as a visual indicator of important information, you will fail to convey the information intended with color to roughly 4,686 red green colorblind anesthesia providers (32,103 male anesthesiologists and 14,760 male CRNAs currently in practice). A more unusual form of color blindness is blue yellow, which occurs equally in men and women but is limited to 5% of the 10% of color blind individuals (0.5% of the population).

Most monitors that display 6 or 8 waveforms on a screen will undoubtedly require more colors than are presently available. The issue

is not just waveforms but includes numerics as well, especially if they display respiratory gas information. The general consensus appears to be that standardization of colors would be useful, but most likely could not be fully implemented in many patient monitoring systems.

Discussion of these issues leads to the recognition that 1 factor, such as color, will probably not satisfy requirements for unique identification of physiologic parameters as discussed above.

In summary, the following points should be taken into account:

1. Color may be adequate for the most simple configuration of patient monitoring, but remains a problem for the 4,700 red green colorblind anesthesia providers.
2. Position of the waveform and numerics on the screen through a defined hierarchical mechanism may complement colors, but when a large number of numerics are displayed their absolute positions on the screen will change.
3. Recognition of waveform morphology is helpful, but it doesn't help link the waveform to the numerics without color.
4. Recognition of the expected numeric values associated with the patient's physiology comes into play. For example, a cvp of 9 (single digit pressure) will not be confused for heart rate once the ECG waveform is visualized. It will not be confused with arterial pressure because that display includes systolic, diastolic, and mean pressures. It will not be confused with SpO<sub>2</sub> or temperature.

In reality all 4 of the factors mentioned above contribute in part to identification of a parameter of interest, which cannot be generally reduced to simply color.

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

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## Letter to the Editor:

# Endotracheal Tube Pilot Line Leak in the Single Use ILMA-Fastrach™

Loss of endotracheal tube cuff pressure compromises secure airway and can increase aspiration risk. Common explanations for apparent endotracheal cuff pressure loss include tube migration after changes in patient positioning leading to partial extubation, cuff trauma from direct patient or laryngoscope contact, and product defects such as pilot balloon valve incompetency.

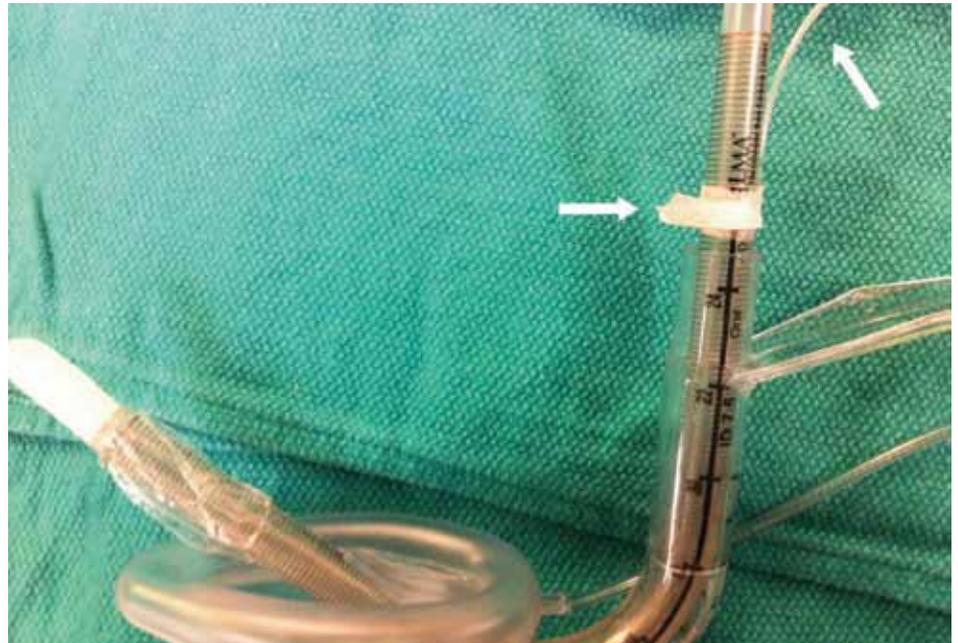
This case illustrates an unexpected product defect in the pilot line of the Single Use ILMA-Fastrach™ (The Laryngeal Mask Airway Company, San Diego, California) silicone endotracheal tube. This is the first case report documenting this remediable defect, thereby addressing a meaningful airway device knowledge gap.

A 31-year-old man with a BMI of 23 kg/m<sup>2</sup> and no aspiration risk factors presented for incision and drainage of a right-hand abscess. Prior to intubation, silicone tube cuff patency was confirmed via brief air insufflation followed by rapid deflation, and the tube was lubricated and passed through the ILMA. General anesthesia was induced using fentanyl and propofol, followed by blind, facile first pass endotracheal intubation via the Single Use ILMA-Fastrach™. The silicone tube was secured at a depth of 25 cm at the ILMA airway tube 15-mm connector. The ILMA cuff was deflated after confirmation of consistent, spontaneous rhythmic end-tidal CO<sub>2</sub> return.

