

The APSF: 20-Year Anniversary of the First Patient Safety Organization—Past, Present & Future

by Jeffrey B. Cooper, PhD

Our founding father and first president, Ellison C. Pierce Jr., MD, described his recollections of the history of APSF in the 1995 Rovenstine lecture.¹ The first APSF executive director, Dr. E.S. Siker, also wrote a history that can be found on the APSF website (http://apsf.org/about/brief_history.msp). As one who has been involved in patient safety from the earliest days, I can say that those recollections coincide with mine. Yet, they are written from the view of anesthesiologists, who rightly see things from the perspective of personal experience in caring for patients. My perspective is different. It is that of an engineer who had the opportunity to observe and document with an eye that had not been trained to accept the normalcy of the way things were being done. During my orientation to anesthesia, I had the good fortune of spending time in operating rooms with an astute, young anesthesiologist who was able to identify what wasn't right about the accepted ways of doing things.² He opened my eyes to see needed improvements in patient safety. It's from this point of view that I write this account of the APSF, how it came to be, what it has done, and to share some interesting side notes along the way.

Dr. Pierce formed the idea for the APSF in Boston in 1984 at the International Symposium on Preventable Anesthesia Mortality and Morbidity (ISPAMM). The conference was born of a suggestion to Dr. Richard J. Kitz, then chair of the Department of Anesthesia at the Massachusetts General



Original APSF Board Members (L to R): Dr. J. S. Gravenstein, Dr. J. B. Cooper, Dr. E. S. Siker, Mr. I. E. Holzer, Dr. E. C. Pierce, Mr. B. A. Dole, and Mr. W. D. Rountree.

Hospital. Dr. Kitz had given a lecture at the Royal College of Anaesthetists. His topic was human error and preventable mishaps in anesthesia, and was based on information from the critical incident studies conducted by the Anesthesia Bioengineering Unit at the MGH during the mid to late 1970s. Professor Cecil Gray, an esteemed academician, concluded that the information presented demonstrated the need for an international meeting to consider the occurrence of harmful, preventable outcomes. Dr. Kitz carried that idea across the pond and teamed with Dr. Pierce, then president of the ASA, and me, to organize the meeting. Since Dr. Pierce and his department had been involved as subjects in the critical-incident research, and since

he had a great amount of personal experience and observations, he was primed to take on the challenge. We gathered 50 invited participants to deliberate on this topic, and received grant support from various companies. As a result, Dr. Pierce conceived of the need for the APSF. He then set about to change his vision into a reality.

The time was right. Dr. Pierce had already formed the ASA's Committee on Patient Safety and Risk Management. His efforts were supported by a provocative ABC 20/20 report on the dangers of anesthesia. The show featured patients who died or were in a vegetative state as a result of an adverse anesthesia event. Public awareness was so aroused that many patients arriving to the operating room the next day asked if an oxygen analyzer would be used during their anesthetic. In a majority of cases the answer was probably no. That situation was soon remedied.

Dr. Pierce put the political wheels in motion to create a foundation. I recall a meeting in a hotel room at the ASA meeting at which we worked out many of the details of structure, membership, and most important, financing. The ASA agreed to underwrite the startup with \$100,000. That was matched with gifts from the Puritan Bennett Foundation, through the efforts of Burton Dole, then CEO of Puritan Bennett, and from Ohmeda, through the efforts of its CEO, the late Dekle Rountree.

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Looking Back: Doctor Pierce Reflects

by Ellison C. Pierce, Jr., MD

(An excerpt from the 1995 Emery A. Rovenstine Lecture)

On Thursday, April 22, 1982, there appeared on ABC television a segment of the program 20/20 entitled, "The Deep Sleep, 6,000 Will Die or Suffer Brain Damage." The announcer opened the program, "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 had 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. Later in the program, the following dialog ensues. An unidentified spokesperson advises Tom Jerriel, one of the hosts, that, "There is a hospital in New York City where there are two anesthesia people covering five operating rooms." Jerriel is incredulous, and asks, "How do they do it?" The spokesperson replies, "Well, they run quickly and pray a lot."

The 20/20 program was a watershed for anesthesia patient safety endeavors. At the time, I was ASA first vice president and decided to establish a new ASA

committee, the Committee on Patient Safety and Risk Management. Howard Zauder was the first chairman. The ASA had, of course, been involved in quality assurance for some time with its Committee on Peer Review, but never before had the concept of patient safety been so specifically addressed by our specialty society. Among its first endeavors the Committee developed a series of patient safety videotapes. . . . with me as executive producer. In 1984, Cooper, Richard Kitz, and I hosted the first International Symposium on Preventable Anesthesia Mortality and Morbidity (ISPAMM), held in Boston. Some 50 anesthesiologists from the United States, Australia, Great Britain, South Africa, and Belgium attended. Debate was loud and strong; controversy among the nations was extensive, especially considering use of monitoring equipment. Perhaps the area of greatest agreement was in the definitions of outcome, morbidity, and mortality. That international meeting has now been held every 2 years since.

The Anesthesia Patient Safety Foundation (APSF) was established as an outcome of the Boston meeting. Considerations of attaching a safety society to other entities, such as the World Health Organization, were rapidly abandoned because of the probabilities that international controversy would prevent effective actions.

Dr. Pierce is currently retired as chairman emeritus of the Department of Anaesthesia at Deaconess Hospital and is the founder and former executive director of the APSF.



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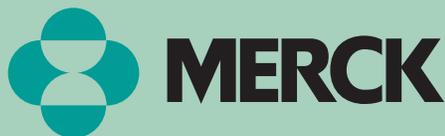
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Dr. Cooper Remembers our Roots

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I recall a brief discussion about the name and simply saying, why not just call it what it is, the Anesthesia Patient Safety Foundation? It seemed so natural that it stuck without much discussion. I think one of our most important early decisions was the adoption of a simple mission statement: “To ensure that no patient is harmed by the effects of anesthesia.” We altered that just a bit a few years later (dropped “the effects”) and more recently expanded the concept to more of a vision with more specific targets as our mission. However, the basic, simple idea still stands and drives all that we do.

A 40-person board was assembled that included a truly interdisciplinary group of patient safety advocates reflecting one of Dr. Pierce’s most important visions: that to be effective and successful, the APSF must be broadly based, allowing cross-fertilization, and engaging manufacturers in the process of developing patient safety solutions. In an effort to reach all anesthesia providers, existing political differences were put aside and 3 CRNAs were appointed to the board.

I am proud to have been counted among the members of the first Executive Committee, although those who know me may be hard pressed to recognize the guy with the hair and beard in the original photo from the *APSF Newsletter*, Volume 1, No. 1.

The initial strategy of the APSF continues very much to this day, originally driven by the knowledge that we must be lean and highly leveraged. We quickly agreed that a newsletter would be the main communication vehicle and that it must be delivered to all anesthesia providers without allowing cost to become an obstacle. That was the only way to be sure the message would get to everyone who needed the hear it. We were fortunate to have John Eichhorn ready to take on the role of editor. His college editorial experience came in very handy. The first 10 years of *Newsletters* have been compiled into a single volume.³ The excellence continues to this day in the able hands of Dr. Robert Morell.

Everyone agreed that research must be a core element of the APSF activities. We wisely recruited Dr. Arthur Keats to guide the formation of a scientific evaluation committee and review process. His years of research experience were invaluable. At the time he was not a strong advocate of the need for a patient safety movement and was actually skeptical that credible research could be done. That was exactly the reason we needed him, to be sure we didn’t fool ourselves. Having set up a robust process, Dr. Keats passed on the committee leadership to me. I was gratified to receive a letter saying how he was both surprised and pleased that the committee had worked out so well. It is working well to this day, now under the highly competent leadership of Dr. Sorin Brull.

During those first years, there were a few key projects and actions that the APSF undertook to make patient safety visible. I think the most important was the strong support for pulse oximetry and, later, for capnometry. These technologies have obviously become standards of care and continue to play a tremendous role toward insuring patient safety.

Other important APSF initiatives and a review of research accomplishments are described in other articles in this special issue. Many of the most important initiatives in those early years were those led or instigated by Dr. J.S. (Nik) Gravenstein, a key innovator, intellect, and driving force on our Executive Committee from the beginning and for many years. He arranged symposia (including one on cost containment and patient safety in anesthesia), developed useful relationships with our industry colleagues, and generated much academic material and many ideas for the *Newsletter*.

Given my special interest in simulation, I will make the case that it was one of the most important developments to arise from our research support, as evidenced from the now widely disseminated programs in simulation in anesthesia and every other health care domain. Anesthesiology can be proud of its leadership as a specialty and the many leaders, innovators, and researchers it has produced in this relatively new field.

We did some things in our early years that either didn’t work out at all or didn’t achieve the kind of leverage for which we had hoped. I especially recall the Grand Anesthesia Symposium that we planned. We had great hopes for a great conference to which we would attract many anesthesia providers and stakeholders to learn the various aspects of anesthesia patient safety. It was a flop. Almost no one signed up. There was not enough interest at the time or perhaps we just didn’t know how to market such things. Over the years we learned how to wisely plan such events, to wit, symposia and workshops on patient safety and cost reduction, simulation, and more recently, long-term outcomes. In addition, the annual workshops of the Board of Directors have grown to be highly interactive, stimulating meetings on timely topics, e.g., high reliability organizations (2004), the patient experience of adverse events (2005), and the dangers of patient controlled analgesia (2006).

As the APSF took hold, we began to outstrip our 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. E.S. (Rick) Siker was stepping down as chair of his department. Recognized as one of ASA’s most effective presidents, Rick 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 compensation of a small fraction relative to the



Jeffrey B. Cooper, PhD, APSF Executive Vice President

value of the dedicated effort he gave. Later, as Dr. Pierce and Dr. Siker were preparing for retirement we struck gold again, and Dr. Robert Stoelting 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, we reorganized to reflect our new needs, and Dr. Stoelting became the full-time president and 2 executive vice presidents positions were established to expand our capabilities, initiatives, and infrastructure. Mr. George Schapiro and I currently occupy those positions.

