



Dr. Ellison C. (Jeep) Pierce, Jr., receives award from Dr. Robert K. Stoelting at his retirement from APSF.

SPECIAL
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Technological intensification in the OR has increased monitoring and equipment training needs.

The APSF at 25: Pioneering Success in Safety, But Challenges Remain 25th Anniversary Provokes Reflection, Anticipation

by John H. Eichhorn, MD

A quarter-century after establishing "patient safety" as a specific concept and a discipline, the Anesthesia Patient Safety Foundation (APSF) pauses in the autumn of 2010 for its 25th anniversary celebration to reflect on its innovative contributions and accomplishments and also on the many challenges yet ahead.

From the start, the APSF has been driven by the vision "that no patient shall be harmed by anesthesia." The APSF was the very first patient safety organization. While rarely recognized as the true pioneer it is, the APSF can legitimately be credited with igniting the "patient safety movement" which has (appropriately) blossomed into one of the major forces in modern health care everywhere. Every patient safety organization, committee, and program as well as every patient safety department and officer have followed after the original inspiration of the APSF. The "patient safety movement" was borne from the profession of anesthesia, where the term "patient safety" originated. The APSF was, and remains, the driving force behind this movement as the organizational catalyst.

As detailed below, while inspiring so many others outside anesthesiology, the APSF has worked

tirelessly since 1985 to accomplish its mission: "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."

Since its first issue in 1986, the *APSF Newsletter* has been a main vehicle for communication and education on issues related to anesthesia and patient safety. This highly respected quarterly publication became, and remains, the anesthesia publication with the largest circulation in the world and serves to transmit safety-related news, ideas, and opinions. The APSF research grant program helped validate high-fidelity simulation as an education and research tool and, beyond that, has funded many projects that have provided insight into and suggested solutions for safety problems. Over the years a cadre of patient safety investigators has evolved as a result of the APSF research program. Safety advocacy and educational efforts have included publication of books, co-sponsorship of a large video series, and organization of the heavily-trafficked "patient safety booth" among

the exhibits at the ASA and AANA annual meetings. More recently, APSF has sponsored targeted workshops and consensus conferences resulting in

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A Blast From the Past! Selected Articles in the APSF Newsletter Archives

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- March 1986** Is There Minimal Essential Monitoring?? I.S. Gravenstein, MD
<http://www.apsf.org/newsletters/html/1986/spring/#article%202>
- March 1987** Outpatient Anesthesia: No Double Standard Bernard V. Wetchler, MD
<http://www.apsf.org/newsletters/html/1987/spring/#article%203>
- March 1989** FDA Applauds APSF Efforts Joseph S. Arcarese and Peter B. Carstensen
<http://www.apsf.org/newsletters/html/1989/spring/#art%201>
- Spring 1991** ASA Standards Amended: CO₂ Seen After Intubation Now the 'Standard of Care' John H. Eichhorn, MD
<http://www.apsf.org/newsletters/html/1991/spring/#art1>
- Fall 1995** Simulator Training in Anesthesia Growing Rapidly David Gaba, MD
<http://www.apsf.org/newsletters/html/1995/fall/simulator.html>
- Spring 1998** Lancet Article Addresses a Different Type of Safety Question: Elderly Suffer Prolonged Postoperative Cognitive Dysfunction J.S. Gravenstein, MD
<http://www.apsf.org/newsletters/html/1998/spring/07lancet.html>
- Winter 2000** Landmark Report Published on Patient Safety David Gaba, MD, and Jeffrey Cooper, PhD
<http://www.apsf.org/newsletters/html/1999/winter/01Safety.htm>
- Winter 2001** APSF Endorses Use of Automated Record Keepers
<http://www.apsf.org/newsletters/html/2001/winter/02ARK.htm>
- Winter 2003** Virtual Anesthesia Machine Has Worldwide Impact Sem Lamptang, PhD
<http://www.apsf.org/newsletters/html/2003/winter/14virtual.htm>
- Winter 2003** Cannister Fires Become a Hot Safety Concern Michael A. Olympio, MD and Robert C. Morell, MD
<http://www.apsf.org/newsletters/html/2003/winter/01fires.htm>
- Spring 2004** Dear Safety Information Response System (SIRS) Debut Column Michael A. Olympio, MD
http://www.apsf.org/newsletters/html/2004/spring/05dear_sirs.htm
- Summer 2007** Beach Chair Position May Decrease Cerebral Perfusion. David J. Cullen, MD & Robert R Kirby, MD
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- Summer 2007** Cardiology Experts Share Perspective on Stents Lisa Newsome, MD, Roger Royster, MD, and Richard Prielipp, MD
http://www.apsf.org/newsletters/html/2007/summer/05_cardiology_stents.htm
- Winter 2007** Dangers of Postoperative Opioids Matthew B. Weinger, MD
http://www.apsf.org/newsletters/html/2007/winter/01_opioids.htm
- Spring 2008** Lipid Emulsion: The Time Has Come for Treating Systemic Local Anesthetic Toxicity (Letter to the Editor) Guy L. Weinberg, MD, David Mayer, MD
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- Spring 2010** APSF Hosts Medication Safety Conference
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Bonnie F. Burkert - Graphic Designer since 1998

And the invaluable contributions made by other members of the APSF Newsletter Editorial Board throughout these 25 years.

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NEWSLETTER

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Driving Forces Behind the Creation of the Anesthesia Patient Safety Foundation

"25th Anniversary," From Cover

recommendations for definitive action. It now hosts the popular APSF website (www.apsf.org) that includes a wealth of safety-related resource material and attractive interactive features such as the monthly poll on a current anesthesia question and also the Virtual Anesthesia Machine, which the APSF helped to support over the years.

Success and Recognition

The success of the anesthesia patient safety movement was recognized significantly in 1996 when the American Medical Association and corporate partners founded the National Patient Safety Foundation (NPSF), based directly on the APSF as the model. The NPSF persists today as a major national and international force in patient safety advocacy. Further recognition of the APSF for leadership and safety efforts came in the landmark 1999 report "To Err is Human" from the Institute of Medicine on morbidity and mortality caused by errors in medical care. The APSF was the only organization mentioned as one that had made a demonstrable positive impact on patient safety. [While honored, the APSF felt compelled to publicly respond to the IOM report and advocate for more of a quality management "systems" approach to patient safety rather than their proposed program to identify and punish "bad practitioners."] Further, a June 21, 2005, front page article in the *Wall Street Journal* singled out the anesthesia profession, the ASA, and APSF for their roles in making anesthesia safer resulting in dramatic decreases in professional liability insurance premiums paid by anesthesiologists.

A "culture of safety" has developed in anesthesia practice, by the hard work of the APSF, the ASA, the AANA, and as well as by the adoption of a more systems-based approach by many anesthesia departments and groups and all of the anesthesia professionals interested in optimizing anesthetic outcomes. Overall, the combined impact of all these efforts has been a 10- to 20-fold reduction in mortality and catastrophic morbidity for healthy patients undergoing routine anesthetics. This is an evolutionary accomplishment of which the entire profession can be justifiably proud. By the early 1990s, liability payouts from anesthesia accidents had decreased from a disproportionately high share to something less than would be expected for such inherently risky work. The insurance "risk relativity rating" for anesthesia practice compared to other specialties had been reduced dramatically.

Original Serendipitous Coincidence

As with most major historical developments, coincidence played a role in the creation of the APSF.

"If you are going to go into anesthesia, you are going on a long trip and you should not do it, if you can avoid it in any way. General anesthesia is safe most of the time, but there are dangers from human error, carelessness and a critical shortage of anesthesiologists. This year, 6,000 patients will die or suffer brain damage. . . . The people you have just seen are tragic victims of a danger they never knew existed—mistakes in administering anesthesia."



Excerpts from *"The Deep Sleep: 6,000 Will Die or Suffer Brain Damage,"* aired on the ABC television show 20/20 in April 22, 1982. They reported an error by an anesthesiologist in which the nitrous oxide was turned up and the oxygen was turned off at the end of the case, causing severe brain damage in the patient. The public concern provoked by this show provided an opportunity for Dr. Ellison C. Pierce, Jr., soon to be ASA president, and with a strong interest in anesthesia accidents, to direct ASA's organizational efforts around patient safety research and education.

Several factors came together to facilitate the development of an idea held by Ellison C. ("Jeep") Pierce, Jr., MD, who was then chair of Anesthesia at the New England Deaconess Hospital in the Harvard Medical School system. As he related in his 1995 Rovenstine lecture to the ASA,¹ Dr. Pierce was originally stimulated in 1962 as a junior faculty member when assigned to give a lecture on "anesthesia accidents." After that, he kept files, notes, and clippings and spoke often of his concerns about major anesthesia accidents that harmed patients, particularly unrecognized esophageal intubations. Then, in April 1982, the ABC television program 20/20 aired a segment entitled "The Deep Sleep: 6,000 Will Die or Suffer Brain Damage." It opened with: "If you are going to go into

anesthesia, you are going on a long trip and you should not do it, if you can avoid it in any way. General anesthesia is safe most of the time, but there are dangers from human error, carelessness and a critical shortage of anesthesiologists. This year, 6,000 patients will die or suffer brain damage." Following scenes of patients who suffered anesthesia mishaps, the program went on to say, "The people you have just seen are tragic victims of a danger they never knew existed—mistakes in administering anesthesia." In another example shown on the program a patient was left in a coma following the anesthesiologist's error in turning off oxygen rather than nitrous oxide at the end of an anesthetic. This watershed presentation provoked public concern about the safety of anesthesia. Dr. Pierce transformed this potential problem for the specialty into an opportunity to take positive, proactive measures. Taking advantage of his impending year as ASA president starting in October 1983, he convinced the ASA leaders to create the Committee on Patient Safety and Risk Management. He saw that the problems of anesthesia accidents and malpractice costs had the same solution—making anesthesia safer.

At the same time, ground-breaking research led by Jeffrey B. Cooper, PhD, a bioengineer in the Department of Anesthesia at the Massachusetts General Hospital, had focused on revealing how human errors were a major and fundamental cause of preventable anesthesia accidents. He and his colleagues adapted the techniques of "critical incident analysis," used in the study of aviation accidents, to study analogous events that were occurring in anesthesia.² Based on Cooper's work, Richard J. Kitz, MD,



Ellison C. ("Jeep") Pierce, Jr., MD, founding APSF president, stands at APSF booth announcing the APSF research award established in his honor.

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Early Organization Formed by APSF Founding Members

“25th Anniversary,” From Preceding Page



Front page of the first issue of the APSF Newsletter, Vol. 1, No. 1, March 1986 with a photo of the first APSF Executive Committee members.

then chair of that anesthesia department, lectured on this topic in England to the Royal College of Anaesthetists. The esteemed Professor T. Cecil Gray was in the audience. He was stimulated to suggest that an international meeting be convened to reveal more about these preventable anesthesia injuries. Dr. Kitz brought the idea to Drs. Cooper and Pierce, who was by then president of the ASA. The three collaborated to organize and host in Boston the International Symposium on Preventable Anesthesia Mortality and Morbidity in 1984, timed to follow immediately the ASA meeting that year. Fifty invited participants attended and grant support from various corporations was raised to fund the meeting. At the closing session, Dr. Pierce reflected on the obvious great interest and relevance of the topic, the lively debate, the need for action, and the potential to raise funds to support efforts to make anesthesia safer. After the close, a small nuclear group stayed behind and Dr. Pierce outlined his proposal to build on the idea and create an independent foundation dedicated solely to improving the safety of anesthesia care to the point “that no patient shall be harmed by anesthesia.” Enthusiastic agreement was unanimous. Dr. Pierce asked, “What should we call it?” Dr. Cooper suggested that it simply be called what it would be, the “Anesthesia Patient Safety Foundation.” And, so it was.

APSF Organized

Dr. Pierce, having just finished his term as ASA president, envisioned a relatively small dedicated core group driving an independent foundation that was not directly controlled by any large organization. This would facilitate nimble, rapid, targeted action unfettered by a slow bureaucratic approval process and also open engagement on the politically sensitive

topic of anesthesia accidents. Importantly, this would allow a very broad base of participants including all possible interested groups of constituents: anesthesiologists, nurse anesthetists, nurses, bioengineers, epidemiologists, equipment and pharmaceutical manufacturers, government regulators, risk managers and insurance industry executives, and even surgeons.

An organizational executive meeting was held in July 1985. Initial goals for the APSF were established:

1. Sponsor investigations that will provide a better understanding of preventable anesthetic injuries.
2. Encourage programs that will reduce the number of anesthetic injuries.
3. Promote national and international communication of information and ideas about the causes and prevention of anesthetic injuries.
4. Establish an information newsletter to be delivered free of charge to all anesthesia providers.

Potential by-laws, committees, directors, and funding were discussed. Dr. Pierce agreed to approach the ASA with a request for an annual contribution equivalent to the funding for the ASA Committee on Research.

At the 1985 ASA meeting, over 30 potential APSF officers and directors met. Importantly, an initial contribution of \$100,000 from the ASA had been secured and this also was matched by contributions from the Parker B. Francis Foundation (an offshoot of the Puritan Bennett Corporation) and from Ohmeda, Inc. Accordingly, with the viability of the foundation clearly established, the articles of incorporation dated October 2, 1985, were accepted. It was then agreed that the four officers would be members of a 7-person executive committee (EC) and that there would be a 30-person Board of Directors with half appointed by the ASA and half by the APSF.

By the time of the New York Post-Graduate Assembly in December, the EC was set:

- President: Ellison C. Pierce, Jr., MD
- Vice President: W. Dekle Rountree, Jr. (CEO of Ohmeda)
- Secretary: E.S. Siker, MD (a past president of the ASA)
- Treasurer: Burton S. Dole (CEO of Puritan Bennett)
- At large: Jeffrey B. Cooper, PhD, Joachim S. Gravenstein, MD, and James E. Holzer (CEO of the Risk Management Foundation, Harvard's liability insurer)

Committees were addressed. The proposed quarterly newsletter was considered the top priority. Dr. Pierce, recognizing the potential value of the prior newspaper editing experience of John H. Eichhorn, MD, persuaded him to create and edit the *APSF Newsletter* and chair the editorial board. An ambitious

target was set to publish the first issue that coming March (which was achieved). The research grant program was the other priority. Arthur S. Keats, MD, was named chair of the Scientific Advisory Committee. He stated his intention to structure this effort along the rigorous lines of an NIH study section, including seasoned senior researchers as grant reviewers. The Committee on Education and Training was formed and J. S. Gravenstein, MD, was appointed as its chair. The Committee on Technology was also formed (David B. Swedlow, MD, would later become its chair).

All but one of the members of the Board of Directors were appointed. As hoped, and crucial to the undertaking, the make-up of the Board did achieve the goal of an extremely wide cross-section of professionals interested in anesthesia patient safety and empowered to act on that interest. Included were relevant ASA committee chairs, officials, and members who were respected researchers, as well as representatives of the profession of nurse anesthesia, the medical liability insurance industry, the FDA, and anesthesia equipment and pharmaceutical corporations.