Shortly thereafter, diminishing inspiratory and expiratory tidal volumes led to suspicion of secure airway loss. Silicone tube inspection revealed inadequate pilot balloon insufflation refractory to attempted air re-inflation. Given bilateral breath sounds and unchanged tube depth, an endotracheal tube cuff leak was suspected. Since adequate oxygen-



**Figure 1.** Saline injected into the pilot balloon is seen ejecting from the pilot line defect. [Arrows]



**Figure 2.** The ILMA silicone tube utilizes a short exterior pilot line [Arrows], thereby affording access to and sealing of the defect (26 cm) while potentially maintaining tracheal intubation (25 cm).

ation and ventilation were present, the decision was made to leave the silicone tube in situ.

After uneventful completion of surgery and airway device removal, the silicone tube cuff was inflated with normal saline in an attempt to localize the cuff leak. A defect was noticed in the outer pilot line at the point where it invaginates into the endotracheal tube [Figure 1].

Loss of endotracheal tube cuff pressure can be a concerning event for an anesthesia provider. Exchanging an endotracheal tube intraoperatively can involve considerable risk, especially if a patient has a difficult airway, is positioned non-supine, or if the surgical field limits access to the tube. Pragmatic solutions to temporarily maintain cuff pressure and avoid airway device exchange have been previously reported. These include use of continuous insufflation of the endotracheal tube cuff with air, cuff inflation with a viscous liquid such as normal saline or lidocaine jelly, and use of a 3-way stopcock to fix a leaky pilot balloon.<sup>1-4</sup>

When attempting to localize the source of an endotracheal tube cuff leak, it is possible to overlook pilot line inspection given the rarity of such defects. Upon removal this pilot line defect was readily apparent by injecting saline into the pilot balloon. Had the pilot line leak been localized intraoperatively, various options would have existed to maintain cuff patency. For example, leakage from the pilot line defect could have been sealed using tape. This is possible with the ILMA silicone tube since it has an exterior pilot line

that invaginates 26 cm distal from the endotracheal tube tip [Figure 2]. Note that this can readily be accomplished with the silicone tube remaining in the trachea. Alternatively, the defect could have been circumvented by inflating the cuff with normal saline [Figure 3]. In short, localization of the defect to the pilot line can circumvent endotracheal tube replacement with the intention of secure airway maintenance.

The ILMA-Fastrach™ has been gaining popularity as a useful conduit for blind intubation in difficult airway situations. It is easy to use and exhibits high success rates of intubation on the first or second attempt, even with novice users.<sup>5,6</sup> The endotracheal tube cuff, however, has been scrutinized for its high-pressure, low-volume design<sup>7,8</sup> and the manufacturer admits there is no information regarding prolonged intubation with the included silicone tube. Given the location of the pilot line defect present in this case, it is possible that this is a vulnerable portion of the tube which is susceptible to damage. However, a search conducted using RASMAS software (Noblis Inc., Virginia) did not detect any product recalls or notifications from the Federal Government. Per FDA policy, the manufacturer was informed of this potentially hazardous event. Figure 4 demonstrates pilot line invagination differences between the ILMA-Fastrach™ and a standard plastic endotracheal tube (Sheridan/CF® Endotracheal Tube, Hudson RCI®, California).

See “Line Leak” Next Page

## Detection Allows for Secure Airway Preservation and Avoids the Risk of Endotracheal Tube Exchange

### “Line Leak” From Preceding Page

In conclusion, this pilot line defect is easily detectable and repairable in situ, allowing for secure airway preservation and avoiding the risk of endotracheal tube exchange.