The Executive Committee has turned over almost completely since 1986. 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 Foundation’s mission. After 20 years, I believe that the APSF is even more vibrant than it has ever been and that those who support it in the anesthesia professions are even more committed to its mission: To ensure that no patient is harmed by anesthesia. Of that, you can all be very proud.

Dr. Jeff Cooper is executive vice president of the APSF and one of the founding members of that organization and Associate Professor of Anesthesia, Harvard Medical School, Boston, MA.

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Education and Training Committee Has Strong History & Exciting Future

by Richard C. Prielipp, MD

The Committee on Education and Training is composed of 16-20 members of diverse professional backgrounds and medical expertise, including anesthesiologists (affiliated with the ASA), surgeons (ACS), nurse anesthetists (AANA), anesthesiologist assistants (AAAA), pharmacists (ASHP), and human factors/simulation scientists (PhD scientist-members of the ASA). The goal of this APSF Committee is to illuminate, communicate, and disseminate information vital to patient safety in the perioperative period. We utilize a host of communication media to stay connected with our constituents, including the *APSF Newsletter*, the APSF booth at the annual ASA and IARS meetings, reports and summaries of special safety symposia, and the ever-expanding APSF website (www.apsf.org). Most recently, the APSF has linked with *Anesthesia & Analgesia* as the organization's new scientific journal, and a new section editor for Patient Safety, Dr. Sorin J. Brull, will work closely with its editor-in-chief.



Richard C. Prielipp, MD, Chair, APSF Committee on Education and Training

Our target audience includes clinical anesthesia providers, students of anesthesiology, anesthesiology and safety scientists, anesthesiologist assistants and OR technicians, acute care pharmacists, and corporate vendors who provide us with reliable medical monitors, anesthesia machines, and novel pharmaceutical agents. In addition, our topics and discussions are frequently relevant to the nation's risk managers, society officers such as the Board of Governors of the American College of Surgeons, the liability insurance industry, the Joint Commission, the FDA, and congressional staffers responsible for health care information. The past, present, and future contributions of the Committee are highlighted below.

THE PAST

Improvements in Education, Training, and Monitoring

The improvements in patient safety have been the result of the sustained focus of APSF leaders and committee members on the science of safety in medicine. Today, anesthesia providers are highly-trained, tested, certified and, increasingly, recertified to standards that include safety practice guidelines. We enjoy record numbers of highly-trained, skilled, and certified physicians, nurse anesthetists, and anesthesiologist assistants working today in the United States. In the last 3 decades, the combined efforts of these skilled providers, along with the tireless energies of APSF members, have resulted in a decline in anesthesia-related deaths from 1 in 15,000 anesthetics to 1 in 250,000 today. With healthy patients, the risk is even lower—a rate of “defects” that approaches Six Sigma levels of reliability.

ics to 1 in 250,000 today. With healthy patients, the risk is even lower—a rate of “defects” that approaches Six Sigma levels of reliability.

ASA Patient Safety Videotape Series

The ASA has produced a series of patient safety videotapes, at a cost of \$50,000 per topic, for use in anesthesiology residency and SRNA training programs. The videotapes are also a rich source of institutional and departmental continuing education programs. A total of more than 30 videotapes have been produced and distributed on various topics, including: Difficult Airway, Central Venous Catheters, Infection Control, Crisis Management, Fatigue: Implications for the Anesthesiologist, Production Pressure in Anesthesiology, Medication Errors, and Pediatric Safety. While this medium is

Past Recipients of the APSF Ellison C. Pierce, Jr., MD, Research Award for Best Scientific Exhibit at the Annual ASA Meeting

Year	Primary Investigator(s)	Exhibit
2007	Your Name goes here!	To be determined!
2006	Roger Johnson, CBET, Chad Vandrovec, MD, Steven F. Bulz, MD, Neil E. Farber, MD, PhD, Gregory Diciaula, BA <i>Children's Hospital of Wisconsin, Milwaukee, WI</i>	“Anesthesia Machines: Mishaps and Mistakes” <i>This is a multimedia format that highlighted components of the anesthesia machine, and how to avoid machine related mishaps.</i>
2005	Brett L. Arron, MD, Richard Gillerman, MD, James E. Peacock, RN <i>Rhode Island Hospital, Providence, RI</i>	“MacIntosh and IBM-compatible Laptop-based Videography of Airway Management for teaching airway management and record keeping”
2004	Susanne Shamsolkottabi, MD <i>University of Minnesota Medical School, Minneapolis, MN</i>	“Medication Error Prevention” <i>A visual and PowerPoint presentation.</i>
2003	Prof. Pierre A. Diemunsch <i>C.H.U. Hautepierre, Strasbourg, France</i>	“Virtual Model for Navigation in the Upper Airway as a Teaching Tool for Fiberoptic Intubation”
2002	Not Awarded	N/A
2001	Sem Lampotang, PhD <i>University of Florida, Gainesville, FL</i>	“WEB-based ‘virtual anesthesia machine,’ which is an interactive, computer simulation of the anesthesia machine and ventilator.”
2000	John Schaefer, III, MD <i>UPMC Health System, Pittsburgh, PA</i>	“Simulation Based Training in Applying the ASA Difficult Airway Algorithm”
1999	Elizabeth C. Behringer, MD <i>Veterans Affairs Healthcare System, Long Beach, CA</i>	“The Cuffed Oropharyngeal Airway (COPA) – A Review and Demonstration of its Use in Fiberoptic Intubation”
1998	Maya Suresh, MD, David Ferson, MD <i>Northwestern University Medical School, Chicago, IL</i>	“Laryngeal Mask Airway: Its Contributions to Anesthesia Practice and Airway Management”
1997	Dietrich Gravenstein, MD, Sem Lampotang, PhD, Richard Melker, MD <i>University of Florida, Gainesville, FL</i>	“Fiberoptic Imaging Stylet for Intubation”

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Anesthesia Providers Voice Concerns, Generate List

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now dated, the contribution of this series to education and training is immeasurable.

The APSF Ellison C. Pierce, Jr., MD, Research Award for Best Scientific Exhibit at the Annual ASA Meeting

A subcommittee (committee chair, along with members of the ASA, AANA, ASHP, and AAAA) reviews approximately 50 exhibits each year at the Annual ASA Meeting for the Ellison Pierce Award. The awardees and their exhibit are featured in the winter edition of the *Newsletter* after the meeting. The 10-year history of awards is summarized in the table on page 4. We hope to see you compete for this prestigious award in San Francisco this coming year!

THE PRESENT

APSF Safety Grants Expanded to Specifically Include Education

The Education Committee worked with the APSF leadership to expand the focus of the APSF Safety Grants in 2004 to advocate specifically for

areas of . . . educational content . . . which include new clinical methods for prevention and/or early diagnosis of mishaps; evaluation of new and/or re-evaluation of old technologies for prevention and diagnosis of mishaps; identification of predictors of patients and anesthesiologists at increased risk for mishaps; development of innovative methods for the study of low-frequency events; methods for measurement of cost effectiveness of techniques designed to increase patient safety; innovative methods of education and training to improve safety; specific or thematic development of educational content or methods with application to patient safety; and development or testing of educational content to measure and improve safe delivery of perioperative anesthetic care.

Research grants that include the following attributes are of special interest:

- Development or testing of educational content to measure, develop, and improve safe delivery of anesthetic care during the perioperative period; and
- Development, implementation, and validation of educational content or methods of relevance to patient safety.

What Are the Current Concerns of Anesthesia Providers?

The Education Committee sampled and recently summarized the areas of ongoing safety concerns of anesthesia providers. Indeed, because of the work of the APSF over the last 20 years, all members are well-educated and focused on topics relevant to patient safety. The extensive (but not exhaustive)

Vision

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



Mission

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

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

list identified by committee members includes

- Medication “syringe swap” or “drug swap” with look-alike ampoules
- Definition and interpretation of FDA Black Box Warnings
- Methods to optimize OR teamwork
- Optimal labels (labeling procedures) of all medications
- Perioperative MD/RN/Team Communication
- Production pressure
- Obstructive sleep apnea, opioids, and respiratory depression
- The anesthesia machine checkout
- Correct surgery policies (the OR “time out”)
- Awareness during general anesthesia
- Anesthesia “hand-offs”
- Provider fatigue (including call obligations)
- Fires in the OR
- Audible alarms
- Desiccants: toxic metabolites, CO, and other issues
- Beta-blocker protocols (prevention of perioperative MI)
- Neuraxial anesthesia and anticoagulants
- Antibiotic surgical prophylaxis: dose, timing, compliance
- Optimal perioperative glucose management
- Catheter-related sepsis: aseptic technique in the OR
- Parents’ presence during pediatric anesthesia induction?
- Difficult airway management/ASA difficult airway algorithm
- Positioning related injuries (neuropathy and tissue injury)

- Update on AHA / CPR algorithms
- NPO adult and pediatric recommendations
- DVT prophylaxis
- Normothermia and temperature maintenance
- Distractions/noise/music/reading in the OR
- Anesthesia in out-of-OR or office-based locations
- Sedation by non-anesthesia providers
- Training/certification for users of new anesthesia equipment
- Certification and documentation of competence
- Impaired practitioners (drugs, ETOH, etc.)
- Locked OR carts/access to emergency drugs
- The role of the patient (and family) in Patient Safety concepts
- Design of the new OR and anesthesia workstations
- Other, yet to be determined safety issues!

VAM: The Virtual Anesthesia Machine

The free Virtual Anesthesia Machine (VAM) simulation is the flagship transparent reality simulation developed by a team led by Sem Lampotang, PhD, and supported by the Department of Anesthesiology at the University of Florida College of Medicine and multiple APSF Safety grants. First implemented in 1999, the interactive and illustrated simulation of a generic anesthesia machine with an oxygen-driven bellows ventilator now includes legends in 23 languages and 6 medical gas color codes. Users can interact with controls and settings of the anesthesia machine via a pointing device such as a mouse or trackball. Audible cues enhance the realism of the learning experience. The VAM website at <http://vam.anest.ufl.edu/wip.html> includes a free 60-page APSF anesthesia machine workbook that provides structured learning exercises for self-paced learning and the APSF simulation of the 1993 FDA anesthesia machine pre-use checklist. In a study with premed students, transparent reality simulation (where the inner processes of a system are made visible, e.g., gas flow) provided better 24-hour knowledge retention on 3 of 5 objective measures of learning.