At that meeting, a proposal was adopted that the first APSF research grants would be awarded at the APSF annual meeting in October 1986, in the amount of up to \$35,000. Also, a lively discussion about the potential value of standards for intraoperative monitoring and whether the APSF could have a role was held with no resolution or recommendation resulting. Dr. Pierce initiated that discussion in part because of his awareness of three related efforts: the work of the Harvard Risk Management Committee, chaired by Dr. Eichhorn, and the recent adoption of formal anesthesia monitoring standards within the Harvard system; a meeting of an industry-sponsored “Anesthesia Safety Consortium” that wanted to support standards; and the work on monitoring by the newly formed ASA Committee on Standards of Care (initiated during Dr. Pierce's presidency of the ASA). Eventually a consensus was achieved that the APSF would not hold itself out as a formal standards-setting organization but rather would focus on education and advocacy to further the improvement of anesthesia patient safety.

Early Action

Organizational efforts came to fruition. Bookkeeping and secretarial functions were formalized and divided among the ASA office, Dr. Pierce's office in Boston, and Dr. Siker's office in Pittsburgh. Efforts to create, edit, print, and mail the initial *Newsletter* proved to be a formidable task for Dr. Eichhorn. That work was significantly facilitated by a generous further donation to the APSF from Mr. Dole and the Puritan Bennett Corp. of free use of that company's graphic arts and printing facilities outside Kansas City. (Likewise, somewhat later, an additional

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Adverse Events Associated with Neonatal Laparoscopy: Are They Truly Rare Events or the Tip of the Iceberg?

by Susan P. Taylor, MD

The surgical literature is replete with studies extolling the benefits of minimally invasive surgery. Indeed, for many operations its advantages over conventional techniques are well proven. Reduced pain and analgesic requirements, shorter convalescence and hospital stays, and improved cosmetic results have contributed to the popularity of laparoscopy among surgeons and healthcare consumers alike. As the indications for laparoscopic procedures expand, often without adequate scientific studies to assess the risks and benefits, anesthesia professionals may be among the first to recognize patient safety issues. Recent reports of catastrophic events associated with neonatal laparoscopy may suggest that its popularity is unfounded for minor procedures. Although studies in the surgical literature report statistically significant reductions in hospital stay and time to enteral feeds for laparoscopic compared with open pyloromyotomy, these results are measured in hours and may be clinically and financially unimportant.

Case 1

A 1-day-old term male infant with trisomy 21 suffered sudden cardiovascular collapse following insertion of the umbilical trocar for repair of duodenal atresia. The procedure was abandoned following successful resuscitation that included 20 minutes of chest compressions. Despite "seizure-like activity" that night, magnetic resonance imaging (MRI) failed to show any anatomic abnormalities the next day. He underwent uncomplicated open repair the following week.¹

Case 2

More than 30 minutes of chest compressions, intratracheal and intravenous epinephrine and blood transfusion were administered prior to return of spontaneous circulation in a 12-day-old term female infant who experienced cardiac arrest during initial insufflation of the abdomen for laparoscopic pyloromyotomy. Analysis of respiratory gases prior to the arrest demonstrated higher levels of expired than inspired nitrogen, suggesting that air emboli contributed to her arrest. Computerized tomography of the head revealed intra-arterial gas bubbles 3 hours following the arrest, which resolved following hyperbaric oxygen therapy. An MRI 5 days later showed a pattern of watershed infarct. Three years later, her development appears normal.²

Case 3

A 3-week-old former 34-week premature twin experienced hypoxia and hypotension at the time of abdominal insufflation for laparoscopic pyloromyotomy that responded to volume, epinephrine, and calcium gluconate administration, without the need for

chest compressions. He had a protracted hospital stay prior to uneventful open pyloromyotomy,³ without known long-term complications following his intraoperative resuscitation.

The transitional circulatory anatomy of the neonate, variations in surgical laparoscopic inflation techniques, and the equipment itself may contribute to increased risks in young patients. A bleeding umbilical vein was believed to be the source of gas embolism in the preceding cases. A patent ductus arteriosus in case 1, and patent foramen ovale in case 2, increased the likelihood of paradoxical emboli and adverse outcomes.

Numerous clinical reports and animal experiments outline the effects of CO₂ embolus during laparoscopy. The importance of rate and volume, as well as solubility of a gas delivered to the circulation, is well recognized. The summarized cases suggest that the presence of ambient nitrogen may be clinically relevant, creating emboli highly refractory to treatment. Other possible causes of cardiovascular and respiratory arrest must also be considered during laparoscopic procedures. Elevated intra-abdominal pressure contributes to respiratory embarrassment and compromises venous return resulting in low cardiac output. Pneumothorax and pneumomediastinum can occur when gases escape from the abdominal cavity through congenital diaphragmatic defects, retroperitoneal dissection, or injury to the falciform ligament. Vascular injuries associated with initial instrumentation of the abdomen or during dissection of solid organs may result in hypovolemic shock.⁴

An understanding of laparoscopic equipment and the techniques employed for insufflation will aid the anesthesia professional during adverse events. The adoption of laparoscopic equipment designed for adults without modification for pediatric surgery may bring unnecessary risk to neonates. Newer insufflation equipment does have pediatric settings that limit the maximum pressure and flow rates during insufflation. High volume tubing allows significant air contamination of insufflated gases if the tubing is not purged with CO₂ prior to use. In fact, the volume of tubing in use at our institution is >200 ml, more than the volume necessary for initial abdominal insufflation in many neonatal cases. Some surgeons do not routinely purge the insufflating system of air prior to the start of laparoscopic procedures. In such cases, all or most of the original gas delivered to the body cavity is nitrogen-containing air. Unfortunately, in such cases the perceived advantage of CO₂ as an insufflating gas is lost.⁵

It is unclear whether these cases are, indeed, extremely rare events, or if they represent a unique

risk of laparoscopy in neonates whose circulatory anatomy differs from the older population. Both author and publication bias limit the number of events reported in the literature. An effort to ascertain the incidence of adverse outcomes and possible contributing factors is currently underway. The Food and Drug Administration Division of Post-Market Surveillance is interested in learning more about this safety concern. The urgency of their response, however, is determined by the frequency and severity of events, as well as the age of the patient, with pediatric patients receiving priority. Only reliable reporting will allow the medical community and regulating bodies to appreciate the true significance of such complications. **Please submit any adverse events related to neonatal laparoscopy to the FDA through their MedWatch online reporting system <https://www.accessdata.fda.gov/scripts/medwatch/>. Any questions regarding the submission process may be directed to sutaylor@mcw.edu or rsm@fda.hhs.gov.**

References

1. Lalwani K, Aliason I. Cardiac arrest in the neonate during laparoscopic surgery. *Anesth Analg* 2009;109:760-2.
2. Taylor SP, Hoffman GM. Gas embolus and cardiac arrest during laparoscopic pyloromyotomy in an infant. *Can J Anaesth*. 2010 Apr 30. [Epub ahead of print]
3. Kudsi OY, Jones SA, Brenn BR. Carbon dioxide embolism in a 3-week-old neonate during laparoscopic pyloromyotomy: a case report. *J Pediatr Surg* 2009;44:842-5.
4. Gutt CN, Oniu T, Mehrabi A, Schemper P, Kashfi A, Kraus T, Büchler MW. Circulatory and respiratory complications of carbon dioxide insufflation. *Dig Surg* 2004;21:95-105.
5. Taylor S, Hoffman G. Unpublished data.

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Photo showing the complexity of neonatal laparoscopic surgery.

Successful Implementation of the New Paradigm for Medication Safety: Standardization, Technology, Pharmacy, and Culture (STPC)

by Tim Vanderveen, MS, PharmD, and Sally Graver, MA,

with Jennifer Noped, PharmD; Michael A. Olympio, MD; Betty Petree, CRNA; Sallie Simpson; Frank Sizemore; Melanie Williamson, RN

Medication errors causing harm to patients in the operating room remain a persistent problem. To develop new strategies for “predictable prompt improvement” of medication safety in this setting, the Anesthesia Patient Safety Foundation (APSF) convened a multidisciplinary consensus conference on January 26, 2010. The conference called for a “new paradigm” for future safety efforts to include 4 critical elements: **Standardization, Technology, Pharmacy / Prefilled / Premixed, and Culture (STPC)**.

The recent intravenous (IV) infusion safety initiative at Wake Forest University Baptist Medical Center provides an excellent illustration of how implementing the new paradigm can successfully improve medication safety, clinician satisfaction, and operational efficiency from the operating room to post-operative care. One anesthesiologist described the initiative as “the smoothest implementation of a new technology” in his entire career. Selection and implementation of a new “smart” IV infusion safety system with syringe and large-volume pumps on a common platform was the catalyst for standardizing infusion technology, drug libraries, concentrations, dosing units, and dosage limits Medical-Center wide.

In this case study, operating-room and intensive-care IV infusion therapy at Wake Forest Baptist before and after the initiative, the change process, lessons learned, and results achieved through the implementation of STPC are reviewed.

NEED TO IMPROVE IV MEDICATION SAFETY

At Wake Forest Baptist, an 872-bed academic medical center in Winston-Salem, NC, variability in infusion pumps and medication use negatively affected both operating rooms and intensive care units (ICUs). Inconsistencies created difficulties for pharmacy in preparing the medications and for ICU nurses in managing patient care, e.g., when they had to set up new infusions, switch from syringe to drips, and calculate dosages using different concentrations and dosing units.

Staffs for cardio-thoracic (CT) surgeries, anesthesia and ICU medical, nursing and pharmacy had previously collaborated on process improvements, e.g., standardizing inotrope use by sharing the syringe pumps. Transitions were still required for non-standard concentration drips and large-volume drips such as lidocaine and amiodarone, which anesthesia often infused by syringe. Admitting a CT-ICU patient could take 20 minutes or longer, and patients could become hyper- or hypotensive as a result of the changes.

With unstable patients, nurses delayed switching from syringes to drips and had to use different technology from what they routinely used. Syringe pumps were supposed to go back to the operating room, but frequently anesthesia providers could not



find proper pumps for operating room care. Variable pump programming increased frustration. Anesthesia staff members were dissatisfied with ICU volumetric infusion (used throughout non-operating room areas) and often discarded those drips for their own syringe infusions, after transporting patients into the operating room.

Pharmacy prepared some IV medications, and concentrations may have differed, depending on anesthesiologists' preferences. Materials management struggled with hoarding, misplaced pumps and misplaced detachable electrical plugs. Changing the drug libraries in the large-volume pumps would have required manually uploading changes to each individual pump—if they could all be found. Syringe pumps were not “smart” (computerized), and site-specific infusion-mode options varied among the pumps.

In operating rooms, ICUs, pharmacy, and central supply, lack of standardization increased waste, inefficiencies, clinician stress, the potential for errors and, most importantly, the possibility of patient harm.

Accomplishing Change

Throughout 2007 frustration with lack of standardization increased. In addition, the syringe pumps were going out of service and would no longer have vendor support. The contract for the large-volume pumps was going to expire.

In November 2007 and February 2008 ECRI published articles on the advantages of new “smart” infusion technologies, including a modular IV infusion safety system that combined syringe and/or drips on a common platform with robust dose-error-reduction software (DERS).¹⁻³ The multidisciplinary Wake Forest Baptist Infusion Pump Utilization Committee, with representatives from anesthesia, materials management, nursing, pharmacy, and risk management, decided to organize infusion pump trials and a formal pump evaluation to obtain staff feedback on various technologies. The modular system's appar-

ent bulkiness was a concern, and no consensus was reached.

A similarly representative Wake Forest Baptist team visited local hospitals that used various technologies, and then traveled to several medical centers using the modular system. Staff at those medical centers reported that the modular system was effective and easy to use, even in smaller operating rooms, and strongly supported the standardization concept.

These visits convinced the Wake Forest Baptist team that it could achieve what it wanted to accomplish. Senior leadership was willing to purchase as many pumps as necessary to standardize infusion therapy and prevent hoarding. In May 2009 Wake Forest Baptist announced that the modular IV medication safety technology^a would be implemented throughout the Medical Center.

Key deciding factors for this group were recommendations in the unbiased literature¹⁻³ and the combination of volumetric and syringe infusion pumps on a single platform with a common user interface. The new technology would allow operating rooms and the rest of the Medical Center to use the same robust IV medication safety system. “Go-Live” was set for February 2, 2010, leaving 9 months to prepare.

Standardization / Pharmacy

APSF has long recommended standardizing medication use to reduce opportunities for error. The Wake Forest Baptist implementation team was now convinced that standardizing IV medications hospital-wide—concentrations, dosing units, method of infusion (syringe or drip)—was desirable and possible. Standardization was fully supported by Wake Forest Baptist's Chief Medical Officer, Chief Pharmacy Officer, Chief Nursing Officer, Chiefs of Anesthesia, Critical Care and Emergency Medicine, ICU nurses, pharmacists, and critical care, anesthesia and emergency physicians.

Two teams were established to standardize adult and pediatric concentrations. Standardization efforts were spearheaded by the anesthesiologist who chaired the Anesthesia Department Equipment Committee and who had chaired the APSF Committee on Technology. The vendor provided extensive technical and training support in helping pharmacy set up the drug library and helping staff scrutinize practices to identify possible improvements.

Multiple iterations and faculty and staff reviews resulted in a list of standardized concentrations, dosing units, dosage limits, and method of infusion (syringe or pumps). Drug preparation and method of infusion would remain unchanged from the operating

^aAlaris® System with Guardrails® Suite MX Software, Alaris® Systems Manager, CareFusion, Del Mar, CA.

Incorporating the STPC Paradigm to Improve Medication Safety

“STPC Paradigm,” From Preceding Page

room to the ICU and vice-versa. Some drugs would only be available for use by anesthesia professionals. No local anesthetics were to be delivered by infusion pumps outside the operating room. For a limited number of vasoactive drugs, the double concentration (2X) was also standardized. Weight-based or non-weight-based dosing was largely determined by anesthesiology and critical care attending physicians. (See Table.)

In October 2009 anesthesia providers were concurrently and cooperatively presented with a draft list of the medications pharmacy would prepare for use in operating rooms and ICUs, eliminating the need for anesthesia to formulate their own vasoactive, sedative, insulin and other drips. Pharmacy, anesthesia, nursing, ICU, emergency department and faculty directors met with the standardization committee and gave their support.

The final Go-Live version of the data set was distributed by pharmacy on December 4, 2009 and the data were entered into the DERS drug libraries. Shortly before Go-Live, anesthesia prepared a single-page summary that showed the concentration, method of infusion, dosage limits, bolus range, bag versus syringe, and “anesthesia only” for every anesthesia drug. This was laminated and placed in the operating rooms as a ready reference.

Technology

The modular design of the new infusion safety technology with DERS combines syringe and large-volume pump modules on a common user interface, eliminating the need for different systems in anesthesia, critical care and general nursing. Hospital-defined “profiles” in the software adjust pump settings to meet the needs of particular patient care areas or patient types. Each profile has a hospital-defined drug library with standardized drug names, concentrations, diluents, dosing units, and maximum-minimum dose and bolus limits. If programming exceeds the pre-established limits, the software provides a “soft” (can be overridden) or “hard” (cannot be overridden) alert that must be addressed before infusion can begin.

“Anesthesia mode” allows providers to access anesthesia-specific drugs, concentrations and limits. Alerts, dosage limits, infusion “pause,” clinical advisories and other settings are customized for anesthesia use. After surgery, when the system is unplugged from AC power, it automatically reverts to nursing mode. All running infusions continue at the anesthesia-mode rate/dose and dosing units until reprogrammed by the nurse.