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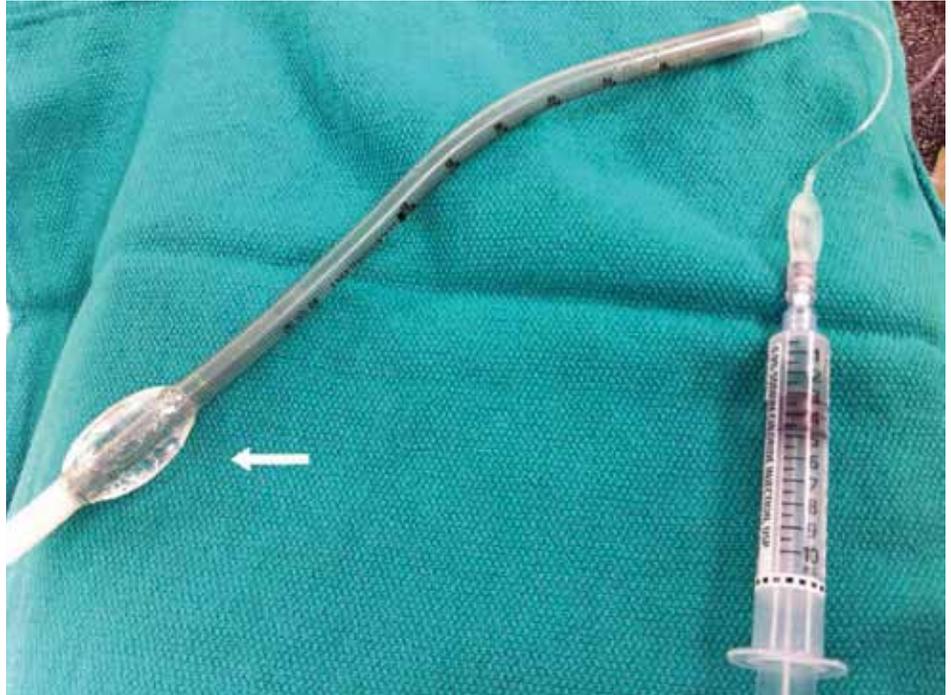


Figure 3. The silicone tube cuff can be filled with saline, circumventing the pilot line defect and maintaining cuff patency. Note that the pilot balloon cuff remains deflated.

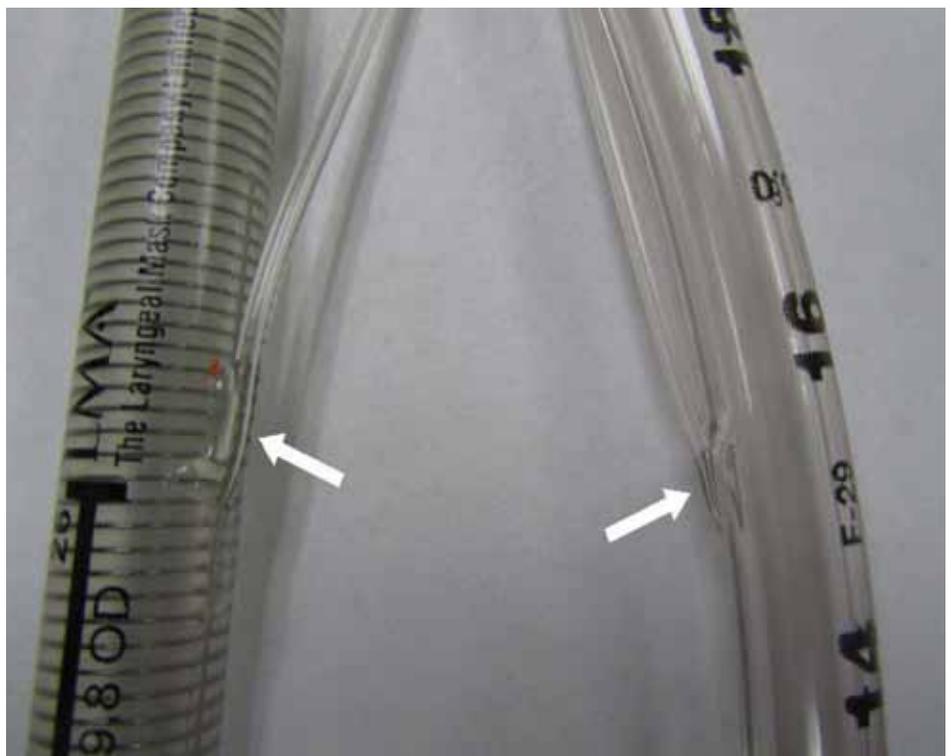


Figure 4. The pilot line of the ILMA silicone tube invaginates into the endotracheal tube more distally (26 cm from the tip) than a standard endotracheal tube (15 cm - Sheridan/CF® Endotracheal Tube, Hudson RCI®, California). Differences exist in protection at the junction where the pilot line enters the main endotracheal tube [Arrows], with the standard tube employing less pliable material.



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The Anesthesia Patient Safety Foundation (APSF) believes that anesthesia professionals should be competent to use advanced medical technology to provide safe patient care. In this regard, APSF, through its Committee on Technology has developed and the APSF Executive Committee has endorsed recommendations for **Advanced Medical Technology Training (AMTT)**.

The goals of this conference will be to engage all stakeholders (anesthesia professionals, technology manufacturers, accrediting and regulatory agencies, professional technology organizations, insurers, hospital administrators, risk managers) to discuss and refine the existing **APSF Advanced Medical Technology Training** document.

The attendees will be asked to develop a consensus for "Considerations" that are intended to guide anesthesia professionals, anesthesia technicians, health care organizations and technology manufacturers as they develop educational programs to train and confirm anesthesia professionals' continued competence to use advanced medical technology.

- Considerations for Anesthesia Professionals
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