THE FUTURE

Vision and Mission Statements for APSF

Vision and mission statements are fundamental to the identity of an organization. The commemoration of our 20-year anniversary is an appropriate time to reflect upon these important “directional beacons” for the APSF. A vision statement refers to our future hope and goals, consistent with our founder’s goals. Essentially our vision is that defined by Ellison C. Pierce, Jr., MD. . . and his hope for the APSF’s contributions to society:

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

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Your Committee on Technology: Perspectives from the Chair, 1999-2007

by Michael A. Olympio, MD

Prelude

As a mid-level faculty member in the Department of Anesthesiology at Wake Forest University School of Medicine, I was invited by then member, and current *APSF Newsletter* editor, Dr. Bob Morell, to join the Committee on Technology (COT). Having assured me that it would not require more than 2-4 hours of effort per year, and a single annual meeting, he gladly informed Dr. E.S. Siker, then chair of the COT, of my willingness to board the patient safety train, particularly with the COT's emphasis on technology.

Major efforts in 1999, however, were directed not on technology *per se*, but to the office-based-anesthesia (OBA) safety issue, and the manner in which the states regulated such practice. Ongoing initiatives included medication errors associated with labeling discrepancies; medical gas pipeline construction, quality, and safety; consideration of producing a technology guide of standards pertaining to OBA; standardization and hazards of new wireless communications; and publication of comparable data on anesthesia equipment that had already caught the attention of ECRI. In 1999, the COT team consisted of Drs. Siker, Andrews, Moss, Peterson, Foster, Goldman, Olympio, and Petty, and industry representatives Argentieri, Cross, and Evans.

By 2000, the group had expanded with the addition of Calkins and Narbone, and by 2001 there was internal frustration with the difficulty in getting ideas to materialize into safety products. A quarterly article entitled "From the Committee on Technology" was suggested by Chairman Siker, and would include such topics as equipment analysis, how things work, and problems/solutions with specific pieces of equipment. However, there was "the usual APSF policy" of avoiding naming specific products, which was perceived as a significant barrier to open discussions (let alone publication) of equipment limitations, and a barrier to the promotion of equipment safety. These ideas and obstacles created the foundation for inevitable change that was to begin in October 2002.

Formation

The first question from a provider that I had ever received through the COT came from a Dr. Forstot, who wanted to learn more about perceived "rebreathing" in his new Datex-Ohmeda Aestiva 3000 gas machine. I recall feeling how "wasteful" the discussion had been, even though a response was provided, because no other clinicians in the anesthesia community would learn from it without publication. At my first meeting as the new COT Chairman, I directed the group to adopt a new and specific set of goals for the Committee:

1. To ensure that no person shall be harmed by anesthesia technology.
2. To foster investigations that will provide a better understanding of preventable equipment-related injuries.

3. To promote communications of information and ideas about the causes and prevention of equipment-related injuries.

Furthermore, realizing the provocative nature of this mission and the importance of sensitivities to special interest, the COT had the desire and the intent of working constructively together, to promote safety for our patients. The COT was deliberately constructed of a group of clinicians and industry representatives who chose to identify and/or to resolve equipment safety issues. At that meeting, which laid the foundation for all subsequent endeavors, I recall asking each member to describe how they might contribute to such a mission.

The 2002 membership slate included Siker, Olympio, Abramovich, Baumgart, Chamoun, Moss, Narbone, Wyman, Andrews, Argentieri, Calkins, Foster, Goldman, Peterson, and Cross, each of whom described a number of specific initiatives, with new emphasis upon investigation and communication of findings. This was an energetic and hard-working group of individuals determined to share their interests with the readership.

A plan rapidly took shape, as we described how "Modern Anesthesia Machines Offer New Safety Features" in the Summer 2003 *APSF Newsletter*, and placed a unique series of overlapping breathing circuit diagrams on the APSF website (www.apsf.org) for clinicians to understand new technologies in fresh gas decoupling. More importantly, the global plan for communications first recognized the accomplishments of ECRI through its "Hazard Alerts" and "Hazard Bulletins," but wondered whether enough of the clinical anesthesia community was aware of those articles, or had the opportunity to gain the manufacturers' perspectives.

Dear SIRS Conceived

The COT decided that its communications, "would involve input, participation, and feedback from the manufacturers," and I, as chair, informed the Board of Directors in October 2002 that the COT would "work with industry to promulgate appropriate reports." Although the Committee initially toyed with the concept of conducting independent and original device research, that idea was well ahead of its time, and would not come to fruition for another 4 years. By December 2002, the seeds for *Dear SIRS* had been planted in the minds of committee members, and as chair, I asked a seasoned Dr. Erv Moss what we should do with increasing numbers of clinicians' questions being delivered to the committee's doorstep. In my report to the January 2003 APSF Executive Committee, I asked for "advice and direction" in the manner of communicating with clinicians who encountered device safety concerns, reiterating the Committee's desire to "communicate such concerns to industry, and when possible, to provide a joint statement about the concern in the *Newsletter*."

At the May 2003 Executive Committee meeting, a systematic process was developed that would target specific representatives of industry for

interactions with me, the COT chair, acting as intermediary for the question/answer process. Finally, the concept crystallized at the October 2003 meeting in San Francisco as I walked along Fisherman's Wharf with *Newsletter* editor, Bob Morell, debating "Safety Issues Reporting System (SIRS)" versus "Safety Information Response System" (*Dear SIRS*). Only we know the exact details of that conversation! It was agreed that that column would be "pre-emptive" in nature and not deal with issues that had already caused harm to patients.

Membership and Representation Expand

The year 2003 brought the first wave of dramatic expansion in membership with the welcomed increase of CRNA representation to the COT, and new representation by the American Society of Anesthesia Technologists and Technicians (ASATT). Over the next several years, the committee would continue its growth, adding more physicians, industry representatives, and the chair of the Department of Anesthesia Sciences in Savannah, GA, a school for Anesthesiologist Assistants. Today, the ranks include some 25 members who voluntarily participate to varying degrees in the many projects of the COT.

Liaisons with Other Organizations

Frequently, the COT mission overlaps with the efforts of other organizations. Several members of COT have actively participated in the ASA Committee on Equipment and Facilities' (ASA-CEF) "Statement on Machine Obsolescence," under the meticulous leadership of Dr. Jerry Dorsch, which provides helpful guidelines for both clinicians and hospital administrators to determine whether or when an anesthesia machine should be replaced and/or eliminated from practice. Those guidelines were published in the September 2004 *ASA Newsletter*, and described both absolute and relative criteria. The absolute criteria were further divided under 1) lack of essential safety features, and 2) presence of unacceptable features. Such guidelines could herald stricter future requirements with regulatory agencies, as the desirability of new features, or dangers of older or missing features, become more apparent. In fact, elevating the significance of machine obsolescence was the most frequently cited topic for future efforts among COT members at the October 2006 annual meeting.

The COT has been further represented within the ASA-CEF by my leading the last 3 panel presentations at the ASA: "The New Generation of Intraoperative Mechanical Ventilation" (2004), "The New Generation of Anesthesia Ventilators—Why, How, and for Whom?" (2005), and "Hazards of the Modern Anesthesia Workstation" (2006). Participation by the COT is again expected in 2007 with the proposed resurrection of the ever-popular anesthesia machine workshop. This year promises to introduce the modern technologies in conjunction with the newly proposed Checkout Recommendations.

See "Technology," Next Page

Technology Committee Launches Major Initiatives

“Technology,” From Preceding Page

Several COT members participated in the revision of the 1993 FDA Anesthesia Apparatus Checkout Recommendations under Dr. Jeff Feldman, to accommodate the complexities of new designs and automated checkouts, which may or may not contain all of the steps previously expected in the FDA recommendations. That document is currently in submission to the ASA Board of Directors for their consideration. Along with that effort came the development of language by Dr. Don Martin, chair of the ASA-CEF, for the recently proposed Practice Alert on “Safe Operation of the Anesthesia Workstation.” Within that proposal are the recommendations that “anesthesia machines and workstations should be used to provide patient care only by qualified anesthesia providers who have satisfactorily completed an institutionally approved, machine-specific, training program and demonstrated competence in the use of that particular machine or workstation.” The COT was separately and actively pursuing efforts to improve technology training (discussed below), and considers this language to be one of the first steps in implementing mandates for technology training.

This discussion would not be complete without recognizing the contributions of the APSF to the advancement of health care simulation education. Two pioneers in simulation, David Gaba and Jeffrey Cooper, both sit on the APSF’s Executive Committee, while Matt Weinger and I joined their ranks to further promote the national effort. I formed and led the ASA Workgroup on Simulation Education until the ASA approved an official Committee on Simulation Education at the October 2006 House of Delegates meeting. The combined efforts of those individuals produced a White Paper on “ASA Approval of Simulation Education Programs,” (which would direct the establishment of high quality training programs), a website on simulation: <http://www.asahq.org/SIM/>, a needs-assessment survey of the ASA membership, and a Directory of Simulation Education Opportunities for anesthesia clinicians. I also conducted a roundtable discussion and produced a report on Simulation Center Credentialing at the 2007 International Meeting on Simulation in Healthcare.

Major Safety Initiatives Launched

Three major safety products of the Committee on Technology all came to light during the October 2003 annual meeting. First, the complexity of new anesthesia machine technologies was perceived as a barrier to patient safety if clinicians did not know how to operate or troubleshoot their equipment, and concurrent APSF efforts in High Reliability Organizations begged the question of whether clinicians should be certified to use such technologies. These initial discussions helped to launch the Technology Training Initiative described below, and fueled our interest in the ASA efforts for checkout and training statements, above.

The second safety product, so to speak, arose from a mandate by the APSF Executive Committee for the COT to publish a discussion on the use of audible alarms on physiological monitors and the use of an audible beep tone from the pulse oximeter during all anesthetics. Drs. Julian Goldman and Fred Robertson from the COT prepared a pro/con article on the January 2004 JCAHO Safety Goal #6, “to improve the effectiveness of clinical alarm systems,” and the APSF’s EC organized its Fall 2004 Board of Director’s Workshop to specifically consider the adoption of an ASA Standard of Care for clinicians to maintain the audible feature of the pulse oximeter and capnogram alarms. The Corporate Advisory Council of the APSF enthusiastically agreed that such discussions were not only warranted but strongly desired. Industry was looking for direction from the APSF regarding audible monitoring standards and default settings. Details of that effort are described below.