The infusion system stays with the patient and allows easy selection of either syringe or large-volume pumps. If the current infusion completes, a new infusion container of the same drug/concentration can be hung, a new volume-to-be-infused established, and the infusion continued. If a patient returns to the operating room, the anesthesia provider can quickly return to anesthesia mode without

Table. Standardization of IV infusion medications at Wake Forest Baptist

Before	After
Anesthesia prepared most IV medications for use in the operating room	Pharmacy prepares standardized drips and syringes, eliminating the need for many IV medications to be prepared by anesthesia providers
Multiple IV infusion concentrations	Standardized on one IV concentration for the majority of medications; also standardized the double concentration for a limited number of vasoactive drugs
Multiple drug dosing options	Standardized on one dosing unit for each IV medication
Specific medications prepared in either bag or syringe, depending on care location and physician preference	Standardized on bag or syringe for individual drugs
No IV infusion limits with syringe pumps; limited IV infusion limits for large-volume preparations	Dosage limits for all infusions, alerts when limits exceeded
Infusions and pumps switched upon transfer from operating room to ICU due to non-standard concentrations and inconsistent modes of infusion	Pumps and infusions remain with patient from operating room to ICU and vice-versa, with no manipulation of infusions
ICU volumetric infusions discarded in the operating room and changed to syringe mode	ICU infusions remain intact throughout operating room and back to ICU

interrupting the infusion or doing any additional programming.

Each infusion system is automatically connected to the hospital’s wireless communication system, facilitating the rapid transfer of an updated drug library, if new drugs are added or dose limits adjusted. Continuous quality improvement (CQI) data logs provide data on “alerts” (dosage limit has been exceeded) and averted errors (alert resulted in reprogramming or canceling the infusion). CQI data are wirelessly transferred to the infusion system server, allowing analyses to be performed by hospital staff or the vendor to help identify opportunities for improving IV medication safety and best practices.

Culture

A major factor contributing to the implementation’s success was the very strong culture of cooperation, respect, dedication, and decency at Wake Forest Baptist. Leaders have the respect of their people, who want to see them succeed. Everyone engaged in this effort from an overall standpoint of safety. Instead of the “silo” approach found in many medical centers, there was a well-functioning team, albeit one that required deliberation and vetting. Throughout the standardization process, there was give-and-take and real compromise. Anesthesia got some things they really wanted, as did pharmacy and nursing. The end result was win-win, and people are happy with the outcome.

Staff members were involved from the very beginning. When it came time to implement the system, an overwhelming majority of staff was trained, which was key. Now everyone knows how to use both syringes and drips, so when a patient is taken to their post-operative destination, the pumps stay right with that patient with no interruption or changeover to another system.

Training

Based on previous experience the implementation team recognized that training had to be mandated to

have everyone attend. They got this commitment from the senior leadership, department heads, and others. Every clinician was told by their leadership that this was going to be the new pump, implementation will occur at a specific hour, no exceptions.

Training included hands-on experience, lectures, and 75 two-hour workshops held day and night (e.g., 2:00 a.m.) so all could attend. Workshops were designed so that everyone had his or her own pump. The instructor covered material rapidly to keep attendees invigorated and excited. The consensus opinion stated that all who took the training found the new pumps easy to use, and many said good things about the pumps, which encouraged others to attend and built excitement. A few Wake Forest Baptist physicians had come from a hospital where they had been using the modular system, so they also spoke to how standardization on the new system would work.

Installation

Months before Go-Live the vendor’s project manager helped develop a schedule and held vendor and hospital staff accountable for staying on track. Vendor representatives checked the devices, ensured the profiles and drug libraries were properly loaded into the DERS, all the electrical safety checks were done, and that everything needed was there.

A pre-Go-Live meeting was held on February 1, and a final memo and reminders with HELP listings and numbers sent to anesthesia staff. On February 2, 2010, the Go-Live was implemented successfully. The technical support team from the vendor helped ensure that timelines were met, devices were moved into place, pumps were working properly, and connectivity was working in all areas of the Medical Center. Post-implementation meetings were held to discuss the few difficulties, and the vendor sent updates to all staff responding to any concerns.

See “STPC Paradigm,” Next Page

Buy-in, Planning, Training, and Feedback Key to Successful Implementation of New Technology

"STPC Paradigm," From Preceding Page

Results

- The new IV medication safety system with syringe and large-volume pumps on a common platform is now used throughout Wake Forest Baptist, with the specialized "anesthesia mode" used in the operating room.
- Drug concentrations and dosing units are standardized across the Medical Center (Table).
- Bags using standard concentrations for the operating room are prepared by pharmacy.
- Medications that are still delivered via syringe for the operating room (e.g., narcotics, amnestics) are drawn directly out of single-use vials and may require dilution.
- IV infusion pumps used in the operating room remain with the patients upon transfer to critical care and vice-versa.
- Nurses no longer switch out infusion pumps and medications or tear down lines, decreasing ICU patient admission time from an estimated 20 minutes to 5 to 10 minutes.

Lessons Learned

- Find champion workers among respected thought leaders.
- Do careful needs assessment before selecting a new system.
- Do a detailed analysis to determine how many devices are needed, before going through the purchase agreement.
- Involve nurses in the selection process and throughout implementation.
- Allow plenty of opportunities for as many clinicians as possible to provide input into the creation of the drug library.
- Have leadership support standardization and emphasize (mandate) training.
- Educate, train, educate, and train end users.
- With pharmacy preparing all drips for anesthesia, make sure the drips are always available, especially at night.
- Have enough medication on hand for an anesthesia provider to make the proper dilution, when pharmacy-prepared bags are not readily available off-hours (e.g., an epinephrine drip at 3 am).

Discussion

The leadership team professed that the implementation of the new modular IV infusion safety system was one of the easiest, well-planned, well-organized, and coordinated implementations Wake Forest Baptist has ever done, especially one of this size. The technology's features catalyzed an overhaul of the system that otherwise might not have happened. The successful implementation depended on the hospital's support of all 4 pillars of the new medication-safety paradigm:

Standardization - Extensive staff involvement and multiple iterations resulted in agreement on a single administration mantra for each drug.

Technology - Being able to combine all pumps into a single user interface allowed all areas to use the same system.

Pharmacy - The Department of Pharmacy prepares standardized drips and syringes, eliminating the need for many medications to be prepared by anesthesia providers.

Culture - Most importantly, the Wake Forest Baptist culture of safety and dedication to patients' best interests enabled the entire team to collaborate to achieve this success.

Conclusion

At Wake Forest Baptist implementation of the new user-friendly infusion safety technology with syringes and drips on a common platform achieved highly positive results. IV medication use was standardized throughout the hospital system. Staff moved from focusing on their own dealings with individual patients to a more global awareness of patient and medication safety implications outside the operating room and throughout the hospital.

As a result of implementing the 4-pronged approach of STPC, Wake Forest Baptist improved IV medication safety, clinician satisfaction, and operational efficiency, not only in the operating room and post-operative care but also Medical Center-wide.

Acknowledgements:

Dr. Vanderveen is Vice President, Center for Safety and Clinical Excellence, CareFusion, San Diego, CA. He serves on the APSF Board of Directors and is a member of the APSF Committee on Technology. Ms. Graver is Senior Medical Writer with CareFusion, San Diego, CA. Affiliated with Wake Forest University Baptist Medical Center in Winston-Salem, North Carolina, are Dr. Noped, Assistant Director of the Pharmacy, Infusion Pump Utilization Committee Co-manager; Dr. Olympio, Tenured Professor of Anesthesiology, Chair of the Anesthesia Department Equipment Committee, and former Chair of the APSF Committee on Technology; Ms. Petree, Director of Nurse Anesthesia, Director of Clinic Operations, Operating Room; Ms. Simpson, Director of Materials Management; Mr. Sizemore, Central Services Manager, Infusion Pump Utilization Committee Co-manager, and Ms. Williamson, Nursing Unit Manager, Cardiothoracic ICU.

References:

1. ECRI Institute. General-purpose infusion pumps. *Health Devices*. October 2007;309-36. Update, November 2007.
2. ECRI Institute. Syringe infusion pumps with dose error reduction systems. *Health Devices*. February 2008;37(2):33-51.
3. ECRI Institute. Infusion pump criteria. *Health Devices*. February 2008;37(2):52-8.

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Dear SIRS

Measurement of Expiratory Limb Circuit Pressure: A Potential Anesthesia Machine Safety Issue

SAFETY INFORMATION RESPONSE SYSTEM

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

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

Dear SIRS:

Our department was recently contacted to investigate a possible issue in the Datascope AS3000 Anesthesia System (Mindray North America, Mahwah, NJ), which is one of the manufacturers of anesthesia machines that measure breathing circuit pressure only in the expiratory limb. During testing of the system by engineers at GE Healthcare (Madison, WI), it was found that producing a complete occlusion of the expiratory limb at the junction of the disposable breathing circuit and the connection to the absorber during operation of the machine was not detected. Indeed, during the experimental occlusion of the expiratory limb of a circuit, the system indicated zero airway pressure and alarmed for low pressure, when in fact the circuit pressure was independently measured and found to be 63 mmHg.

In order to determine whether or not this was an event isolated to one particular anesthesia machine we asked 2 other users of Datascope AS 3000 systems to perform an experiment in which they placed a piece of plastic over the expiratory portion of the absorber and connected a disposable breathing circuit. In all instances, when the expiratory limb was occluded, the Datascope AS 3000 system's airway pressure gauge showed zero airway pressure while the reservoir bag, used as a test lung, continued to grow larger.

We understand that other manufacturers' machines respond in a similar fashion, and we would suggest that, in general, future anesthesia machine designs incorporate airway pressure measurements within the breathing circuit rather than in the absorber behind the one-way valves where the pressure transducer is isolated from the breathing circuit. It is not difficult to imagine a situation where the expiratory limb of a circuit may be either externally or

internally occluded, and subsequent build up of fresh gas flow and ventilation with undetected high pressure could result in an untoward event.

*George Mychaskiw II, DO, FAAP, FACP
Professor and Chair, Department of Anesthesiology
Drexel University College of Medicine
245 North 15th Street
Philadelphia, PA 19102*

Disclaimer: Dr. Mychaskiw is a consultant to and has received research support from GE Healthcare, Inc.

Reply:

Mindray appreciates the opportunity to respond to Dr Mychaskiw's concerns regarding the Datascope AS3000 anesthesia machine. We appreciate receiving all comments and concerns regarding our products and take these very seriously. Mindray has patient safety at the forefront of product development and recognizes the value and responsibility of providing education concerning the safe use of anesthesia delivery systems and all medical equipment.

The issue in this case involves the fact that the Datascope AS3000 measures airway pressure in the expiratory limb of the circle breathing system (see Figure 1). When the exhalation limb becomes completely occluded, as in the case of a defective breathing circuit, the pressure in the lungs is not monitored correctly either by the electronic sensor or the circle pressure gauge (see Figure 2). Many manufacturers choose to sense airway pressure only in the expiratory limb. Ironically, Dorsch and Dorsch¹ state that placing the sensor on the expiratory side of the circuit has an

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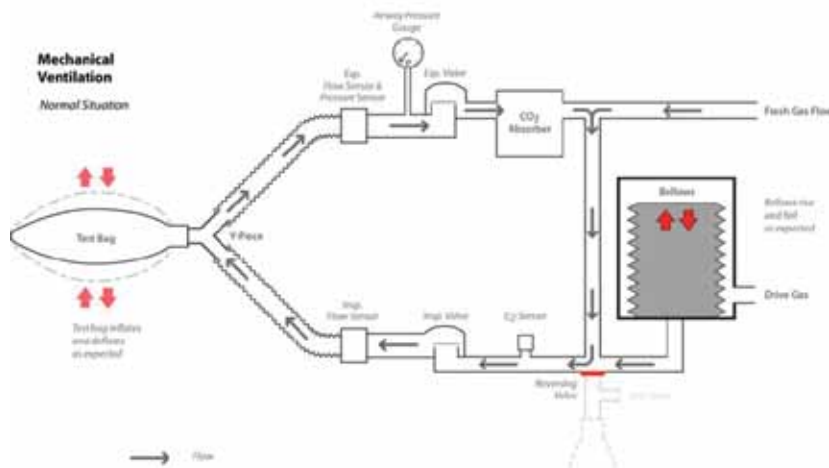


Figure 1. The Datascope AS3000 circle breathing system with inspiratory and exhalation sensors during mechanical ventilation.

Expiratory Pressure May Falsely Read Zero During Circuit Occlusion

“Dear SIRS,” From Preceding Page

advantage over placement in the inspiratory side of the circuit, if there is an obstruction in the inspiratory limb.

We have thoroughly investigated the issue of measuring breathing circuit pressure only in the expiratory limb during complete occlusion of the breathing circuit at the connection to the exhalation port on the absorber. It is pertinent to note that Dr. Mychaskiw's finding came from bench laboratory studies and that no such no related adverse clinical events have ever been reported on the AS3000.

There are 2 rare but potential clinical occurrences that would fully occlude the expiratory port:

1. A manufacturing defect in the breathing circuit, where the occlusion was in place before the pre-use checkout and the beginning of the case.
2. A situation where the expiratory limb is placed over an already occluded expiratory port (i.e., the expiratory limb is forced over a piece of rubber or plastic that is large enough to entirely occlude the expiratory port.)

Figure 1 illustrates the normal breathing circuit operation with breathing circuit sensors during mechanical ventilation, while Figure 2 illustrates the effects of occluding the expiratory limb in this mode. Note that the pressure sensor and the pressure gauge are located in the expiratory limb before the expiratory valve. Other anesthesia machine manufacturers have taken this approach to monitoring breathing circuit pressure. Figure 3 illustrates the same breathing circuit in the manual mode with an occlusion in the expiratory limb from a defective breathing circuit. The breathing bag is filled from the fresh gas inflow from the anesthesia machine. As the breathing bag is squeezed, gas is displaced from the bag and travels through the inspiratory limb to the test lung made from another breathing bag. The pressure created in the breathing circuit, and registered on the pressure gauge as the bag is squeezed, is a function of breathing circuit compliance and fresh gas inflow. Because the expiratory limb is occluded, gas that enters the test lung when the bag is squeezed will be trapped in the test lung. The maximum pressure will be determined by the compliance of the “test lung” (breathing bag) and the APL valve in the manual mode, or the pressure limit set on the ventilator while in the mechanical ventilation mode. The pressure on the bag side of the inspiratory valve will be atmospheric until the fresh gas inflow fills the bag again. Meanwhile, the gas volume and pressure in the test lung remains due to the occlusion in the expiratory limb and a closed inspiratory valve disk. Additional gas volume can be added to the test lung by squeezing the breathing bag. If the fresh gas inflow is low or zero, squeezing the bag translocates the gas to the test lung and the breathing bag remains empty. In other words the breathing circuit appears to have a large leak, only the gas is accumulating in the test lung.

The purpose of the pre-use checkout is to detect potential problems before they impact the patient.