Third, and perhaps most dramatic, were a few circulating reports of spontaneous fires or explosions that had erupted within the gas machine absorber. A confluence of stories and individuals all in the right place, at the right time, created a flurry of intense activity that quickly resulted in a “Dear Health Care Professional” letter from Abbott Laboratories that sevoflurane in the presence of desiccated Baralyme® could result in the formation of intense heat, or fire in the absorber. The COT and the APSF worked with Abbott Laboratories, the FDA, and the ECRI to disseminate this critical information in the Winter 2003/2004 APSF Newsletter, article entitled “Canister Fires Become a Hot Safety Concern.” This preliminary investigation would later launch the Absorbent Safety Conference. Of particular significance to the COT, this article was the first to foster a new relationship with the AANA, as APSF granted permission for that organization to reprint this and other articles in the AANA News Bulletin. This soon led to the agreement with AANA that the APSF Newsletter would be mailed to their membership.

Dear SIRS Published

With the first publication of *Dear SIRS* in the Spring 2004 Newsletter, came the realization of a dream that industry and clinical anesthesia could openly discuss and publish device safety issues, with the intent of improving a product or improving the clinician’s understanding of a product. It should be noted how grateful the Anesthesia Patient Safety Foundation and its readership are to have major corporations willing to publish potentially embarrassing information about their products for the promotion of patient safety. It is truly a commendable accomplishment. That first commentary by James M. Berry, MD, and Steve Blanks, CRNA, with response by Michael Mitton, Director of Clinical Affairs at Datex-Ohmeda, then a part of GE Medical Systems, explained how a misplaced valve in the scavenger system could and did result in a potentially dangerous situation. The real value in the column, however, was the attention drawn to

the mechanism of operation of a little-understood component of the anesthesia machine. Subsequent quarterly columns have enlightened our readership with the following titles:

- O₂ Blender Causes Concern
- Common Gas Outlet Concern Leads to Corrective Action
- Clinician Recognizes Importance of Machine Checkout
- Cause of Ventilator Failure is Unclear
- Descending Bellows Drives Question
- Dear SIRS Making a Difference

See “Technology,” Next Page



**& ANESTHESIA
& ANALGESIA**

The APSF is very pleased to
announce our new
relationship with
“Anesthesia & Analgesia”
(A&A).

A&A is now the
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of the APSF.

Dr. Sorin J. Brull, Chair of
the Scientific Evaluation
Committee, has been selected
Section Editor of the new
Patient Safety Section of
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We are grateful to
Dr. Steve Shafer, Editor of
A&A and the Trustees of the
IARS for sharing our vision
and facilitating this initiative.

Technology Training Initiative Continues As High Priority

"Technology," From Preceding Page

- Absorbent Wrapper Design Questioned
- Channeling Causes Concern
- Line Isolation Still Important
- Is an In-line Oxygen Monitor Still Necessary?
- Reader Seeks Standards for Equipment Check

Audible Alarms Become a Standard of Care

As the above mentioned discussion of audible alarms appeared in the Summer 2004 *Newsletter*, the APSF's EC was working behind the scenes to arrange a panel of expert presentations for October, while proposing a new standard of care for debate during the conference breakout sessions. Until that time, no other Standard for Basic Anesthetic Monitoring addressed audible tones and alarms except one, and that was the disconnection of the breathing circuit. After stunning testimony and debate within the roundtables, the APSF subsequently announced their recommendation: "When the pulse oximeter is utilized, the variable pitch pulse tone and the low threshold alarm must be audible. When capnography is utilized, a capnography alarm for hypoventilation must give an audible signal."

At the time, Dr. Bob Stoelting described this proposal as "low hanging fruit," which was subsequently adopted in similar form effective October 25, 2005 (exact wording published in the Spring 2006 *Newsletter*), by the ASA House of Delegates and the American Association of Nurse Anesthetists. Stoelting commented that such a likely addition would probably not have been possible without the efforts of the APSF.

Absorbent Safety Issues Heat Up

Following the Winter 2003/2004 reports of fire in the breathing system, subsequent revelations of intense heat and agent destruction within desiccated, strong-base absorbents prompted Michael Mitton of GE Healthcare to request that the APSF moderate an industry-wide conference on absorbent safety. That conference was convened on April 27, 2005, with the intent to "develop a consensus statement on the use of carbon dioxide absorbents to reduce the risk of adverse interactions with volatile anesthetic drugs," and was attended by representatives and experts of the scientific community, ASA, AANA, drug and equipment manufacturers, carbon dioxide absorbent manufacturers, ASATT, AHA, ECRI, AORN, JCAHO, AAAA, and The Doctors Company. A significant effort preceding the conference produced a comparative table of then-current carbon dioxide absorbents. The table was used during the presentation to keep the myriad of names, contents, and manufacturers straight, and was published in the Summer 2005 *Newsletter* as a lasting comparison of strong-base and catalyst contents. Comments by industry representatives explained the "soda lime cycle," informed the audience that all of the companies were developing non-reactive absorbents, and explained potential methods for monitoring carbon

monoxide, desiccation, and heat generation. Finally, and within a single day, a consensus statement was achieved:

The APSF recommends use of carbon dioxide absorbents whose composition is such that exposure to volatile anesthetics does not result in significant degradation of the volatile anesthetic.

The APSF further recommends that there should be institutional, hospital, and/or department policies regarding steps to prevent desiccation of the carbon dioxide absorbent should they choose conventional carbon dioxide absorbents that may degrade volatile anesthetics when absorbent desiccation occurs.

Conference attendees generally agreed on specific steps to promote safety, consistent with ECRI recommendations.

Mandated Technology Training Initiative Gains Momentum

Initial High Reliability Organization discussions in October 2003 (mentioned above) were followed by the concerns of the Corporate Advisory Council in October 2004. From the perspective of their field instructors, many clinicians were unresponsive or unable to receive meaningful training. Frustration and/or concern was voiced over the ignorance of checklists and even automated checkout procedures, responsibilities for providing training, most effective types of training, physician refusal to participate in training, credentialing use in simulators, complexity of new machines, and specific accountabilities in receiving training. The impetus for launching a significant effort came through Dr. Michael Cox's question in the *Dear SIRS* column, Winter 2004/2005, when he commented, "I want to propose . . . that we really need to pay some organized, formal attention to increasing our facility with our machines." Through the combined efforts and interest of Bonnie Reinke, then General Manager of Anesthesia Delivery at GE Healthcare, and Abe Abramovich, then Director of Anesthesia Systems Development at Datascope Corp., we developed an intent to mandate a new and extensive training program prior to the introduction of modern new machines at Wake Forest University Baptist Medical Center. Institutional buy-in was essential to accomplish the 4-step training program. It included preliminary web-based study, lecture, workshop and simulation, followed by written MCQ examination, and was implemented in the winter of 2005/2006. The unintended results demonstrated how a late failure to mandate training among faculty members (as compared to SRNAs, residents, and CRNAs) dramatically and progressively reduced participation levels (Fall 2006 *Newsletter*). Although operational performance outcomes were not measured, the implication was that a failure to receive training would hinder the safe and satisfying use of the new technology. The effort required to conduct this training program raised serious questions about the ability of any

organization to successfully credential a large number of diversified clinicians on the use of an essential device, prior to installation. Rare testimony of successful mandates from another department chair, and from 2 other corporate installations suggested that it might be possible and beneficial. In a called conference during the October 2006 ASA meeting, GE Healthcare presented 2 examples of installations that either completely or only partially implemented the prescribed training program. The company was able to demonstrate a significant reduction in the consumption of resources (e.g., service calls) in the department that followed the prescribed plan. Meanwhile, the COT was developing the Technology Training Initiative (TTI) as a multi-institutional pilot study that would attempt to show the benefits, the capability, the difficulties, and the outcomes of a mandated technology training program. That study is currently under development and will be initiated by summer 2007.

The significance and need for such mandates and equipment credentialing is not lost on the APSF. The October 2007 Board of Directors' Retreat will consider this topic in depth and may provide recommendations for device credentialing soon thereafter.

Q&A Column Responds to Readers' Needs

With so many technology questions and answers relayed through COT (38 to date), it quickly became impossible or inappropriate to publish all of them in the *Dear SIRS* column. That column was originally intended to "expeditiously communicate technology-related safety concerns raised by our readers, with input and responses from manufacturers and industry representatives." It is a forum for the APSF to intervene and moderate a discussion between clinical anesthesia providers and device manufacturers, specifically. However, it was apparent that the COT had to develop another column, "Q&A," which could provide ". . . quickly answered questions . . . by knowledgeable committee members . . . whose responses would be of value to the general readership." Now entering its fourth column, the "Q&A" has provided yet another service to the APSF readership.

Summary

The COT has been tremendously active, responsive, and visionary over the past 5 years, and has tackled some provocative technology safety issues. COT members thoroughly enjoy their opportunities to participate in the patient safety movement, and have repeatedly witnessed their efforts providing benefit to patients and clinicians. More exciting developments are in the works for the second 20 years, but none of this would be possible without the completely voluntary efforts of otherwise fully-employed, safety-conscious anesthesia professionals!

Michael Olympio, MD, is chair of the APSF Committee on Technology and co-founder of the Dear SIRS Initiative. He is also Professor of Anesthesia at Wake Forest University Medical Center, Winston-Salem, NC.

The APSF Newsletter—20 Years and Counting

by Robert C. Morell, MD

The spring 2006 issue of the *Anesthesia Patient Safety Foundation (APSF) Newsletter* marked its 20th year of publication, with the *Newsletter* now recognized as having the largest circulation of any anesthesia publication in the world. As this *Newsletter* reaches its 80,530 readers, I call attention to Volume 1, Number 1, published in the spring of 1986. This landmark issue included an article that addressed why the APSF was organized, announced that the APSF would fund and award grants for research in patient safety, explored the question of minimal essential monitoring, and listed initial founding officers, directors, and committees. It was 8 pages in length.

Over the past 20 years the *APSF Newsletter* has grown and matured, first under the editorship of Dr. John Eichhorn (1986-2002) and currently under my direction (2002-Present). During the 16 years with Dr. Eichhorn as editor, the now widely known story of the dramatic improvement in anesthesia patient safety unfolded and was chronicled quarterly in the *APSF Newsletter*, along with an abundance of breaking news and controversial issues. The promulgation and implementation of monitoring and other anesthesia practice standards were frequent early, then recurrent, topics. The ASA Closed Claims Study was outlined initially and then covered episodically, including recent coverage of the timely topic of postoperative visual loss. The FDA equipment checkout protocol was introduced to the anesthesia community. A multitude of presentations, exhibits, and technology displays at a wide variety of meetings, as well as groundbreaking publications of many kinds, have been reported on since the earliest issues. Debates on fatigue, work hours, and provider impairment appeared periodically. Medication errors due to inconsistent drug packaging have been a recurrent theme throughout the *Newsletter's* existence. The potential huge role of sophisticated simulators in anesthesia training was first touted in these pages and also was one of many subjects reviewed as topics of grant research funded by APSF. Recently, the value of anesthesia information systems has been highlighted and the Data Dictionary Task Force continues to provide an infrastructure to facilitate the utility and cross compatibility of AIM systems, a development that will greatly expedite outcomes research. Among the "breaking news" items were CO production by carbon dioxide absorbents in certain situations, danger from succinylcholine in children, 5% lidocaine in spinals, reuse of disposables, overly aggressive liposuction, poorly organized office-based anesthesia care, and sulfites in generic propofol. Still more recent hot topics included fires and explosions from overheated carbon dioxide absorbers, a recall of contaminated sevoflurane, post-anesthesia blindness, decrements in cognitive function, and a variety of equipment

issues (such as gas pipeline problems), and human factors discussions (such as production and cost pressures as well as reading in the OR).

During the last few years a number of exciting initiatives have been added to the *Newsletter's* content, which is now produced in color. These initiatives include the *Dear SIRS* column (developed by Dr. Michael Olympio and Dr. Robert Morell), and the *Q and A* column (inspired by Dr. Stoelting and developed by Dr. Olympio and the Committee on Technology), both of which appear in each issue of the *Newsletter* and address important technology queries brought to our attention by our readers. The *Dear SIRS* feature is quite unique in that technology-based queries are addressed by manufacturers and industry representatives, along with Dr. Olympio and members of his committee. The exchange of information and response to reader questions help to disseminate technology based safety concerns and provide a line of communication between the clinician and industry. It truly has been a win-win initiative.



Robert C. Morell, MD, Editor, APSF Newsletter

The latest initiative is the new partnership between the APSF and the journal *Anesthesia & Analgesia (A&A)*. Tremendous gratitude is extended to Dr. Steve Shafer, editor of *A&A*, for his vision and enthusiasm in forging this cooperative venture as *A&A* becomes the official scientific journal of the APSF. Similarly, appreciation is expressed to the Board of Trustees of the International Anesthesia Research Society for their support of this endeavor. Coincident with this joint venture is the establishment of a new section on patient safety within *A&A*, of which Dr. Sorin Brull has been selected the new section editor.

The APSF Editorial Board continues support of the *Newsletter* and its editor with creative, hard-working individuals who provide critical reviews,

feedback, and fresh ideas while frequently contributing to the *Newsletter's* content. Drs. Murphy, Vender, and Greenberg continue to review scientific abstracts presented at the annual ASA meeting, Drs. Lee and Posner have contributed several important articles including cutting-edge news on postoperative visual loss and important messages from the closed claims database; Dr. Eichhorn shares his depth and breadth of experience and continues to contribute articles including the annual review of ASA scientific and commercial exhibits; Dr. Christie is our liaison with the annual APSF booth and is highly creative in sharing ideas for new articles and initiatives. Ms. O'Brien is our liaison with the American Society of PeriAnesthesia Nurses (ASPAN) and has extensive editorial experience herself. Dr. Jan Ehrenwerth is a source of tremendous knowledge and experience in patient safety and helps us keep our direction and focus on track. Rodney Lester, CRNA, PhD, is past president of the American Association of Nurse Anesthetists and is a willing and enthusiastic contributor. Dr. Sorin Brull is chair of the APSF Scientific Evaluation Committee and tirelessly keeps our grant announcements up-to-date while authoring the extensive reviews of our annual grant award recipients and their proposals. As previously mentioned, Dr. Brull has recently received the honor of being selected the first section editor of patient safety for the journal *Anesthesia & Analgesia*. I would also like to personally express my appreciation and gratitude to Wilson Somerville, PhD, for his tireless efforts as he reads and rereads each and every word of each issue of this *Newsletter*, insuring quality, accuracy, and clarity. His expertise as a medical editor and his friendship and support are invaluable. Ms. Addie Larimore is the glue that holds all of this together as the *Newsletter* evolves from rough copy, through formatting and editing, to final production. Her organizational and editorial skills are outstanding and exceeded only by her patience. The APSF is truly fortunate to have the production and publication support of Bonnie Burkert and her colleagues at GrafikPharm. Through her efforts we continue to improve our appearance, our processes, influence, and appeal to our readership. Finally, our most valuable asset is our readership. Without the support and input (letters, questions, queries, criticism, suggestions, ideas and articles) of our readers this *Newsletter* would be mere words on a page.

Dr. Morell is editor of this newsletter, Clinical Associate Professor of Anesthesiology, Wake Forest University Health Sciences, Winston-Salem, NC, and Adjunct Clinical Associate Professor of Anesthesiology, University of Florida School of Medicine, Gainesville, FL. Dr. Morell is in the private practice of anesthesiology and resides in Niceville, FL.

APSF President Looks Toward Exciting Future

by Robert K. Stoelting, MD, President, APSF

Any attempt to predict future directions that the Anesthesia Patient Safety Foundation (APSF) may take in pursuit of its vision that “no patient shall be harmed by anesthesia” requires an appreciation of the past. I believe that future activities of APSF will reflect, in large part, what has been learned over the first 20 years of the foundation’s existence. This does not imply satisfaction with past successes and a desire to sustain the comfort zone provided by the status quo, but rather the recognition that future successes will likely be built on the structure (people, committees, governance, safety initiative models) that has evolved during the brief history of APSF. The continued support of the American Society of Anesthesiologists (ASA) will be vital in the future. Without the financial support of the ASA, the APSF would have never happened and without this support in the future, the APSF will not remain viable.

Anesthesia was the first medical specialty to champion patient safety as a specific focus. An important component of the anesthesia patient safety movement was the presence of a highly visible and respected advocate, Ellison C. Pierce, Jr., MD. Over the years others have functioned as the “invisible” volunteers who make patient safety happen. This laudable characteristic of those who give freely of their time and expertise is as vital for the future as it has been in the past. The APSF is a highly leveraged organization that achieved results recognized by the 1999 Institute of Medicine report as unique to American medicine with a budget of less than \$1,000,000.

Grant Awards

In 2006, the APSF awarded \$750,000 for patient safety grants representing an investment in the future that was greater than 50% of the budget for that year. This emphasis on patient safety research will continue in the future as the APSF has embarked on the goal to provide more than \$1,000,000 annually to fund meritorious grant applications. As is the past, a cadre of investigators and scholars can look to the APSF for helping develop their academic careers. In the long term, the most important contribution of anesthesiology and the APSF to patient safety may be the development of a culture of safety that “permeates” our specialty and translates into safer patient care and improved outcomes.

APSF Newsletter

The *APSF Newsletter* is the “APSF,” and will remain the single most important vehicle for rapid dissemination of patient safety information. The current circulation exceeds 80,000 recipients and

will almost surely grow in the future. Recently the APSF has formalized its relationship with *Anesthesia & Analgesia* with the establishment of a *Patient Safety Section* in the journal with a section editor. Along with the *APSF Newsletter*, this partnership with a peer-review journal will further advance patient safety, education, and research.

Automated Information Systems

I believe the future of anesthesia patient safety is inseparably linked with automated information systems. These systems will improve our future ability to link intraoperative events to both short-term and long-term outcomes. Collection of real-time data obtained from millions of anesthetics administered annually worldwide could lead to a better understanding of best anesthesia practices and improved patient safety. The Data Dictionary Task Force, under the sponsorship of the APSF and with industry as a partner, has developed standard anesthesia terms for use in automated information systems. The APSF is committed to continued support of this project. The handwritten anesthesia record is a dinosaur that deserves to be placed in the “past history” of our specialty.

High Reliability Organization Theory

In the future, operating rooms will need to function more like a “high reliability organization” with teamwork and communication among all participants an accepted and expected pattern of behavior. The APSF has advocated application of high reliability organizational theory to the operating room and is eager to further refine this concept, ideally in cooperation with the national societies that represent nurses and surgeons.

Patient Simulators

In the late 1980s, supported by APSF grant funding, realistic patient simulators were introduced into anesthesiology. Anesthesiology became the leader in the application and adoption of simulators that enhance patient safety through education (residents learning new skills for the first time on a mannequin), training (teamwork, critical event management), and research (human performance). Use of realistic simulators has now become common in other medical specialties and the APSF will continue to advocate this technology in the future.

Lessons Learned

Past successes of the APSF have often reflected the ability of a nimble and efficient organization with minimal bureaucracy to rapidly address patient safety issues that become apparent

(although not necessarily new) as risks to patients. The APSF was able to organize, on short notice, a conference that included clinicians and industry to discuss risks of carbon dioxide absorbent desiccation and extreme exothermic reactions with volatile anesthetics. Although the APSF does not write standards (and will not do so in the future) this conference developed a consensus statement and recommendations for avoiding this patient safety problem. Similarly, changing monitoring standards for use of audible physiologic alarms was made possible by the APSF initiating discussion of this question and placing the question, for the first time, “on the radar screen” of those national societies (American Society of Anesthesiologists and American Association of Nurse Anesthetists) who could ultimately change their monitoring stan-



Robert K. Stoelting, MD, President, APSF

dards to include the ability of the anesthesia professional to hear audible alarms at all times in the operating room. This role of the APSF in identifying patient safety issues and bringing them to the attention of the appropriate societies and individuals will continue to be a vital strategy in the future.