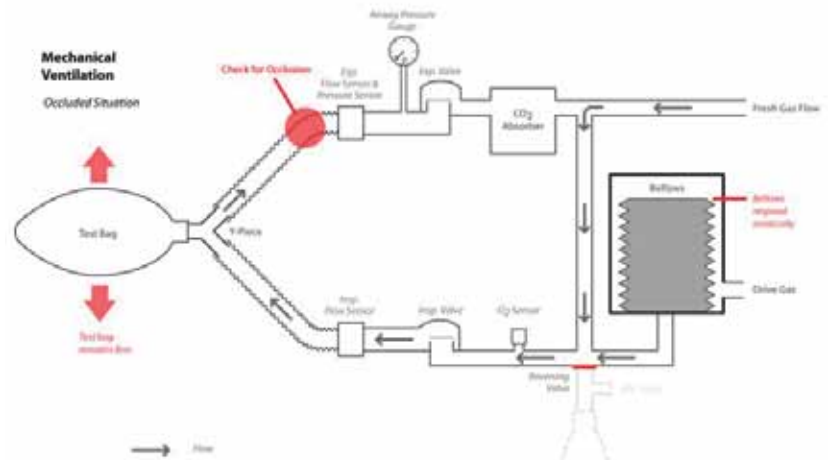


Figure 2. The Datascope AS3000 circle breathing system with expiratory limb occlusion during mechanical ventilation.

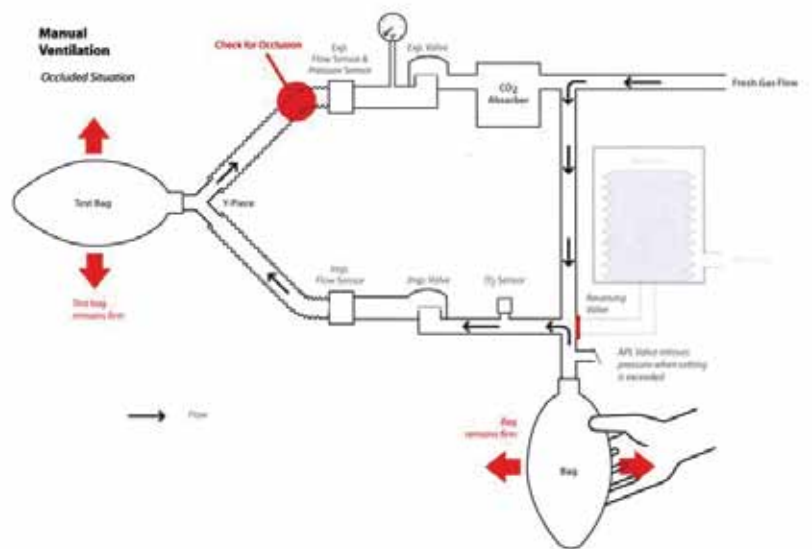


Figure 3. The Datascope AS3000 circle breathing system with expiratory limb occlusion during manual ventilation.

The manufacturers of anesthesia delivery devices all have effective safety concepts and alarm algorithms, but each manufacturer implements these differently. In this regard, the AS3000 is similar to many other anesthesia delivery systems in the United States. A simple, but effective method for detecting events like occlusion of the exhalation valve can be found in the recommended machine checkout procedures and the recommended machine checks between cases in the same room.^{2,3} For example, it is recommended that the breathing circuit be tested for the ability to effectively deliver positive pressure ventilation before the beginning of each case. A simple leak test by itself is of minimum value, but testing the ability to properly ventilate a test lung is essential and can quickly identify an occluded expiratory limb and other breathing circuit problems. At the start of each case, or before the start of each case to follow in that room, simply removing the breathing bag from the bag arm and connecting it to the patient connection

(elbow or wye piece on the disposable circuit) will permit evaluation of the machine's ability to ventilate the patient. The ventilator can be set to deliver a specific tidal volume to the test lung and verified by the exhaled tidal volume monitor. Observing that the test lung (breathing bag) inflates as the bellows descend, and that the test lung volume decreases during the exhalation phase, along with observing that the measured exhaled volume closely matches the tidal volume set on the ventilator, will provide a level of confidence necessary to proceed with the induction of anesthesia. With the fresh gas inflow set to minimum, or zero, if the bellows fail to rise to the same height during each exhalation then a leak should be suspected, identified, and repaired.

This simple and quick evaluation is the minimum checkout that should be performed between cases. Other published checkout procedures are somewhat

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Dear SIRS: Is Yellow Desflurane Safe to Use?

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more involved, and may evaluate other aspects of the machine, but making sure that a test lung (breathing bag) can be effectively manually or mechanically ventilated indicates that the patient has a high probability of being ventilated.

Specifically in the case of the Datascope AS3000:

As explained above, in the case of an occluded expiratory limb caused by a defective breathing circuit, using the checkout procedure that evaluates the ability of the machine to mechanically ventilate a test lung (the breathing bag) while the fresh gas inflow is set to zero, the occlusion would be easily recognized:

1. Visually the breathing bag will inflate further with each delivered breath, because it cannot exhale.
2. There will not be an appropriate indication of breathing circuit pressure on the pressure gauge or the monitor as the breath is being delivered.
3. The exhaled volume monitor will indicate zero exhaled volume, and it will activate an apnea alarm because the delivered volume measured by the inspiratory flow sensor will not be detected by the expiratory limb flow sensor.
4. A low pressure alarm will be activated because the expiratory sensor does not detect a rise in pressure associated with an expiratory breath.
5. The ventilator bellows will not rise during the exhalation phase and will collapse after delivering a few breaths.

These not so subtle signs of breathing circuit problems should alert the anesthesia provider to troubleshoot the breathing circuit or call for help.

If the semi-automated checkout procedure for the AS3000 is performed while the expiratory limb is occluded, the following abnormal results will be observed:

1. Under the Leak Test heading, depressing the oxygen flush button until the PAW is between 25 and 35 cmH₂O is between 25 and 35 cmH₂O will cause the pressure measured at the circuit to increase abnormally and extraordinarily slowly, possibly never reaching 25 cmH₂O as required by the test, providing the first indication of an abnormal condition.
2. Under the Safety Valve test, pushing the oxygen flush button to fill the bellows results in an abnormal sound associated with excess pressure venting through an internal relief valve.
3. Under the Leak Test, the machine indicates a leak greater than 1 liter/minute because flow is not detected by the expiratory flow sensor.

During this condition the machine disables the ventilator and will not permit the clinician to use mechanical ventilation, until the issue is resolved and the leak test is re-run and passed.

Clearly, the most useful pre-use checkout procedure that works for any anesthesia machine is to set up the breathing circuit, relocate the breathing bag from the bag arm to the breathing circuit patient connection, set all flowmeter to off or minimum, depress the oxygen flush button and fill the bellows, then turn on the ventilator and observe the ventilation of the breathing bag connected to the disposable breathing circuit. Additionally, note the exhaled tidal volume on the monitor and verify that it is close to your set tidal volume. Look for the bellows to re-inflate without loss of volume, indicating that there is not a leak in the breathing circuit.

Mindray is driven to the highest product quality and performance standards. Based on our research and testing of the expiratory limb occlusion, we feel this scenario, which was identified and duplicated in the laboratory, is a rare clinical event that would be readily detected during both the startup testing and during a normal pre-use machine check out. An understanding of specific equipment functionality and conducting the recommended pre-use pressure, leak, and flow tests will assist the anesthesia provider in identifying rare untoward events such as complete occlusion of an expiratory limb of a disposable breathing circuit. We sincerely appreciate the opportunity to interact with the anesthesia community regarding the performance of our products. Our goal is to continually enhance new product performance based upon input from clinicians.

*Sincerely,
Scot C. Carriker, MBA
Strategic Marketing Manager
Anesthesia and Ventilation*

*Richard G. Cipolli
Director
Anesthesia Systems/Hardware Engineering
Mindray North America
Mahwah, NJ 07430*

References

1. Dorsch JA, Dorsch SE. Understanding anesthesia equipment, 5th ed. Philadelphia: Wolters Kluwer/Lippincott Williams & Wilkins, 2008: 246.
2. Olympio MA. Dear SIRS: Reader seeks standards for equipment check. *APSF Newsletter* 2006-07; 21(4):78-9.
3. Sub-Committee of ASA Committee of Equipment and Facilities. Recommendations for pre-anesthesia checkout procedures (2008). Available at: <http://www.asahq.org/clinical/FINALCheckoutDesignguidelines02-08-2008.pdf>. Accessed July 29, 2010.

Dear SIRS:

We noticed yellowing of the desflurane in the site glass of the Dräger (D-Vapor) desflurane vaporizer some time ago. We stopped using it completely and notified our hospital Baxter representative. He had

someone from Baxter call us and fax a letter saying something to the extent of, "This is an old issue, it has been investigated by the company, desflurane is interacting with the plastic components in the vaporizer, no harm to patients, nothing to worry about." Is there any current information regarding the discoloration of desflurane?

*Alex Wolfson, MD
Princeton, NJ*

Response:

Dear APSF:

The observation of Dr. Wolfson and his colleagues at University Medical Center at Princeton is similar to other customer reports received by Baxter of discoloration of SUPRANE® (desflurane, USP) observed either in the vaporizer sight glass or in liquid drained from the vaporizer sump. Baxter has conducted investigations of these reports. What follows is a summary of the results of this testing through which we conclude that the discoloration occasionally observed in the sump of a vaporizer does not impact the quality of SUPRANE® (desflurane, USP) delivered.

SUPRANE® (desflurane, USP) is a clear, colorless, volatile liquid, manufactured and tested under state of the art quality controls. It is chemically stable and does not degrade under any known storage or vaporizer use condition. Although Baxter has never encountered discolored SUPRANE® (desflurane, USP) in an unopened bottled Drug Product, Baxter and customers have observed discolored SUPRANE® (desflurane, USP) in the vaporizer sight glass or in fluid drained from the vaporizer sump.

Baxter first learned of discolored SUPRANE® (desflurane, USP) following an observation reported to Baxter in 2004. As part of Baxter's investigations since that time, multiple samples of discolored desflurane obtained from customers were tested in several ways. First, samples were heated and evaporated in laboratory equipment designed to simulate the processes normally occurring in a vaporizer. The vaporized material was condensed, assayed, and tested for visual appearance, total impurities, and nonvolatile residue. In all instances, the condensate was clear, colorless, and met SUPRANE® (desflurane, USP) Drug Product release specification for these tests.

Additional experiments were conducted by placing discolored desflurane samples directly into commercially available GE (Tec 6 Plus) and Dräger (D-Vapor) vaporizers that were then tested under normal operating conditions. Again, the vaporized material was condensed, assayed, and tested for visual appearance, total impurities, and nonvolatile residue, and determined to be clear and colorless,

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No More Difficult Airway, Again! Time for Consistent Standardized Written Patient Notification of a Difficult Airway

by Heidi M. Koenig, MD

Note: This article offers a reminder and a template to facilitate standard written communication of a patient's difficult airway as recommended by the ASA difficult airway taskforce.

Introduction /Historical Perspective

Difficult airways happen. Difficult intubations have variably been reported to range from 1-18% in the operating room.¹ Although the incidence is unknown, some patients also have a second or recurrent unanticipated difficult airway event. With today's ability to communicate, there is no reason for a patient to risk having a second unanticipated difficult airway or for an anesthesia professional to suffer the stress of encountering an unanticipated difficult airway.

On several occasions I have encountered unanticipated difficult airways. One situation escalated to a "cannot-intubate, cannot-ventilate" adequately event that led quickly to a tracheotomy. Later we reviewed the patient's history and interviewed her in detail—she was never told of any problems with her airway. However, after delving further into her history we found that several years before she had an elective outpatient surgical procedure cancelled on the table and was admitted to the hospital with a very sore throat. She was told only that she did not need the procedure after all. Would this have been our only clue?

Difficult intubation is not necessarily related to difficult airway otherwise.² Previous difficult intubation has a better positive predictive value (69-78%) than other independent predictive values. In particular, individuals with normal body habitus and exams who present with a difficult airway need to be informed precisely of the situation. We have, as a specialty, done many things to improve patient safety, one of which is to write letters for patients regarding airway difficulties encountered during their care. Since the above described encounter, I have been driven to simplify and improve the process of patient notification of a clinically occult /unknowable difficult airway. My goal is to make standardized notification the norm. A template is presented in the Appendix that can be quickly completed; it uses standard terminology to thoroughly describe the difficulty with the airway and how it was managed successfully. This can be copied and distributed to the patient, the primary care provider, the surgeon, and the facility. Such documentation facilitates effective communication of the presence and management of a difficult airway to future care providers.

The ASA Difficult Airway Taskforce published updated guidelines to facilitate management of and reduce adverse consequences of the difficult airway in 2003.³ The algorithm they developed and many workshops the society has sponsored to practice its application have led to greater comfort and timely successful effective airway management of the

difficult airway whether anticipated or unanticipated. This taskforce suggests the use of standard terminology to describe the difficulty with the airway: difficult facemask ventilation, difficult laryngoscopy, difficult tracheal intubation, and failed intubation . . . and elaboration on the details as necessary to convey important points to future practitioners. Prior to the practice guidelines regarding the management of the difficult airway there was little or no literature regarding benefits of patient notification of difficulty with management of their airway. The practice guidelines recommend informing the patient or responsible party of the presence of and basis for a difficult airway, unsuccessful management strategies, and successful ones. Further, in 1992 the ASA and others recommended the creation of a National Difficult Airway registry. Via numerous letters to the editor and obscure publications, anesthesiologists have given recommendations and offered templates for such notification. Their recommendations included having the patient wear an identification bracelet, registering the patient with an emergency notification service, notifying the surgeon and primary care provider, and documenting the event in the patient's chart.

Non-standardized notification practices are common. Anesthesia providers all notify difficult airway patients in some way. Most orally inform the patient and loved ones in the PACU. However, this may not be the ideal time for this notification as the patient is somewhat sedated and the loved ones are anxious about the surgical findings and the patient's recovery from anesthesia and surgery. In fact, 50% of patients informed orally immediately after surgery forget the information,⁴ which suggests that oral communication is not sufficient.

Many practitioners use a letter to notify patients of the difficult airway. This is time consuming and requires time at a computer with at least one original paragraph about the patient's specific anatomy, techniques that worked, and those that did not. Also, if mailed later, there is no verification that the patient understands the significance of the situation.

I propose using a standardized written notification. This will force inclusion of a number of details that are part of the multifactorial prediction of a difficult airway. In addition it will allow for additional comments specific to the patient and his/her medical condition. The template presented here includes a standard introductory paragraph, a fill-in-the-blank airway exam, check boxes of the Mallampati grades⁵ and Cormack Lehane⁶ laryngoscopic views, as well as a checklist of possible approaches to the airway. There is, of course, room to add additional comments. Once completed, the original should be given to the patient or the party responsible for his or her healthcare decisions. Copies should be given to the surgeon and the primary care provider, and filed in the patient's medical record at the facility where the event took place.

The patient and loved ones need to understand how important it is to give a copy to future anesthesia providers. John Eichhorn who founded the APSF

Newsletter in 1986 states that empowering the difficult airway patient with their own health information during followup has always been a good idea, and anything you can do to advance this cause is appropriate. Making the patient responsible also bypasses all the HIPAA limitations that could be problematic with a website that allows access to the patient's medical information. Whether the information is in a registry or in a letter, patients or their advocates must be able to tell the provider to look for the information. At the local Veterans Administration Hospital, we have the template available electronically. Once the template is entered into the patient's electronic medical record, a posting on the patient's cover sheet is automatically generated indicating the patient has had a difficult airway. The same process is activated for allergies and advanced directives. Also, the practitioner can add difficult airway as a diagnosis to forewarn future practitioners. A copy is printed and given to the patient. At the University of Louisville Hospital, the paper template is available in the PACU and on the difficult airway cart for manual completion. A copy is also available as an e-document, but still requires manual completion, copying, and distribution. For the medical record it must be scanned into the patient's permanent record.