Technology Training

“Would you fly on an airplane with a pilot who knew as much about his equipment as you know about your anesthesia machine?” This observation begs the question, “Should training be mandatory before an anesthesia professional uses new equipment in the operating room?” The APSF believes the answer is “common sense,” and industry would welcome increased compliance with “in service” activities. I believe that the APSF has the structure (neutral umbrella for industry and clinicians to work together on common safety issues) to improve technology training for those responsible for using new equipment on patients.

See “Future,” Page 14

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 Walter C. Dunwiddie, MD
 Norig Ellison, MD
 Jan Ehrenwerth, MD
 Basim I. Elhabashy, MD
 Thomas R. Farrell, MD
 Anthony Frasca, MD
 B. L. Friedberg, MD
 Thomas R. Farrell, MD
 Jane C. K. Fitch, MD/Carol E. Rose, MD
 Ian J. Gilmour, MD
 Barry M. Glazer, MD
 James D. Grant, MD
 Griffin Anesthesia Associates
 William D. Heady, CRNA
 Alexander A. Hannenberg, MD
 Peter L. Hendricks, MD
 James S. Hicks, MD
 Dr. and Mrs. Glen E. Holley
 Victor J. Hough, MD
 Howard E. Hudson, Jr., MD
 Indianapolis Society of Anesthesiologists
 Robert. H. Intress, MD
 Robert E. Johnstone, MD
 Tamos Kallos, MD
 Daniel J. Klemmedson, DDS, MD
 Kansas Society of Anesthesiologists
 BettyLou Koffel, MD
 Maine Society of Anesthesiologists
 Alan P. Marco, MD
 Maryland Association of Nurse Anesthetists
 John P. McGee, MD
 Tom L. McKibban, CRNA
 Cora B. McKnight, CRNA
 Medical Anesthesiology Consultants Corporation
 Mississippi Society of Anesthesiologists
 A. J. Montes, MD
 Roger A. Moore, MD
 Ervin Moss, MD
 New Hampshire Society of Anesthesiologists
 New Jersey State Society of Anesthesiologists
 New Mexico Society of Anesthesiologists
 L. Charles Novak, MD
 Denise O'Brien, RN
 Michael A. Olympio, MD
 Pennsylvania Association of Nurse Anesthetists

Mukesh K. Patel, MD
 Gaylon K. Peterson, MD
 Physician Specialists in Anesthesia
 Richard C. Prielipp, MD
 Rhode Island Society of Anesthesiologists
 Gail I. Randel, MD
 Henry C. Safford, CRNA
 Eduardo A. Salcedo, MD (Salmon Medical Innovations)
 Drs. Chris and David Santamore
 Muthia Shanmugham, MD
 Eugene P. Sinclair, MD
 Society for Obstetric Anesthesia and Perinatology
 Society for Technology in Anesthesia
 South County Anesthesia Association
 Shepard and Marlene Stone
 Sara L. Strom, AA-C
 The Woodlands Anesthesia Associates
 University of Maryland Anesthesiology Associates
 Vermont Society of Anesthesiologists
 Virginia Society of Anesthesiologists
 Matthew B. Weinger, MD
 West Virginia Association of Nurse Anesthetists
 West Virginia State Society of Anesthesiologists
 Andrew S. Weisinger, MD
 Dr. and Mrs. Wetcler
 Wichita Anesthesiology, Chartered
 Lawrence Wobbrock, JD
 Benjamin and Elizabeth Yoder

In Memoriam

In memory of Dr. Marc Balin (anonymous)
 In memory of Robert M. Chapman, MD (Texas Society of Anesthesiologists)
 In memory of Dr. Anthony J. DiGiovanni (Texas Society of Anesthesiologists)
 In memory of Oneita M. Hedgecock, MD (Texas Society of Anesthesiologists)
 In memory of Laurie A. Noll, MD (The Coursin family)
 In memory of Bonnie J. Slarsky (Jeffrey B. Cooper, PhD)
 In memory of June Thomas (Sunrise Trauma Anesthesia and Resuscitation Services)
 In memory of Rex E. Thomas, MD (Texas Society of Anesthesiologists)
 In memory of Leroy D. Vandam, MD (Dr. and Mrs. George Carter Bell)

Dear SIRS

Can Soda Lime Canisters Spread MRSA?

SAFETY INFORMATION RESPONSE SYSTEM



Michael Olympio, MD,
Chair of the APSF Committee on Technology
and Co-Founder of the Dear SIRS Initiative.

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

Dear SIRS:

A question has come up that no one seems to be able to answer. It pertains to the possible spread of methicillin-resistant *Staphylococcus aureus* (MRSA) in the operating room. Should soda lime canisters be changed after use on a MRSA patient? Under certain circumstances? I could not find any literature to answer this and thought you might know.

Thank you.

Laura Stokowski, RN, MS

In Response:

If we change the absorbent, are we also obligated to sterilize the entire breathing apparatus, as the pathways both to and from the absorbent may well be colonized? I asked our circuit filter manufacturing representative (see Martino and Anderson, below) to comment on the effectiveness of the bacterial filters to remove MRSA. We use a double-filter type of circuit, at both the inspiratory and expiratory machine ports, but I am not sure if that is adequate either. This discussion would not be complete without input from infectious disease experts (the CDC), particularly with comment on how few organisms are considered "safe enough."

Sincerely,

Dr. Michael A. Olympio
Chair, Committee on Technology

In Response:

I do not think that there is any so-called written document stating that the absorbent needs to be changed. However, I do not think that it is a bad idea, especially if you consider the potential for MRSA transmission to another patient. The cost of MRSA versus a bag of sodasorb is self-explanatory. At our hospital, we make it part of the clean-up of the OR suite to change the sodasorb.

Sincerely,

Jonnalee Bill
Immediate Past President
American Society for Anesthesia Technicians and Technologists

In Response:

The environment within the absorbent material is not constant and not uniform. The extent of moisture, the internal temperature, and the pH are all influenced by the relationship between the fresh gas flow, the minute ventilation, and even the I:E ratio. These will alter the probability that organisms may thrive

within the absorbent material. I have spent considerable time exploring these variants over the past several years and am amazed at the way these variables alter the environment of the absorber and the absorbent.

While an academic discussion is always exciting, especially to me, Jonnalee makes not only a compelling comment, but also one that is economically sound. Change the absorbent. When in doubt, change the absorbent. This is a good idea for other issues as well. Is the absorbent desiccated? Change the absorbent. How old is the absorbent? Change the absorbent. Is the absorbent exhausted, just "re-colored?" Change the absorbent. It's cheap. It is readily available. It eliminates the problem.

Sincerely,

Michael Mitton
GE Healthcare (Formerly Datex-Ohmeda)

In Response:

I am no expert in this field; however, I would question the value of changing the absorbent (pH >14) unless the facility also sterilizes the complete breathing system, including all parts coming into contact with patient gas. It seems the soda lime is the least of your worries.

Sincerely,

Robert Clark
Dräger Medical, Inc.

In Response:

Organisms have been cultured from the machine breathing circuits, but I'm not sure as to which "side" of the absorber those samples were taken from. Surely, very few if any would find it easy to sterilize the entire breathing circuit for every MRSA patient, as we seem to have many in a single day.

Dr. Olympio

In Response:

While MRSA is not the driving influence, Europeans have demanded anesthesia machines with a breathing system that is autoclavable for some number of years. This is why our newest machines all include systems that can be sterilized. Some Europeans actually do sterilize the breathing system regularly and often, though I don't know of any who do it for every case. I guess that begs the question, "When should it be sterilized?" Do we always know which patients have "infected" the system? Who is

See "Dear SIRS," Next Page

MRSA Transmission Unlikely But Hard Data Lacking

“Dear SIRS,” From Preceding Page

clean and who is dirty? One other point, filters. What does filtering actually mean? I attended an Association for Low Flow Anaesthesia meeting in Bristol, UK, last year where this topic was discussed. To my surprise, filtering does not mean removal of the contaminant, only elimination of SOME contaminant.

Michael Mitton

In Response:

Another comment on MRSA and anesthesia: I read about studies that found that doctors’ ties are the most dominating source of cross-contamination in a hospital. While I believe such is unlikely for the OR, every reasonable action to avoid the risk should be undertaken. Bacterial filters are certainly helpful, but not perfect. Regardless of brand and construction, they just have statistical retaining specifications. I’m not sure whether 99% or 99.9% or 99.99% makes a big difference as a few single bacteria out of the millions or billions in a cluster can form a new colony. With a better filter it just takes longer. Doesn’t MRSA itself result from a single bacterium’s DNA mutation which grows a new stem? As far as the airway is concerned, Wikipedia tells us that the nose is a common home of *Staphylococcus aureus*, although most of us with an intact immune system don’t suffer from the bacteria. So the airway must be considered. In summary, I would agree: Change the absorbent, and change the filters and tubing wherever possible to protect subsequent patients.

Sincerely,
S. Kästle
Philips

In Response:

Dr. Olympio writes the following to Vital Signs, Inc.:

There is a question circulating through the APSF and that is whether or not the absorbent should be changed for methicillin-resistant *Staphylococcus aureus* "MRSA" patients. What are the specs on our circuit filters for MRSA filtration? Obviously I’m wondering if those 2 filters keep MRSA out of the ventilator breathing circuit.

I am not an expert but have a good understanding of filters and filtering mechanisms and a little microbiology knowledge. I will confirm with some “expert” colleagues, but feel confident in what I am sharing with you. The BFE or VFE (bacterial/viral filter efficiency) of our filters are dependent on several factors, but the resistance of the organism strain is not one of them; it has more to do with its morphology. Our published BFE is in fact developed by

Table 1: Vital Signs Filter Efficiency

	303	303HEPA		Test Challenge
Bacterial Filter Efficiency	99.997%	99.9999%	S. aureus	.5 – 1.0 microns
Viral Filter Efficiency	99.94%	99.999%	Phi-X174	0.025 – 0.027 microns

challenging the filters with a high concentration of *Staphylococcus aureus* (SA). It is a challenge organism widely used and referenced in various filter standards like ASTM F2101 and the Mil STD for surgical masks. It was chosen in part because of its relevancy in the clinical setting, its shape (spherical), and its ability to be cultured. MRSA, simply put, is a *Staphylococcus aureus* morphologically, but is a “strain” that has developed a resistance to, specifically, the antibiotic methicillin. Based on my review, we are confident that our filter would be as efficient as we currently report, if challenged with the same protocol using a MRSA strain in place of the laboratory cultured version of *Staphylococcus aureus* ATCC#6538. I hope I have helped.

Tony Martino
Vital Signs, Inc.

In Response:

This is very helpful information, to know that your reported specs for filtration do indeed refer to things like SA, in particular. I will ask Jeff Anderson to mail or send me the brochure on your company’s various filters, with their specs. Does your company have any official opinion as to whether the machine absorbent needs to be changed if subjected to a MRSA patient, if indeed someone were using your filters properly?

Dr. Olympio

In Response:

What is the standard for the filters we use on our circuits? Why would MRSA be treated any differently than other patients with other bacterial infections?

Erv Moss, MD

In Response:

BFE lists the bacterial filter efficiency; VFE lists the viral filter efficiency. With regard to what is being used in your institution, the #5708 is used on the adult circuit; the #303 is used on the pediatric circuits. This may be more information than you need, but VSI and many other manufacturers use Nelson Laboratories to do third-party bacterial and viral challenge testing of anesthesia /respiratory filters. Nelson Laboratories protocol uses *Staphylococcus aureus* (SA) for the bacterial challenge and a bacteriophage Phi-X174 for the viral challenge. SA is

0.5-1.0 microns and spherical in shape. The Phi-X174 is 0.025-0.027 microns and spherical in shape.

We have discussed this in the past, but when addressing tuberculosis. The Centers for Disease Control (CDC) December 30,2005 / 54(RR17);1-141 Guidelines for Preventing the Transmission of Mycobacterium tuberculosis in Health-Care Settings, 2005 notes that *M. tuberculosis* is carried in airborne particles called droplet nuclei, and that the particles are approximately 1-5 microns in size. On page 21 of this report it lists procedures for the Surgical Suites. Here it recommends using filters that filter particles 3 microns in size with an efficiency of greater than or equal to 95%. Both the #5708 and the #303 exceed this recommended efficiency. According to "Bergey's Manual of Determinative Microbiology," *M. tuberculosis* is a bacteria, rod-shaped, and is sized at 0.3-0.6 x 1.0-4.0 microns. Table 1 above shows Vital Signs' filter efficiency for bacterial and viruses.

Sincerely,
Jeff Anderson
Vital Signs, Inc.

In Response:

Vital Signs has no scientific data, but I always have an opinion. I have not conferred and therefore this is not a company opinion. I do not know of any studies done by filter companies or machine companies that would answer scientifically about changing the absorbents. It is a question you may want to ask of a machine company, although I suspect they will say you should change out if you have a known “infected” person involved. A common sense approach leads me to say the absorber and absorbent would not need to be changed just because a patient had MRSA. Let’s walk it through. Start with a fresh canister and a circuit with filters on the inspiratory and expiratory machine end. The patient potential MRSA source should not make it to the absorber, but since a filter may not be 100% efficient, one could argue there is the potential that a “bug” could get through, but anything that “makes” it to the absorber needs to pass through another filter to reach the next patient.

I would think that the absorbent material (i.e., soda lime) may have some “antimicrobial” properties,

See “Dear SIRS,” Next Page

Filters Possibly Provide Protection

“Dear SIRS,” From Preceding Page

but on the other hand may support bacterial growth as the absorbent may be wet and warm, which is usually a good environment for the little devils. Again, I would say the likelihood or probability is very low to nonexistent, but this has not been studied or documented in the literature I've searched through. I'll do a little more searching and see if there are any infection control protocols for absorbents/absorbers

Here is a study (Langevin, et al., 1999) that relates. It does look like this topic has been an area of interest. I believe this article is on the same line as I was going. It certainly showed that under bench testing, if you do nothing to protect the machine, you could move the resistant organisms through the system. I would have thought the “soda lime” would have contributed more, but the answer lies in preventing the bugs from getting down the expiratory limb and “into” the machine, with redundancy at the inspiratory side. It appears that the use of filters on both limbs would support the exchange of the absorbent based on “exhaustion” rather than “contamination.” (Source: <http://www.chestjournal.org/cgi/content/full/115/4/1107>.)

Tony Martino

Editor's Note:

The article referenced by Mr. Martino is an important one to read. It is very well referenced and states that, “Despite a half-century of research, the true hostility of the environment within the anesthesia

machine and the potential for bacteria to traverse the system remains a matter of debate.” It specifically addresses the issues that we refer to above. Langevin et al. indicate that organisms can indeed pass through the absorbent, but would eventually be killed (presumably by high pH) if left undisturbed for greater than 1 hour within the absorbent. This research (“The potential for dissemination of *Mycobacterium tuberculosis* through the anesthesia breathing circuit” in *Chest* 1999;115:1107-1114) also indicates that a 0.22 micron filter “eliminated organisms from the inspired gas flow,” and references other studies demonstrating, “There are now several filters commercially available. . . that can remove 100% of the bacteria, even under considerable bacterial loads.” I recommend that our readers consider the authors' numerous conclusions and referenced materials in order to draw their own conclusions on this highly debated issue, and to seek more recent literature on the topic.

Dr. Olympio

In Response:

Here is the latest CDC recommendation (2003) as published in *MMWR* March 26, 2004; Vol. 53: No. RR-3:

8. Anesthesia machines and breathing systems or patient circuits
 - a. Do not routinely sterilize or disinfect the internal machinery of anesthesia equipment (IB) (80).

- b. Between uses on different patients, clean reusable components of the breathing system or patient circuit (e.g., tracheal tube or face mask) inspiratory and expiratory breathing tubing, y-piece, reservoir bag, humidifier, and tubing, and then sterilize or subject them to high-level liquid chemical disinfection or pasteurization in accordance with the device manufacturers' instructions for their reprocessing (IB) (24,26).

- c. No recommendation can be made about the frequency of routinely cleaning and disinfecting unidirectional valves and carbon dioxide absorber chambers (Unresolved issue) (81).

- d. Follow published guidelines or manufacturers' instructions about in-use maintenance, cleaning, and disinfection or sterilization of other components or attachments of the breathing system or patient circuit of anesthesia equipment (IB) (82,83).

- e. No recommendation can be made for placing a bacterial filter in the breathing system or patient circuit of anesthesia equipment (Unresolved issue) (4,84-89).

The 2003 CDC Guidelines for Preventing Health-Care-Associated Pneumonia is the complete report of the Healthcare Infection Control Practices Advisory Committee. The article by Vézina et al. entitled “Anesthesia breathing circuits protected by the DAR Barrierbac S[®] breathing filter have a low bacterial contamination rate” (*Can J Anaesth* 2001;48:748-54) is the most recent reference I can find on this topic. Bottom line—I don't think we know exactly what to do, and while the risk is low from these ancillary sources, it is not zero, but it is probably higher than some of the risks that anesthesiologists worry about in many of our conferences.

Sincerely,
David L. Bowton, MD, FCCP, FCCM
Professor and Head, Section on Critical Care
Department of Anesthesiology
Wake Forest University School of Medicine

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Important to “Do the Right Thing”

“Future,” From Page 10

Model for the Future

As in the past, I believe future safety successes will often reflect the desire to do the “right thing because it makes sense.” Doing the right thing has and will be 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 become a secondary goal but rather the recognition that safety changes that impact rare events may not lend themselves to traditional “*randomized double blind studies*” to confirm efficacy.

Achievements characterized as improved anesthesia patient safety cannot be attributed to any single practice or development of new anesthetic drugs or even any type of technologic advance, but rather to application of a broad array of changes in process, equipment, organizations, supervision,

training, and teamwork. No single one of these changes has ever been proven to have a clear-cut impact on mortality. Rather, anesthesia safety has been achieved by applying a whole host of changes that made sense, were based on an understanding of human factors principles, and that had been demonstrated to be effective in other settings. 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.

Robert K. Stoelting, MD
President, APSF

Dr. Stoelting is the former chair of the Department of Anesthesiology at Indiana University School of Medicine, president of the APSF, and author of numerous anesthesia textbooks, many of which are considered classics.



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

Q Dear Q&A,

I have an important airway safety issue, and thus would appreciate your opinion. Currently at my hospital our hand-held jet ventilators for emergency transtracheal jet ventilation (TTJV) are attached to E-size oxygen cylinders on our difficult airway carts. Their lack of a quick connect/disconnect system does not allow one to rapidly change the cylinder when it becomes empty. These are the only designated sources of oxygen for TTJV in our operating room suite. I have been trying to convince my hospital that a system allowing rapid attachment of a hand held jet ventilator to a central oxygen source is essential to insure uninterrupted oxygen supply during this most critical time. However, I continue to meet resistance, and thus, would appreciate your response.

I would also like to suggest that the APSF forward this topic to the ASA Difficult Airway Task Force for their response. Should this become a standard of care, or should each institution continue to employ whatever system they so desire? Some strong direction from our society would be very helpful to improve patient safety, and also to assist all of us who spend time teaching this technique at our institutions and at various meetings throughout the year.

Thank you in advance for addressing my inquiry.

Robert G. Krohner, DO
Pittsburgh, PA

P.S. How long would it typically take for a full E-size oxygen cylinder to become empty when using it with an attached hand-held jet ventilator for emergency TTJV?

A Dear Dr. Krohner,

Your request seems quite reasonable. It would assure a more reliable, longer-lasting source of oxygen (assuming no central gas failure) and is not very expensive to implement. Dr. Jon Benumof at UCSD insisted on this arrangement in all

of the ORs there, and they could provide you with implementation details if you needed them.

One advantage of having your TTJV on the difficult airway cart is its availability for use in out-of-OR locations like PACU. One solution for your issue would be to put a Y-connector on the central oxygen line coming into your anesthesia machine with a quick connect (female) on the end of the extra line. A similar quick connect could also be placed on the airway cart E-cylinder source. The jet ventilation systems (which could then be fewer than one for every room IF you have reliable technician support) could then have the same (male) quick connect to allow rapid installation at any OR site or on the airway cart for out-of-OR use.