Difficult Airway Registries

Many institutions and countries, for example Denmark⁷ and Austria,⁸ have difficult airway registries with extensive standardized documentation. This works well if the patient is receiving care within the same system and the practitioner knows to check the registry. In some instances it is difficult to know the patient is part of such a registry, and even if one is informed, specific information may or may not be quickly and easily accessible to the practitioner faced with the patient's care. Making such information universally available would violate HIPAA regulations. The patient or his healthcare advocate should be empowered to deliver the completed template as a letter or wallet card to future anesthesia providers.^{9,10} This obviates the need for codes and permission slips to access the information. As travelling within the country and around the world has increased, so has the incidence of receiving healthcare in facilities that have no access to medical records from previous surgeries. Using standard notification will facilitate global reporting of the exam and management strategies employed.

In summary, immediate written notification with standardized documentation of the patient's difficult airway can prevent recurrent difficult airway events. Once completed, distribute copies of the documentation to the surgeon and the primary care provider in writing. Place a copy in the medical record of the patient in the facility where the difficult airway was first noted. Offer the patient a wallet card or medic alert ID regarding the difficult airway. Educate patients about their "difficult airway" diagnosis and empower them with their own health information to

See "Airway," Next Page

Difficult Airway Communicated Via Standardized Patient Notification Form

“Airway,” From Preceding Page

avoid recurrent personal endangerment and to protect their privacy by using a simple, thorough template containing accurate standard health terminology such as the one proposed here. Teach patients the importance of self-advocacy without scaring them. All these precautions are aimed at preventing undue risk for the patient and undue stress for future anesthesia providers. We must decrease the likelihood of a second unanticipated difficult airway event and avoid putting the patient at recurrent risk unnecessarily.

References

1. Naguib M, Scamman FL, O'Sullivan C, et al. Predictive performance of three multivariate difficult tracheal intubation models: a double-blind, case-controlled study. *Anesth Analg* 2006;102:818-24.
2. Samsoon GL, Young JR. Difficult tracheal intubation: a retrospective study. *Anaesthesia* 1987;42:487-90.
3. American Society of Anesthesiologists Task Force on Management of the Difficult Airway. Practice guidelines for management of the difficult airway: an updated report by the American Society of Anesthesiologists Task Force on Management of the Difficult Airway. *Anesthesiology* 2003;98:1269-77.
4. Francon D, Bruder N. Why should we inform the patients after difficult tracheal intubation? *Ann Fr Anesth Reanim* 2008;27:426-30.
5. Mallampati SR, Gatt SP, Gugino LD, et al. A clinical sign to predict difficult tracheal intubation: a prospective study. *Can Anaesth Soc J* 1985;32:429-34.
6. Cormack RS, Lehane J. Difficult tracheal intubation in obstetrics. *Anaesthesia* 1984;39:1105-11.
7. Rosenstock C, Rasmussen LS. The Danish Difficult Airway Registry and preoperative respiratory airway assessment. *Ugeskr Laeger* 2005;167:2543-4.
8. ADAIR: Austrian Difficult Airway/Intubation Registry, 1999. Available at: <http://www.adair.at/>. Accessed May 20, 2010.
9. Mark LJ, Beattie C, Ferrell CL, et al. The difficult airway: mechanisms for effective dissemination of critical information. *J Clin Anesth* 1992;4:247-51.
10. Trentman TL, Frasco PE, Milde LN. Utility of letters sent to patients after difficult airway management. *J Clin Anesth* 2004;16:257-61.

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Appendix

Date: (00/00/0000) RE: _____ has a difficult airway, DOB: (00/00/0000)
(Patient Name)

During your recent anesthetic and surgery, your anesthesia providers noted that you have a difficult airway.

Specifically: _____ difficult mask ventilation, _____ difficult laryngoscopy, _____ difficult intubation, or _____ failed intubation.

An unexpected difficult airway is a known potential concern with general anesthesia and can be dangerous. If you should need anesthesia or mechanical ventilation in the future, it is important that you inform your anesthesiologist and surgeon of the potential for a difficult airway. Ideally you would give them this letter to review.

Physical Exam:

Body mass index (BMI) < 25 _____ 25 - 30 _____ > 30 _____
Mallampati airway classification: _____ I- soft palate, uvula, pillars _____ II- soft palate, pillars
 _____ III-soft palate _____ IV-hard palate
Mouth opening: _____ cm
Dentition: Native _____ prominent incisors _____ edentulous
 _____ Jaw protrusion (can protrude lower incisors beyond upper incisors)
Thyromental distance: _____ > 6 cm _____ < 6 cm
Neck extension: _____ full (35°) _____ limited (<15°O)

Details of what actually took place during airway management:

Intubation: _____ emergency _____ elective
Bag and mask ventilation was _____ Easy _____ Difficult _____ Not possible
Muscle relaxants were _____ administered _____ not administered
Cormack/Lehane Laryngoscopic view: _____ I - full view of the glottis opening _____ II - epiglottis and arytenoids
 _____ III - tip of epiglottis _____ IV - only soft palate
Intubation _____ Successful _____ Not successful
 _____ An LMA was placed and anesthesia proceeded without further difficulties
 _____ Intubation was performed _____ through a Fast track laryngeal mask airway
 _____ with video assisted laryngoscopy
 _____ with fiberoptic bronchoscope guidance
 _____ An emergency tracheostomy was performed
 _____ Your surgery and anesthetic were rescheduled
 _____ Decadron was administered to prevent swelling postoperatively
 _____ You were admitted postoperatively for _____
 _____ Other _____

Extubation was _____ routine _____ over a stylet

Complications

Although a minor sore throat is common after general anesthesia, if you experience a persistent severe sore throat, difficulty swallowing or fever, immediately contact your surgeon and the anesthesiologist on call at the facility.

Sincerely,
 Your Anesthesiologist (sign and print your name)

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contribution from The Hewlett-Packard Company of what was then novel technology, a computer that did word processing, also helped the publishing process.)

The first issue of the *Newsletter* was mailed to 45,000 recipients (ASA, AANA, risk managers, corporate and international supporters) in March 1986. Beyond the lead story about the creation of APSF, there was a long article by Dr. Gravenstein questioning whether there was such a concept as "minimal intraoperative monitoring" and also a report of the initiation of the ASA Closed Claims Study. Other stories concerned the expansion of the Confidential Enquiry into Perioperative Death in England, the publication of the statistics on cardiac arrest due to anesthesia at one teaching hospital, and a discussion of the relative dangers of hypoxemia and hypercarbia. The first *Newsletter* was very well received and set the tone for all subsequent issues. Later the first year, there were discussions of: an ECRI report on "Deaths during General Anesthesia," verification of correct endotracheal tube placement, analysis of anesthesia deaths in Australia, and decreasing anesthesia claims at one major insurance company. There was announcement of the first FDA anesthesia machine check-out protocol and reprinting of Dr. Pierce's important article, "Risk Modification in Anesthesiology." Standards figured prominently in early issues as there was extensive discussion of the 1986 ASA adoption of "Standards for Basic Intra-Operative Monitoring" and also the various evolving anesthesia machine device and performance standards (fresh gas ratio protection, vaporizer exclusion, etc.) intended to enhance safety. Strong support for the universal use of intraoperative pulse oximetry, and later capnography, was a major early APSF theme. This support contributed to the establishment of these monitors as standards of care, which significantly help ensure patient safety to this day. The concept of special safety risks outside traditional hospital operating rooms was introduced in the *Newsletter*, as

was the idea of support systems to facilitate the conduct of anesthesia practice, and the idea of provider fatigue as a special danger to anesthetized patients.

The APSF partnered in the beginning with the ASA in co-producing a series of educational videotapes about a wide variety of anesthesia patient safety topics. Dr. Pierce was intensely involved in many of the productions. The finished tapes were distributed to all anesthesia departments in the U.S. by what was then the Burroughs-Wellcome Co. This tradition continued for many years but eventually fell victim to rising costs, corporate consolidations, and evolving media. (However, just recently, such efforts were revived when the APSF partnered with ECRI Institute to produce and distribute a DVD on "Prevention and Management of Operating Room Fires.")

The APSF tradition of education and advocacy though targeted workshops, seminars, and task forces began in 1987 with the convening of a 2-day meeting, "Safety and Cost Containment in Anesthesia." Critical issues of danger to patients created by enforced cost-cutting measures were discussed in detail and contrasts made with the safety conscious commercial aviation industry. The proceedings were published in a book that was used in many hospitals to help advocate for resources (as also were various issues of the *Newsletter* when key safety programs and equipment were presented). An early workshop focused on "Needed Research in Patient Safety." However, there was a learning curve. An overly ambitious proposed national APSF Grand Anesthesia Safety Symposium ("GASS") was cancelled due to a paucity of registrants. Nevertheless, after gaining better organizational skills, in 1990, the APSF, partnering with the FDA, convened an unprecedented expert workshop on human error in anesthesia practice that helped stimulate later advances.

Sponsorship of patient safety research was (and remains) one of the core goals of APSF. In the first year, 27 research grant applications were received and 4 grants were awarded. The titles of the 4 were "Defining Outcomes Associated with Anesthesia,"

"A safer Anesthesia Machine Through Model-Based Alarms," "The Risk of Surgery and Anesthesia: A Retrospective Analysis," and, from David M. Gaba, MD of Stanford, "Evaluation of Anesthesiologist Problem Solving Using Realistic Simulations." Dr. Gaba went on to become one of the founders and leaders of using high-fidelity simulation in patient safety, human factors research, and medical training and research in general, as well as a fixture in the APSF leadership. Others researching human factors have also been supported, and they have contributed to the understanding of the fine details of our OR practices and their safety implications. The first APSF Young Investigator award went to Richard I. Cook, MD, a computer scientist before he became an anesthesiologist, to study the impact of high-tech equipment such as integrated monitors on practice behavior in the OR. Each year since 1986, the research grant recipients and outlines of their projects appear in the Winter issue of the *APSF Newsletter* (the complete catalogue of which is readily available on the website: www.apsf.org). Periodically, articles in the *Newsletter* (Winter, 1994; Spring, 1996; Spring, 2004) have reviewed completed projects and lists of peer-reviewed publications resulting from research funded by APSF grants and also presented follow-up reports of particularly valuable research results. One prominent early example was an important study from the Massachusetts General Hospital that showed the complementary intertwined value of adding capnography to pulse oximetry as a routine intraoperative monitor. Those data soon played a significant role in the evolution of the ASA monitoring standards, changing the routine use of end-tidal carbon dioxide monitoring from recommended to mandatory, which the APSF supported and promoted. APSF funding supported the initial development of "smart alarms" on patient monitors and anesthesia machines. Likewise, seminal human factors research into how anesthesia professionals see, absorb, and process monitoring information was funded by APSF.

Simulation Targeted

The APSF helped organize in 1988 what well may have been the first meetings on medical simulation, featuring 8 types of simulators. Then, in 1989 the APSF sponsored the Anesthesia Simulator Curriculum Conference that, despite just dodging a hit from Hurricane Hugo, attracted 92 exhibitors and educators to an intense, extremely productive meeting that included the first attempt at collaboration to advance anesthesia simulator technology. In 1995, APSF convened a national conference on simulation in anesthesia education. Overall, the APSF extensively supported (intense advocacy, and both regular and special research grant funding over several years) the development and implementation of simulation in anesthesia. The APSF had a major early role in catalyzing and supporting simulation to become a significant tool in research (human performance), training (teamwork, crisis management), and education (residents attempting



Dr. David M. Gaba, a pioneer in anesthesia simulation and APSF Executive Committee member, was instrumental in popularizing anesthesia simulation for education, training and recertification evaluation, and research.

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APSF Advocates for Anesthesia Simulation and Patient Safety Training, Research, and Education

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new skills and procedures for the first time on a mannequin rather than an actual patient). Again, while little recognized over the years, the APSF appropriately deserves credit for a truly pivotal role in the development and popularization of medical simulation, which is now a hugely successful, universal, integral component of health care. As true with the original concept of patient safety and with formal standards of care, with simulation, the profession of anesthesiology was there first and should be proud of its leadership.³ This theme is well captured in a book summarizing the formative years of the APSF, including reprints of key *Newsletter* articles.⁴

Evolution

One important function provided by the APSF over the early years was the documentation of the decrease in morbidity and mortality from anesthesia accidents—the beginning of the remarkable improvement in anesthesia patient safety that persists today. There were multiple *Newsletter* articles, mainly from malpractice insurance companies in the U.S. and from safety researchers in several other countries, as well as editorials and reports at APSF meetings that discussed statistics, trends, and observations of the positive evolution of the safety of anesthesia care. An interesting footnote is a 1990 *Newsletter* announcement that the ASA had published a 12-page brochure, "FYI... A Commitment to Patient Safety," its first on this topic, for distribution to the public and all interested parties, which contained prominent reference to the ASA's support of the APSF.

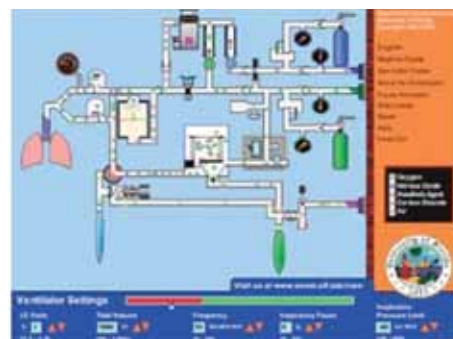
The APSF/Ellison C. Pierce, Jr. Award was established for presentation to the exhibitor and sponsor of the Scientific Exhibit at the ASA Annual Meeting that best demonstrates new and effective methods of safe anesthesia practices. Its first presentation in 1989 recognized an exhibit describing improved approaches to airway management in the OR, one of several winners on this general topic over the years. That October, a runner-up was named and singled out for distinction; it was an exhibit of a computer-generated screen-based anesthesia simulator. Furthermore, each year since its creation, the *APSF Newsletter* has carried an extensive account of the patient-safety related presentations and activities at the ASA Annual Meeting. Possibly one of the most dramatic illustrations of the evolution of anesthesia patient safety is the increase in the emphasis on patient safety at this meeting. It started with a handful of presentations in the late 1980s that had been added to the end of "more traditional" abstract sessions and grew consistently until now when there are multiple entire abstract and poster sessions involving well over a hundred safety-related presentations spread over the entire meeting.

Spreading the Word

Implementing one of the APSF core goals, rapid communication of safety-related clinical information directly relevant to the primary practice of anesthesia

professionals, the APSF has consistently over its history received, researched, and publicized alerts on previously unknown issues. The APSF thus has been a key central clearing house for critical safety information, one of its most important and well-recognized roles in promoting patient safety. In 1991, the *Newsletter* published the first report of "Monday morning carbon monoxide poisoning" from the unusual interaction of desiccated CO₂ absorbent material with halogenated volatile anesthetics. That went on to become a major national story, one that later stimulated the APSF into sponsoring a national workshop to review the topic of CO₂ absorbents and refine recommendations for action. More recently, the related issue of "canister fires" was first publicized by the APSF. Support for and publicity of the ASA Difficult Airway Algorithm has been consistently strong, and this was the subject of one of the APSF videotapes. Checklists such as the pre-anesthesia machine check-out, particularly emphasizing the analogy to pilots preparing for takeoff, have been continually promoted. Latex allergy danger, when it first came to prominence in anesthesia practice, was the subject of an APSF campaign. The first discussion of potential patient danger from sevoflurane contaminated with acid from an alteration in its manufacturing process was published in the *APSF Newsletter* (along with an outline of the remedial action by the manufacturers). The question of danger to allergic patients from the inclusion of sulfite as a preservative in a new formulation of propofol was first raised by an alarming communication to the *Newsletter* from a prominent academic department chair who noted he himself was at risk. More recently, the danger of outbreaks of infectious complications, particularly hepatitis, from use of syringes of anesthetic medication on more than one patient were broadcast by APSF. Another of the widely-quoted "alert" functions has been served by the APSF calling attention to reports of unusual events that harmed patients. One prominent example concerned the unfortunate death of a patient whose IV tubing had been connected to his tracheostomy tube cuff inflation port instead of the adjacent central venous catheter, highlighting the issue of dangers from connection compatibilities (a problem that continues to defy solution). Others involved obstruction to ventilation from a variety of objects somehow accidentally getting wedged in breathing circuits, connectors, or tubes as well as fires that started due to damaged O₂ tank gaskets.

Another key opportunity to raise awareness and advocate for anesthesia patient safety occurs each October at the ASA annual meeting where the APSF "patient safety booth" sits prominently in the exhibit hall. Skillfully organized and crafted by Dr. Robert A. Caplan of the APSF Executive Committee, the booth draws in passers-by with bold displays of intensely relevant current patient safety news, reprints of and from the *Newsletter*, as well as on-screen presentations of safety videos and the Virtual Anesthesia Machine program. A fairly frequent comment from booth visitors is something like, "Wow, I didn't know you guys did all this."

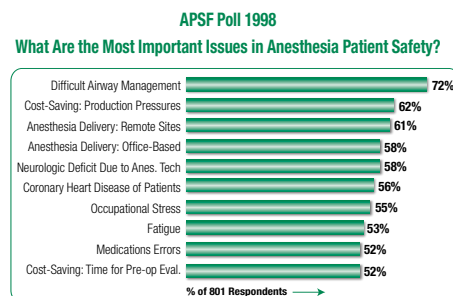


Output from the Virtual Anesthesia Machine.

In the 1990s Dr. Pierce was appointed as the ASA representative to the AMA's newly formed forum on the then-new idea of "practice parameters." He, as a safety expert and as a representative of the APSF, advocated vigorously for the ASA to adopt the practice parameter model, which thrives still today as a significant tool in advancing patient safety.

The patient risks associated with anesthesia professionals not fully familiar with or understanding their own equipment, particularly ever-increasingly complex anesthesia machines, monitors, pumps, etc., were recognized early on by the APSF. This topic in various forms has been (and still is) a major emphasis of the Committee on Technology, the Committee on Education and Training, and the subject of research, workshops, dedicated meetings, and widespread publicity.

One activity that has been especially well received has been the surveys of anesthesia professionals conducted by the APSF. One of the best-known surveys was conducted in late 1998. It asked what were the most important issues (associated with the greatest risks) in anesthesia patient safety. The results (percent of respondents naming an issue) were:



Interestingly, while the terminology and definitions may have changed slightly, these issues likely would be similarly identified today. For the past few years, the APSF website has included a participant poll on one safety issue of interest each month or so. The results appear and stay on the website. Recent poll questions concerned post-op monitoring of OSA patients getting PCA, substitute drugs when propofol is unavailable, and management of patients in the

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APSF Collaborates with Multiple Organizations to Promote Patient Safety

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beach-chair position for shoulder surgery. Another service at one point was the compilation in one file of the applicable regulations from all 50 states governing office-based anesthesia, which was then provided as a resource to anyone interested in this often contentious topic that directly impacts anesthesia patient safety.

Advantageous Alliances

Collaboration with other professional organizations interested in patient safety has consistently been a feature of APSF activities. A few years ago, the APSF partnered with the American College of Surgeons to submit a grant application regarding the feasibility of direct electronic input of relevant data from anesthesia information management systems into the National Surgical Quality Improvement Program (NSQIP). The APSF partnered with the journal *Anesthesia and Analgesia* in 2007, creating a new patient safety section in that journal. The chair of the APSF Committee on Scientific Evaluation, Sorin J. Brull, MD, was named section editor. Submissions of papers concerning anesthesia patient safety and visibility of the topic have increased substantially. Also, the APSF has sponsored panel discussions at the annual meeting of the International Anesthesia Research Society, ably organized and conducted by Richard C. Prielipp, MD, chair of the APSF Committee on Education and Training.

Another major initiative arose from a collaboration (and co-funding) with the inventors and manufacturers of anesthesia information management systems (AIMS). This led APSF to organize the development of a common terminology in clinical anesthesia practice that would allow all the computerized records and information systems to generate consistent, compatible (and comparable) data with standardized definitions. Known as the Data Dictionary Task Force, this effort has been ably chaired by Terri G. Monk, MD, and has worked for several years to develop the anesthesia lexicon for these systems. Its work product has been adopted and incorporated by national and international (IOTA = International Organization for Terminology in Anesthesia) groups responsible for establishing accepted medical terminology. This is a major accomplishment with great impact on the future of anesthesia practice. It is also another instance of very few people being aware of the key seminal role of APSF.

On a different tack, an alliance with the Society for Pediatric Anesthesia along with special APSF funding helped launch "Wake Up Safe," a formally approved patient safety organization that is a network of pediatric hospitals within the Society for Pediatric Anesthesia with the mission of creating an incident reporting system, event analysis paradigm, and safety data clearing house. Recently, the APSF was an endorser of the World Health Organization global safety campaign, "Safe Surgery Saves Lives," which features the "Surgical Safety Checklist," and the APSF conducted an extensive informational campaign to help facilitate implementation.



Collaboration as a Cornerstone: Anesthesiologists and CRNAs from academia and private practice, and industry representatives have collaboratively addressed patient safety issues at special APSF-sponsored conferences and the Annual APSF Board of Directors Workshop. Results of the workshops and conferences were disseminated via the APSF Newsletter to over 80,000 subscribers. Clockwise from top right: a) Drs. Matthew Weinger and David Gaba lead a breakout discussion group at the 2004 Workshop on Audible Alarms in Las Vegas, NV; b) Mr. Burton A. Dole, Jr, former APSF Vice President, and former President and CEO of the Puritan-Bennett Corporation was invaluable in involving industry in solving problems in patient safety; c) Drs. John Eichhorn (original APSF editor) and Robert Morell (current APSF editor) at APSF booth shaking hands; d) Drs. Sorin Brull (Chair, Scientific Evaluation Committee), Roger Moore (past ASA President), and Dr. William Lanier at the 2009 Workshop on Cerebral Perfusion Pressure and the Beach Chair Position in New Orleans, LA; e) Left to right, Drs. Dorsch, Olympio, Kharasch, Woehlck, Stoelting, and Eger speak at the APSF Conference on Safety Considerations of Carbon Dioxide Absorbents in July 20

New News

The *APSF Newsletter* has evolved also. Founding Editor Dr. Eichhorn turned over the proverbial editorial pen and scissors in 2002 to Dr. Robert C. Morell. The next year, *Newsletter* issues became available in .pdf format on the website, so the electronic experience would closely resemble the printed hard copies, which were then mailed to nearly 73,000 readers, making it by far still the largest anesthesia publication in the world (circulation has now grown to more than 80,000). Also, full color was added to the traditional "oxygen-tank green" highlight color that had marked the publication since its birth. Spirited, stimulating "pro-con" debates played out on its pages, covering topics such as the safety implications of anticoagulation and regional anesthesia, routine succinylcholine in children, reading (and now surfing or texting) in the OR during cases (many times), risks of pulmonary artery catheterization, concentrated lidocaine in spinals, safety of PCA narcotic infusion pumps (again), and even a mock debate on syringe reuse. Later, the "Dear SIRS" column ("Safety Information Response System") was added, initiated by Michael A. Olympio, MD, then chair of the Committee on Technology. Technical issues, often involving problems with equipment were discussed by panels of experts, including usually the manufacturer of any equipment in question. This feature quickly became one of the most popular ever in the *Newsletter*. On the strength of that experience, another well-liked column, titled simply "Q and A," was added to handle many of the more focused technical

questions that arrive at the APSF office and are directed to the Committee on Technology. Also, while "Letters to the Editor" always was and is a popular feature, the volume and intensity of submissions has increased in recent years. It is not unusual for there to be 8 or 10 thoughtful letters on a broad spectrum of topics published in a given *Newsletter* issue. Various landmark articles have had widespread impact on perceptions in anesthesia patient safety over the years. Examples include "How Safe is Safe?" by Dr. Gravenstein in 1995 and "Patient Perspectives Personalize Patient Safety," authored by Dr. Eichhorn in 2005. The latter was a report on the dramatic APSF workshop, conceived and organized by Dr. Cooper, in which surviving family members and one actual survivor herself detailed the impact of catastrophic anesthesia accidents (including on the involved providers).

Other recent APSF workshops conducted at the time of the annual meeting reflect and illustrate several of the major initiatives of the APSF and the intense efforts to keep up momentum for improvement of anesthesia patient safety. Long-term patient outcome and the potential for deleterious effects of anesthetics (postulated by some researchers potentially to be related to provocation of inflammation by anesthesia) were dissected in one session. The safety of post-operative opioid medication, particularly administered by patient-controlled analgesia (PCA), has been considered (provoking a special *Newsletter*

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APSF Workshops Focus on Problem Solving for Patient Safety Issues

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editorial: "Dangers of Postoperative Opioids—Is There A Cure?"). Medication safety in the OR and the implications of medication errors by anesthesia professionals is a recurrent subject. A recent iteration in 2008 had "Medication Mishap Mitigation" as its theme, and this was a stimulus for the comprehensive special invitation-only workshop in January of this year designed by APSF to map out a strategy for definitive action to decrease patient injuries from OR anesthesia medication errors. "Technological intensification" and technology training (or the lack of it) for anesthesia professionals faced with an ever-more-complex array of machines, monitors, pumps, and adjunct devices has been a major topic. The danger of decreased cerebral perfusion pressure in "head-up" cases such as shoulder surgery in the "beach-chair" position (billed as "How low can you go?") attracted a great deal of attention and interest. The importance and acuity of this topic led to a special *Newsletter* editorial by a Mayo Clinic world-class neuroanesthesia expert entitled "Cerebral Perfusion: Err on the Side of Caution." Further, the APSF has recently funded a new case registry, Neurologic Injury after Non-Supine Shoulder Surgery (NINSS) (modeled after the ASA Postoperative Visual Loss Registry) to compile and analyze cases of severe neurologic injury occurring after surgery in the beach chair position and develop recommendations to help prevent them.

Copious Concerns

Beyond those already mentioned, the list of other initiatives and projects undertaken by the APSF during its quarter century is long and varied. A partial accounting of additional APSF themes over the years includes action on the patient safety implications of

- Postoperative vision loss, especially in extensive prone spine surgery
- Wrong-site surgery
- Residual neuromuscular blockade and postoperative complications
- Failure to activate audible alarms on anesthesia machines and monitors
- An update of the "adverse event protocol"
- Persistence of deaths from malignant hyperthermia
- Dangers and challenges in patients with coronary artery stents
- An update of the anesthesia machine checkout protocol
- Possible impact of anesthesia management on cancer recurrence
- Persistence of OR fires—leading to production with ECRI of the recent "Fire Safety Video" that is now readily available and has been enthusiastically received and praised.

On the other hand, it is undeniable that certain APSF initiatives, however enthusiastically launched at the time, did not come to the full fruition that was originally hoped within the APSF. In most of these instances, the projects were extremely ambitious, involving proposed profession-wide, resource-intensive behavior modifications that proved to be beyond the sphere of the very influential but still comparatively small APSF. Included in that group would be the plan to devise, establish, and promulgate a uniform patient safety curriculum, continuously updated, that would be taught in every anesthesiology residency and CRNA training program in the U.S. Another example would be the heavily promoted proposed universal adoption of electronic automated anesthesia information management systems. Likewise, the transformation of all surgical suites into "high reliability organizations" (analogous to the extraordinary coordination, efficiency, teamwork, and safety of the deck of a massive aircraft carrier) is a laudable and very logical goal that was featured prominently for some time by the APSF

until it ran into the predictable resource limitations and entrenched cultures. Another topic that still proves difficult to tackle was the desire to try to organize thoughts and then proposed protocols to help deal with the realities of aging (or impaired) anesthesia professionals who might themselves create threats to patient safety. Finally, one of the significant concepts that has been debated, mostly within the APSF, throughout the history of the organization and without resolution is the desire for a genuine incident reporting network coordinated by the APSF, the originator of many of the relevant ideas. It has always been proposed that in addition to gathering and analyzing anonymous legally protected information about anesthesia adverse events and generating insightful recommendations, there would also be a rapid-response accident investigation team of highly experienced anesthesiologists and human factors researchers that could be activated in hours and flown immediately to the facility where a catastrophic anesthesia accident has occurred. This team, analogous to the one the NTSB sends to the scene of an airliner crash, would assist in or even direct the investigation of the anesthesia catastrophe—with complete dissociation and protection from the regulatory and medical-legal processes. Of course, the still-largely-volunteer APSF has not had the resources in time or finances to even begin to overcome the automatic strong resistance from multiple quarters to such a proposal. So, to quote a popular organizational mantra: "We're still working on that."

Research Renaissance

Prior to APSF initiating it, there was no research funding specifically for patient safety. As noted, sponsorship and promotion of research on anesthesia patient safety has remained from the outset one of the top APSF priorities, consuming the large majority of the APSF budget and a great deal of time by its dedicated volunteer reviewers on the Scientific Evaluation Committee. In recent years, significant increases in research grant funding have been made possible by donor contributions of funds targeted for research support. In the current cycle, the maximum possible grant award stands at \$150,000, a dramatic increase (more than double the rate of inflation) from the original 1986 award. The ASA funds 2 full grants. The review committee designates which funding source is matched with which approved grant based on the subjects involved. Various corporate and organization donors have contributed funds specifically for research grants and these donors are named in the Winter issue of the *Newsletter*. (Note that all corporate, group, and individual donors are listed in every issue of the *Newsletter* and those contributions all help fund the regular APSF-sourced research grants.) For the years 2008 (9 grants) and 2009 (6 grants), research support by the APSF reached its peak to date with total awards of approximately \$1 million in funding for each of those years. The downturn in the economy did reduce contributions and, for 2010, there were 5 grants totaling nearly \$670,000.

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- Reuse and attempted reesterilization of disposable equipment
- Outdated anesthesia machines without modern safety features
- Evolution of the practice standards of the World Federated Societies of Anesthesiologists
- OR crisis management, including team work, team training, and resource management
- "Production pressure" causing dangerous omissions and corner cutting
- IV procedural sedation by non-anesthesia personnel
- Contamination of medical gasses and disruption of pipeline flow (including a dramatic travelling exhibit created by Ervin Moss, MD)
- Contamination of IV medications, such as the original propofol
- Office-based anesthesia special risks
- Obstructive sleep apnea patients and their postoperative care
- Postoperative cognitive dysfunction (particularly in the elderly)
- Possible long-term increase in morbidity and mortality after extensive general anesthesia



Annual Research Awards

"The Awarding of nearly \$1.1 million for anesthesia patient safety research by APSF in October 2007 makes APSF the largest private funding source for anesthesia patient safety research in the world."

—Robert K. Stoelting, MD
APSF Newsletter Vol. 22 (4), 2008.

APSF Becomes the World's Largest Private Funding Source for Anesthesia Patient Safety!

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Overall, the spectrum of research topics—funded because of their potential positive impact on safety—is vast and fascinating. A mere sampling of recent projects funded includes: "Obstructive Sleep Apnea and Adverse Perioperative Outcomes," "Pathophysiology of Postoperative Delirium," "Supplemental Oxygen: A Reduction in Pulse Oximetry Sensitivity, or an Increased Margin of Safety?," "Patients after Minor Surgery with Monitored Anesthesia Care: Is It Safe to Drive?," "Evaluation of an Anatomically Guided, Logically Formulated Airway Measure to Predict Difficult Intubations," "Facilitating Patient Safety through Resident Hand-off Training," "User Interface to Prevent Intravenous Infusion Pump Errors," "Educational Value of an Adjustable and Life-Like Laryngoscopy Simulator," "Challenging Others in the Operating Room: Testing an Educational Patient Safety Initiative for Anesthesia Faculty," and "Virtual Anesthesia: An Online Simulation of Intraoperative Hemodynamic Management in Major Surgical Procedures."

Structural Scaffolding

As the APSF took hold in the early 1990s, it began to outstrip its ability to get things done with a 100% volunteer organization. Dr. Pierce was doing things out of the base of his private practice anesthesia group and was clearly stretched. It was a great fortune that Dr. Siker was stepping down as chair of his department in Pittsburgh. Recognized as one of ASA's most effective past presidents, Dr. Siker was a perfect match for what APSF needed. He graciously took on the new role of Executive Director and formed an effective administrative office, with the compensation of a small fraction relative to the value of the dedicated effort he gave. Later, as Dr. Pierce and Dr. Siker were preparing for retirement, the APSF struck gold again, and Robert K. Stoelting, MD, took on the job of part-time president. Dr. Pierce stepped into the Executive Director role for a few years to make an effective transition. When Dr. Pierce fully retired in 2003, the APSF reorganized to reflect its new needs, and Dr. Stoelting became the full-time president and 2 executive vice president positions were established to expand APSF capabilities, initiatives, and infrastructure. Mr. George A. Schapiro and Dr. Cooper currently occupy those positions and bolster the managerial team with APSF Vice President Mr. Nassib G. Chamoun. Matthew B. Weinger, MD, recently took over the position of secretary of the APSF from Dr. Gaba. He continues the high standards set by his predecessor in keeping detailed, accurate accounts of the Executive Committee deliberations. The



E.S. Siker, MD, is Chair Emeritus, Department of Anesthesiology, The Mercy Hospital of Pittsburgh, Pittsburgh, Pennsylvania. He was ASA President in 1973. Siker served as executive director to the newly developed APSF.

Executive Committee has turned over almost completely since 1985 (only Dr. Cooper remains of the original 1986 seven). What is so remarkable is that without exception, each new member has brought new vitality and ideas while maintaining the collegiality that permits lively debate and disagreement over issues of importance to serving the APSF mission. The organization remains lean and highly leveraged, persistently and remarkably effective for a national group with its size and its budget (which is ably managed by long-time APSF Treasurer Dr. Casey D. Blitt).

Reflections and Conclusion

As in the past, future successes in safety will often result from the desire to do the "right thing because it makes sense." This approach is based on sound principles, technical theory, experience, and pursuit of real-life problems that have not been subjected to controlled experiments. This does not mean that evidence-based medicine should be ignored. Rather, this viewpoint recognizes that safety changes that impact extremely rare events may not lend themselves to traditional "randomized double blind studies with $p < .05$ " to determine validity or efficacy.

Leape, Berwick, and Bates, nationally recognized leaders in patient safety, commended the profession of anesthesia as "the only system in health care that begins to approach the vaunted "six sigma" level of perfection" in their seminal 2002 *JAMA* article "What Practices Will Most Improve Safety?"⁵ They noted that achievement of improved anesthesia patient safety cannot be attributed to any single practice or development of new anesthetic drugs or any technologic advance, but rather to application of a broad array of changes in process (including behavior), equipment and technology, resources, organizations, supervision, training, teamwork, and even practitioner personalities. No single one of these changes has ever been "proven" to have a clear-cut impact on morbidity and mortality outcome. Rather, anesthesia safety has been dramatically improved by applying an entire collective host of changes that made sense in all these areas. Anesthesia patient safety in the past and in the future "is doing a lot of little things that in the aggregate make a big difference."⁵ The APSF has led the way in this regard at many junctures over the last quarter century.

One observation by the original visionary, Dr. "Jeep" Pierce, was: "Patient safety is not a fad. It is not a preoccupation of the past. It is not an objective that has been fulfilled or a reflection of a problem that has been solved. Patient safety is an ongoing necessity. It must be sustained by research, training, and daily application in the workplace. I fear that we may be entering an era that could easily undo many of the gains that we cherish so highly. This is the era of cost-containment, production-pressure, and bottom-line decision-making by corporate deal-makers. The forces underlying this new era are driving us to be leaner, faster, and cheaper. To some extent, these changes may bring a measure of immediate health and vigor to the practice of medicine; they also pose a worrisome threat. If we try to meet financial challenges by short-cutting our daily attention to patient safety or by minimizing our long-term commitments to education and research, we may not be able to

carry forward the gains of the immediate past or pursue the exciting insights and innovations that are just emerging. . . . Patient safety is truly the framework of modern anesthetic practice, and we must redouble efforts to keep it strong and growing."¹

The work of improving anesthesia patient safety is by no means done. Systems, organizations, and equipment still at times fail and, also, basic preventable human errors still do sometimes occur. Further, as noted, increasing "production pressure" in anesthesia practice from expanding clinical demands in the face of diminishing resources may threaten previously won gains. The anesthesia profession as a whole must consider and address this danger. The APSF continues to work hard both on established tenets and new safety principles. It serves as a model of the pioneering successful collaboration and commitment of the entire constellation of anesthesia-related professions and groups to the common goal of optimal patient safety. Very proud of its precedent-setting contributions and accomplishments, the APSF persists vigorously in pursuit of its mission "that no patient shall be harmed by anesthesia."

Happy 25th Anniversary, APSF! Many, many more.



John H. Eichhorn, MD, Professor of Anesthesiology, School of Medicine, and Provost's Distinguished Service Professor, University of Kentucky, founded the APSF Newsletter in 1985 and was its editor until 2002. He remains on the Editorial Board and serves as a senior consultant to the APSF Executive Committee.

Acknowledgments

Source material for this retrospective included the minutes of the APSF Executive Committee back to 1985 and each *Newsletter* issue since Volume 1, Number 1 in March 1986, as well as fond memories from some of those named above and occasional borrowing from excellent prior accounts written by Drs. E.S. "Rick" Siker, Ellison C. "Jeep" Pierce, Jr., Jeffrey B. Cooper, and Robert K. Stoelting. Special great thanks to Dr. Cooper for his thoughtful review and editing.

References

1. Pierce EC, Jr. The 34th Rovenstine Lecture: 40 years behind the mask: safety revisited. *Anesthesiology* 1996;84:965-975.
2. Cooper JB. Patient safety and biomedical engineering. In: Kitz RJ (Editor). This is no humbug: reminiscences of the Department of Anesthesia at the Massachusetts General Hospital. Boston: Department of Anesthesia and Critical Care, Massachusetts General Hospital; 2002. p. 377-420.
3. Gaba DM, Howard SK, Fish K, et al. Simulation-based training in anesthesia crisis resource management (ACRM): A decade of experience. *Simulation & Gaming* 2001;32:175-193.
4. Eichhorn JH. Anesthesia patient safety: a modern history. Boston: Anesthesia Patient Safety Foundation; 1995.
5. Leape LL, Berwick DM, Bates DW. What practices will most improve safety? Evidence-based medicine meets patient safety. *JAMA* 2002;288:501-507.

Academic and Private Practice Anesthesiologists, CRNAs, Industry, and Others Find Common Ground in the APSF to Work Together to Improve Patient Safety.

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Dear SIRS: Manufacturer Explains Yellow Discoloration of Desflurane

“Dear SIRS,” From Page 31

meeting all SUPRANE® (desflurane, USP) Drug Product release specification for these tests.

What then causes the discoloration occasionally observed in vaporizer sumps? SUPRANE® (desflurane, USP) has a low boiling point, requiring a bottle closure mechanism designed using carefully engineered materials to produce an effective seal. The best sealing materials are made from elastomers that contain additives that maintain optimal suppleness and sealing characteristics. One of the additives, butylated hydroxytoluene (BHT), is an antioxidant used as an excipient in pharmaceutical drug products, food products, and polymers, including those utilized within the closure system of the SUPRANE® (desflurane, USP) bottle. Since SUPRANE® (desflurane, USP) is an excellent organic solvent, a small amount of BHT and other extractables (totaling < 5 ppm concentration) are leached from the bottle closure system and remain within the SUPRANE® (desflurane, USP) bottle during its storage. These extractables then enter the vaporizer sump during the vaporizer filling process. BHT is oxidized by air to form BHT byproducts. Baxter scientists, utilizing gas and liquid chromatography with mass spectrometry, have determined that the BHT byproducts identified from vaporizer sump samples include: 2,6-di-tert-butyl-benzoquinone, 3,5-di-tert-butyl 4-hydroxybenzaldehyde, 3,3',5,5'-tetra-tert-butyl-4,4'-stilbene-quinone, and 3,5',3'5'-tetra-tert-butyl-4,4'-diphenylquinone. The boiling point of BHT is 265°C, much higher than the approximate 40°C

operating temperature in vaporizers. Some of its oxidation byproducts have a yellow appearance and all known byproducts have a boiling point higher than the operating temperature of vaporizers. Therefore, during the operation of the vaporizer, BHT, its oxidation byproducts, and other extractables accumulate in the sump of the vaporizer with repeated usage and refilling. This was confirmed in further Baxter tests utilizing commercially available GE (Tec 6 Plus, Aladin and Aladin²) and Dräger (D-Vapor and DIVA) vaporizers. In these studies, up to 50 bottles of SUPRANE® (desflurane, USP) were vaporized, and the condensate tested. Discoloration was observed in the sump of the vaporizers during these tests, which is believed to be due to the oxidation byproducts of BHT. Identical to the tests of complaint samples described above, in all instances the condensate was clear, colorless, and met SUPRANE® (desflurane, USP) Drug Product release specification for the tests performed.

Baxter has consulted with both Dräger and GE, manufacturers of the vaporizers. Neither is recommending a change to their current User Manual. However, to address this cosmetic issue, Dräger has developed a flushing procedure for the D-Vapor vaporizer and can be contacted for service. Baxter is evaluating the reduction of extractables that occur during the current drain and fill procedure conducted by GE during repair and maintenance of Tec 6 Plus vaporizer.

In closing, Baxter has confirmed instances where discoloration has been observed either through the sight glass of vaporizers or in the drained contents of vaporizer sumps. Due to the non-volatility of trace extractables (< 5 ppm) contained within bottles of SUPRANE® (desflurane, USP), with repeated use and refilling, these extractables and their byproducts may accumulate over time in the sump of a vaporizer giving its contents a discolored appearance. Baxter has confirmed for all tests performed that even though the contents within the sump of the Suprane vaporizer may be discolored, the vaporized SUPRANE® (desflurane, USP) delivered to the breathing circuit remains clear and colorless and meets SUPRANE® (desflurane, USP) Drug Product release specifications.

Sincerely,
Charles H. McLeskey, MD
Therapeutic Area Leader
Global Anesthesia & Critical Care

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Fospropofol (Lusedra®) May Be An Alternative to Propofol for Monitored Anesthesia Care

by John B. Leslie, MD, MBA

An increasing supply problem with lipid emulsion propofol has forced many practices to revert to alternative sedative-hypnotics that do not provide an ideal intraoperative and recovery profile to anesthesia practitioners using propofol. Fospropofol (Lusedra®) is a water-soluble, non-pyrogenic, iso-osmotic pro-drug sedative-hypnotic agent that is metabolized to propofol, and, if dosed appropriately, may be an alternate drug selection to propofol in some patients undergoing monitored anesthesia care (MAC). Fospropofol, released in November 2009 by Eisai, Inc., has a limited indication of MAC sedation in adult patients undergoing diagnostic or therapeutic procedures. The drug does not provide an approved complete propofol replacement but allows clinicians to reserve limited lipid emulsion propofol supplies for patients requiring general anesthesia. The FDA also placed a Schedule IV restriction on fospropofol, satisfying concerns raised by the ASA and AANA regarding the scheduling status of propofol.

Unlike propofol, there are no shortages of fospropofol; however, the anesthesia community has had limited clinical experience with the drug. It is important to understand that while the pro-drug becomes propofol after metabolism by alkaline phosphatases, there are significant differences in dosing, packaging, onset, peak effects, and duration of action. The pro-drug does not produce any burning or pain at the site of IV injection, but a released phosphate metabolite may be responsible for frequent but transient mild to moderate perineal paresthesia (52-74%) or pruritis (16-28%) that patients report 1-5 minutes after injection of fospropofol loading boluses. Despite this reaction, 95% of fospropofol study patients were willing to receive the treatment again. Staff and patient education may also help minimize misinterpretation of these symptoms.

Fospropofol, once metabolized to propofol, is comparable to propofol lipid emulsion; however, the delayed liberation of propofol from fospropofol results in differences in onset and duration of sedation effects. Clinical studies have demonstrated that sedation onset and peak sedation effect from the initial fospropofol bolus is metabolically delayed 1-8 minutes as is the peak effect. Supplemental doses (calculated as 25% of the initial dose) administered to achieve deeper initial levels of sedation must not be administered more frequently than every 4 minutes to permit metabolism of the drug to release active propofol; this may help prevent over-sedation from a dose-stacking process.

Summary of Clinical Trials

The first trial using the approved MAC fospropofol dosing routine was a double-blind, multicenter study that evaluated safety and efficacy of IV bolus fospropofol for moderate sedation in patients undergoing colonoscopy.¹ One hundred and forty-nine adults (97% ASA PS1-2 and 87% <65 y/o) were randomized to receive the recommended fospropofol 6.5 mg/kg dose after pretreatment with IV fentanyl 50 mcg. Supplemental doses of fospropofol were permitted every 4 minutes to achieve a Modified Observer's Assessment of Alertness/Sedation (MOAA/S) six-point scale score of ≤ 4 (lethargic response to their name spoken in a normal tone) prior to colonoscope insertion. The median time to sedation was 8 minutes, median procedure duration 11 minutes, and median time to alert at the end of the procedure was 5 minutes. The number of supplemental doses averaged 2.3 (± 1.4 SD) doses.

The second clinical trial was a randomized, double-blind, multicenter study evaluating fospropofol in patients undergoing sedation for flexible bronchoscopy.² In this trial, 150 patients ASA PS2-4 (46% ASA P3-4 and 41% ≥ 65 y/o) received the approved dose of

6.5 mg/kg after pretreatment with fentanyl 50 mcg. Supplemental doses of fospropofol were given no more frequently than every 4 minutes to achieve or maintain adequate sedation. The median time to sedation was 4 minutes, median duration of the procedure 11 minutes, and median time to full alertness was 5.5 minutes. The number of supplemental doses averaged 1.7 (± 1.6 SD). Deep sedation (MOAA/S 0-1) occurred in 16% of the 6.5 mg/kg treated patients with an average duration of 3.7 minutes (range 2-20).

The final study completed to date was a prospective open-label non-randomized trial in 123 minor surgical procedures including EGD, arthroscopy, hysteroscopy, bunionectomy, TEE, and others.³ All patients received a dose of 6.5 mg/kg or the Modified Dosing Regimen if they were ASA PS3-4 (19%) or ≥ 65 y/o. The majority of procedures took less than 30 minutes to complete. Fospropofol was found to provide a very safe and effective MAC anesthetic technique with the most frequent adverse events again being transient self-limited paresthesias and pruritus.

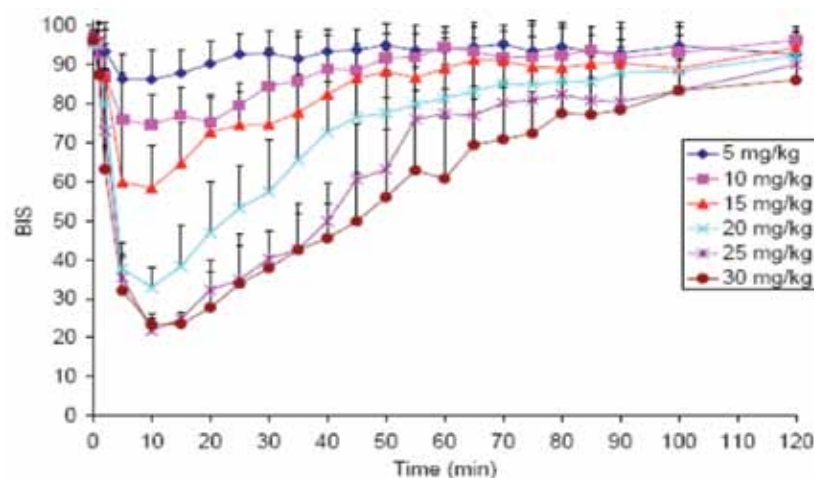
The incidence of adverse events is summarized in the table below. As expected, a greater rate of sedation-related adverse events necessitating an intervention was observed in the bronchoscopy patients compared to the other two trials.

Clinical Trial Adverse Events Summary

	Percentage (N=455 patients in 3 trials)
Paresthesia	74% colonoscopy
	52% bronchoscopy
	63% minor surgery
Pruritis	16% colonoscopy
	16% bronchoscopy
	28% minor surgery
Deep Sedation (MOAA/S 0-1)	4-16%
Hypoxemia	4%
Hypotension	4%
Apnea	<1%

MAC Fospropofol Dosing Safety Concerns

Early adopters of fospropofol have questioned the adequacy of the approved initial 6.5 mg/kg bolus dose of because of the documented frequency of required supplemental doses and the 4-8 minute median time-to-sedation. Prior trials provide limited data with fospropofol at higher doses. Twelve healthy



Effect of increasing i.v. bolus doses of fospropofol on BIS values over time in healthy volunteers. (Approved MAC dose is 6.5 mg/kg.)

See "Fospropofol," Next Page

Fospropofol Has Potential for Stacking Doses

“Fospropofol,” From Preceding Page

subjects administered 10 mg/kg achieved peak plasma levels of propofol released from fospropofol of 2.2 ± 0.4 mcg/mL at 8 min (range 4-13 min) and the minimum mean MOAA/S score reached 1.2 (range 0-3) at 7 min (range 1-15). MOAA/S of 2 = “responds only after mild prodding or shaking;” MOAA/S of 1 = “responds only after painful trapezius squeeze.” Subjects were sedated longer and recovered from the sedative effects of this dose between 21-45 minutes after fospropofol administration.

In another healthy volunteer study, fospropofol at 5-10 mg/kg produced minimum BIS scores consistent with minimal-moderate sedation, while higher doses induced minimum BIS scores indicative of general anesthesia (data on file with FDA and Eisai, Inc.).

The lower 6.5 mg/kg dose was selected for MAC sedation to minimize the incidence of deep sedation and sedation-related adverse events. The most common adverse events, paresthesias and pruritus, were transient and self-limited. As with all sedative-hypnotics, fospropofol may produce additive cardiorespiratory effects when administered with benzodiazepines and opioids. Study patients were not premedicated with a benzodiazepine and only received fentanyl 50 mcg prior to the fospropofol. Other sedative-hypnotics or inhalational anesthetics have been studied in combination with fospropofol.

Neither the dosing required nor the safety of fospropofol used for continuous IV infusion sedation has been well studied. Although the PI lists no specific contraindications to fospropofol for MAC

sedation in adults, several additional safety points should be reviewed. Fospropofol is Pregnancy Category B and there are no adequate and well-controlled studies in pregnant women; therefore, fospropofol is not recommended for use in labor and delivery, including cesarean section deliveries, or for use in nursing mothers. Fospropofol has not been studied in pediatric patients <18 years of age. No formal studies of the abuse potential of fospropofol have been conducted, but euphoria was reported in a small number of subjects who received IV or oral dosing. There is no reversal agent known for fospropofol, and any overdose can cause cardiorespiratory depression requiring manual or mechanical ventilation and cardiovascular resuscitation.

Fospropofol, 35 mg/mL (total of 1,050 mg/30 mL) fospropofol disodium, is supplied as a single-use, aqueous, clear, colorless solution that is compatible with most IV solutions but may precipitate when mixed with midazolam or meperidine. Additional information is available at the company website: www.lusedra.com

Summary

There may be compelling reasons to consider fospropofol as an alternative sedative-hypnotic for MAC sedation procedures in adults where propofol is the preferred agent. There are significant differences in dosing routines, onset and peak sedation effects. Previous clinical trials and approved bolus doses of fospropofol provide a mild-moderate depth of sedation with minimal sedation-related adverse events. Larger initial bolus or supplemental dosing can

increase the depth and speed of onset of sedation but will significantly prolong duration. Fospropofol's pharmacokinetic and effect differences may work well for certain MAC procedures and should require less frequent redosing during the procedure without the need for an infusion pump.

Dr. Leslie is a Professor of Anesthesiology at the Mayo Clinic College of Medicine and a Consultant in Anesthesiology, Mayo Clinic Arizona, Scottsdale, Arizona.

Disclaimer: Dr. Leslie presented the review of fospropofol risks/benefits at the FDA Advisory Board review and has presented clinical research, educational reviews, and CME lectures that included information on fospropofol. He is currently working on an investigator initiated clinical trial with fospropofol that is funded by a grant from Eisai, Inc. Eisai, Inc. is a financial supporter of the APSF.

References

1. Cohen LB, Cattau E, Goetsch A, et al. A randomized, double-blind, phase 3 study of fospropofol disodium for sedation during colonoscopy. *J Clin Gastroenterol* 2010;44:345-53.
2. Silvestri GA, Vincent BD, Wahidi MM, et al. A phase 3, randomized, double-blind study to assess the efficacy and safety of fospropofol disodium injection for moderate sedation in patients undergoing flexible bronchoscopy. *Chest* 2009;135:41-7.
3. Gan TJ, Berry BD, Ekman EF, et al. Safety evaluation of fospropofol for sedation during minor surgical procedures. *J Clin Anesth* 2010;22:260-7.

Letter to the Editor

Technological Intensification Revisited

To the Editor:

We thoroughly enjoyed the article “The Challenges of Technological Intensification.”¹ At a time when anesthesia is demonstrably safer than ever it is important to note that complexity in anesthesia is relevant only if four conditions are met:

- 1) Complexity, or complex interactions to be true to Perrow, must be unambiguously defined.² The current definition “if there are many alternative sub-tasks at any point in its completion” appears to be dependent on both the size of the system as well as its lifespan. Since either could be arbitrary the definition reduces to an arbitrary subset of any given universe of interactions. In such a case the definition reduces to a hollow assertion.
- 2) Complexity must be unambiguously linked with outcome. This raises the secondary problem of

agreeing on a definition of outcome. It is possible that manipulating the definition of outcome drastically changes the incidence of “successful” anesthetics and surgical procedures. We need look only as far as cardiac surgery with its subtle neurologic injury, severe neurologic injury, and death as three recognized outcomes.

- 3) Complexity must be controllable. We must be able to reliably control the interactions of a given system. Yet this hinges on being able to reliably define complexity.
- 4) Finally, if complexity is controllable then it must be controllable in such a manner as to optimize the affect on definable outcomes.

As new technology becomes available the degree of complexity seems less relevant than demonstrable effects on definable outcomes. In essence complexity

as a poorly defined concept makes technological analysis unnecessarily complex while adding little to understanding.

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References

1. Webster CS, Stabile M, Merry AF. The challenges of technological intensification. *APSF Newsletter* 2009; 24(3):33,35,43.
2. Perrow C. Normal Accidents: Living with High-Risk Technologies. Princeton, NJ: Princeton University Press, 1999.

Letter to the Editor

Reader Questions "Triple Low" Conclusions

To the Editor:

I was alarmed at several conclusions reported in the Winter 2010 edition in the article synthesizing scientific papers from the 2009 ASA Annual Meeting. Specifically, the section entitled "Miscellaneous Triple Low" contained statements like, "Increased duration of ["triple-low"] increased the incidence of 30-day readmission and postoperative mortality" and "low BIS levels further increased relative mortality." I do not have to tell you that these studies were retrospective analyses and cannot provide any association of variables other than correlation, certainly not causation. Furthermore, this notion of associating low bispectral index values with specific outcomes is in its nascence, with much remaining to be discovered. The "triple-low" phenomenon, in fact, exemplifies this, as one cannot simultaneously solve the "problem" of low anesthetic concentration and low BIS. To make a statement explicitly identifying a causative link between the two is not only poor form, it is scientifically and medicolegally irresponsible.

Nathaniel F. Simon, MD
Sacramento, CA

In Reply:

As Simon notes, it would be poor form and irresponsible to make statements explicitly identifying a causative link based on observational data. We thus did no such thing.

All of our published and presented work related to Triple Low clearly identifies the observational nature of our work and that we have only identified associations. We were equally clear that Aspect Medical (now Covidien) funded the project and that Aspect employees were involved in the analysis.

Rather than relying on the editorial (which we did not write or review), I encourage readers to review the abstracts on which it was based (A6, A880, and A354). Note use of words such as "predictor" and "associated." Nowhere do we imply causality.

Low mean arterial pressure, low minimum alveolar concentration, and low bispectral index are reported to be independent predictors of mortality. For example, the association of low bispectral index and mortality is the subject of an article and editorial in the May issue of *Anesthesiology*. That combinations of 2 or 3 of these factors would also predict adverse outcomes is thus unsurprising. The purpose of our analysis is to show that specific combinations are especially predictive and, therefore, potential targets for intervention. Based on our current analysis, we hope to soon start a prospective evaluation.

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Letter to the Editor

Depression and Medical Errors: Study in Surgeons Notes Strong Relationship

To the Editor:

Danger to patients from medical care errors caused or aggravated by stress, burnout, and depression has been discussed often as a theoretical patient safety risk, but, until recently, surprisingly little studied. Stress and its effects on physicians is now being evaluated in the medical literature. The association of stress with alcohol and drug addiction is widely reported, and the degree to which these issues can compromise care has been documented. Certainly, stress and burnout are common in all medical specialties, including anesthesiology. Recent studies have looked at not only stress and burnout, but depression and other affective disorders in physicians and the possible role these may play in the commission of medical errors.

A recent study in the *Annals of Surgery*¹ demonstrated that those surgeons with symptoms of depression were twice as likely to have committed an error within the last three months before the survey as their colleagues who were not depressed. While it is true that in this study it was not clear if depression contributed to or was, in fact, a result of the errors, other investigations have shown that depression is linked to an increase in errors, particularly a 2008 study showing that pediatric residents who were depressed made 6-times the medication errors than non-depressed peers.² Interestingly, a repeat study after the implementation of the 80-hour work week for residents showed no decrease in the rate of depression in these residents.³

A 2008 survey of Michigan physicians investigated the incidence of depression in physicians and its effect on the clinician.⁴ The incidence of depression in these physicians was 11%, which is close to the incidence in the general population. The results showed that 43% of respondents knew a physician whose work had suffered because of depression. In addition, 24% reported they were aware of a physician whose professional standing had been hurt from the effects of depression. The majority of respondents who were judged to have moderate to severe depression admitted that their condition negatively affected their professional responsibilities, increased their personal and professional stress level, and decreased their work productivity and satisfaction.

It has been shown that physicians with depression are fearful of the stigma of depression and its potential negative effect on their ability to obtain licensure, privileges, and insurance.⁵ Because of this, many fail to seek treatment, which likely has potential consequences in the care that they provide to patients, including increased risk for errors.

Anesthesia professionals may be at even higher risk for not seeking treatment for depression. We are

often isolated from colleagues in our daily practice; hence, symptoms of depression may not be recognized. The normal stress of our work may mask depression. Affected individuals may seek inappropriate treatment by self-medicating (such as with alcohol) or asking colleagues for prescriptions for antidepressants. It is not known how many cases of substance abuse among anesthesiologists stem from self-medication for depression. It is probably safe to conclude that some substance abuse is a result of depression, while in other cases it is the cause of depression.

Anesthesia professionals, as a group, need to bring attention to the fact that depression can be detrimental to not only ourselves, but to our patients as well. With the ASA Wellness Campaign and the AANA Wellness Program, our professional organizations have recognized the importance of health to the personal and professional lives of their members. Despite this, the part that depression and burn out play in the potential threat to the safe care of patients has not been highlighted. It remains for the APSF, in its capacity as the conscience of the specialty, to bring this issue to the fore by shining a light on this professional and patient safety issue that is likely much more common than abuse of drugs and alcohol.

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References

1. Shanafelt TD, Balch CM, Bechamps GJ, et al. Burnout and career satisfaction among American surgeons. *Ann Surg* 2009;250:463-71.
2. Fahrenkopf AM, Sectish TC, Barger LK, et al. Rates of medication errors among depressed and burnt out residents: prospective cohort study. *BMJ* 2008;336:488-91.
3. Landrigan CP, Fahrenkopf AM, Lewin D, et al. Effects of the accreditation council for graduate medical education duty hour limits on sleep, work hours, and safety. *Pediatrics* 2008;122:250-8.
4. Schwenk TL, Gorenflo DW, Leja LM. A survey on the impact of being depressed on the professional status and mental health care of physicians. *J Clin Psychiatry* 2008;69:617-20.
5. Center C, Davis M, Detre T, et al. Confronting depression and suicide in physicians: a consensus statement. *JAMA* 2003;289:3161-6.

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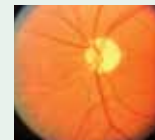
Opinions



Jeffery S. Vender, MD



The late J.S. Gravenstein, MD



High-Risk Environments

Fatigue



Peers



Drs. Stoelting and Pierce flanking Joan M. Christie, MD



Controversy

Patient Safety



The late Arthur S. Keats, MD



Mark A. Warner, MD



Karen L. Posner, PhD



Patricia A. Kapur, MD



Jeffrey B. Cooper, PhD and Mr. Nassib G. Chamoun flank Dr. Pierce



Administration



Glenn S. Murphy, MD



Ms. Wanda Puza



Ms. Deanna Walker

Collaboration

Improving Outcomes