A Dear Dr. Krohner,

We have essentially the same system at the University of Washington Medical Center and it has served us well.

A Dear Dr. Krohner,

I agree with the above comments and suggestions. At our institution, however, we have had dedicated jet ventilators for each anesthetizing location, but have had the luxury of an extra oxygen outlet on those columns. The Y-splitter sounds like a reasonable solution for both the OR outlet and the E-cylinder, if you don't have that extra outlet. If your institution does not want to purchase these inexpensive quick connect fittings for each site, then your portable system might require a second E-cylinder of oxygen for back-up. This expense would seem better utilized on the connectors, however. Your question has even prompted me to check that we have a portable device for off-site locations. I will forward this exchange to the ASA Difficult Airway Task Force for possible future comment or action. The duration of supply oxygen from the full E-cylinder is simply 660 liters divided by the flow rate emanating from your particular TTJV orifice, at the specified regulator pressure. I don't know what those data are.

Perhaps your supplier could provide that information.

A Dear Dr. Krohner,

If one chooses to use the splitter from the wall supply, one would have to assure that connecting 2 medical devices (e.g., the anesthesia machine and a jet ventilator) would not generate any back pressure or pressure reduction issues if both were drawing gas at the same time. It is unlikely, but should be assessed under various conditions. Also, for facilities with potentially limited resources and fewer jet ventilation setups, it makes sense to have jet ventilation capability travel with the emergency airway cart, as you describe.

A Dear Dr. Krohner,

In the years from 1996 to 2003 I documented 3 oxygen pipeline failures in a single academic medical center. These were not failures of the liquid oxygen source that affected the entire hospital, but were local phenomena that affected a single operating room. The causes of these failures were pipeline debris that clogged the wall/column connectors and stopped the flow of oxygen to the anesthesia machines. I suspect that these events are much more common than true failures of the oxygen supply at the source or further upstream. Now when I consult on the design of operating rooms I always specify 2 gas connectors for each gas being delivered to a column, ceiling drop, or wall cluster. This provides a reliable secondary source of gas in the event that one connector becomes clogged from pipeline debris. In each of the 3 cases that I mentioned, a second oxygen connector was available; changing the oxygen hose to the anesthesia machine from one Diamond connector to the other solved the immediate problem. Engineering had to replace the clogged connector. We had jet ventilators in each ENT room and on each difficult airway cart. I would suggest that manual TTJ ventilators are cheap and could be placed in each anesthetizing location with enough hose to connect to the secondary oxygen outlet. If there is concern about a

See "Q&A," Next Page

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More Q&A

Oxygen Cylinders Can Be Adapted for Jet Ventilation

“Q&A,” From Preceding Page

total oxygen system failure, a single cheap adapter hose could be constructed (e.g., oxygen DISS to female Diamond) and kept in the drawer with the manual TTJ system, so that the TTJ ventilator could be connected to an emergency O₂ tank. The difficult airway carts clearly need an O₂ tank and their own manual TTJ ventilator as you describe. My main concern is that we recognize the need for a secondary oxygen outlet and a secondary air connector at each column, ceiling drop, or wall cluster.

Editor's Note:

I wish to thank Dr. Lorri Lee, a member of the APSF Newsletter editorial board, for pointing out that TTJV has the potential for high risk of barotrauma. In the ASA Closed Claims paper on the Management of the Difficult Airway (Peterson et al., *Anesthesiology* 2005;103:33-39), 8 of 9 patients who had TTJV used for a rescue technique for airway emergency developed barotrauma with poor outcome.



Assembled apparatus for transtracheal jet ventilation using an oxygen E-cylinder.

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Q&A Follow Up

Last Quarter, Dr. Matthias asked about the teal/purple color coding on the GE Healthcare Tec 7 isoflurane vaporizer, and we learned from GE and ECRI that the color combination was designed with specific intentions, and was not known to be particularly confusing. However, we have received somewhat contrarian responses from several members of our Committee on Technology, and would like to share those with you now.

A Dear Dr. Matthias,

The color-coded, vapor-specific indicator is near the fill port of each vaporizer and as you mention, it is specific to the color on the bottle. No anesthetic vapors are color-coded turquoise. Is it your belief that either you, or other clinicians have attempted to turn the wrong dial, or fill the wrong vaporizer because of this color issue? Do you know how frequently this might occur?

Q Dear Q&A,

I have turned on the wrong vaporizer many times since getting this new machine because I have the turquoise dial color “in my head” as the sevoflurane vaporizer.

Heddy-Dale Matthias, MD
Madison, MS

A Dear Dr. Matthias,

- Colors should be used sparsely on medical equipment. In life, certain colors are used to evoke certain emotions—a whole design industry is dedicated to that end! Our safety standards in medicine nowadays require certain colors for signaling certain alarms in an intuitive way, e.g., a high priority alarm is red. Also, the 5 common anesthetic agents are color coded to improve intuitive usability. This coding scheme has made its way also into the new gas monitor standard, ISO 21647. The issue here may be that a large (and meaningless?) colored area on the dial may override the intuition of the smaller area of color code with signaling character. Coloring the dial appears to me to be an unfortunate choice—my suggestion: keep the dial and surroundings neutral!
- The answer above outlined the best solution. The safest approach would be to have the dial, the fill cap, and the bottle (and perhaps the vaporizer as well!) distinctly color coded. The more visual cues—the less chance of error. However, I would not push too hard, given that the likely worst case would be anesthetizing with an alternative inhalation anesthetic, which is usually titrated to effect off a dial that is calibrated in roughly equipotent concentrations per degree of turn.

- This shouldn't be a big issue, but... how many drug errors occur due to similar packaging? It could be an excuse waiting to happen! Anything that decreases confusion is appropriate to safety, especially in a residency training situation.

Committee on Technology



The GE Healthcare, formerly Datex-Ohmeda, Tec 7 Vaporizer with teal concentration dial and agent-specific color coding near the agent filler and sight glass areas. Photo courtesy of GE Healthcare, with permission.

Malpractice Insurance Carrier Provides Premium Incentive for Simulation-Based Training and Believes It Has Made a Difference

by Jack McCarthy and Jeffrey B. Cooper, PhD

In 2001, the Consolidated Risk Insurance Company (CRICO), the patient safety and medical malpractice company owned by, and serving, the Harvard medical community since 1976, introduced an incentive for anesthesiologists who received training in Crisis Resource Management at the Center for Medical Simulation (CMS) in Cambridge, MA. CRICO believes that this has made a difference and has since tripled the incentive, which is now 19%. Here's the story of how that happened, what the training does, and why CRICO has come to believe in it.

CRICO is a bit different than many malpractice carriers. It sees its mission as one of improving patient safety. In the mid-1980s, James Holzer, then Director of Loss Control for CRICO, approached the anesthesia chairs of the major teaching hospitals affiliated with Harvard Medical School (HMS). He asked them to work toward reducing their claims, which at the time were high relative to other specialties, and increasing. That request led the chairs to create a committee to review the claims and consider what might be done. The committee decided to develop what became the first practice standards in the specialty, the HMS Standards for Minimal Monitoring during Anesthesia. In the ensuing years, CRICO saw a great improvement in claims. It has since gone on to develop many vigorous efforts to prevent adverse events in other specialties. It truly uses patient safety as the means to reduce malpractice losses.

In early 2000, the chairs of the 4 HMS Departments of Anesthesia approached the Risk Management Foundation (RMF), which manages CRICO's insurance and claims. They asked RMF to give a reduced premium for the training that they were providing to their residents since 1994 and wished to provide to their faculty as well. In late 2000, RMF announced a 6% lower premium for anesthesiologists who had participated in crisis resource management training at CMS. It also offered a grant to offset some of the costs of the initial training. At the time, approximately 25% of Harvard insured anesthesiologists had participated in training, either in a pilot project in the early 1990s or as residents who later joined the faculty of their training programs. RMF's data suggested that those who had participated in the training had a better claims' experience than those who did not. While RMF did not subject their data to scientific scrutiny, their knowledge of the training experience coupled with the data led them to believe that this would be an effective program for risk reduction in anesthesia.

CMS did not then have a program aimed specifically at training its academic faculty. Using the experience in training residents in the Anesthesia Crisis Resource Management principles pioneered by Gaba et al.,¹ the CMS staff and representatives of

the HMS anesthesia faculty created an 8-hour course that included 4 realistic scenarios interspersed with a didactic presentation and facilitated debriefings of the videotaped sessions. The details and evaluations of the faculty are reported in an article by Blum et al.² Overall, the faculty valued the training highly and on average suggested that it be repeated about every 18 months.

The faculty-training program, which the departments support financially, is now in its seventh year. Based on the initial positive evaluations of the participants, CRICO decided to continue the program, requiring training every 3 years to retain the lower premium. Most faculty have participated twice already. Each program has a set of scenarios targeted to their needs and to issues relevant to CRICO's anesthesia claims. CME credits are awarded.

Recently, CRICO actuaries analyzed the malpractice claims experience of anesthesiologists who did participate in the new program and compared it to the relatively few who did not. They came to the conclusion that the program was indeed effective and further increased the differential premium to 19% starting in 2007. Some of the individual anesthesia programs have taken the bolder step of officially requiring the simulation-based training for hospital credentialing; the others do that *de facto*. (Note: Because CRNAs are covered by the hospitals' overall policy, no similar premium incentive yet has been developed for nurse anesthetists.)

Based on its perceived success in anesthesia, CRICO has created a similar incentive program in OB/GYN, where they experience substantially greater losses than anesthesia. Starting three years ago, a 10% incentive was implemented for OB/GYN physicians who participated in either a simulation-based training program or an organization wide teamwork program and several other educational requirements. Although there is not yet sufficient experience with that program, CRICO claims have been trending lower at those institutions with active team training or simulation training. CRICO/RMF is now planning additional incentive programs in other specialties.

Once again, leading efforts in anesthesia have catalyzed positive changes in patient safety initiatives beyond the specialty itself.

Mr. McCarthy is the chief executive officer of Consolidated Risk Insurance Company/Risk Management Foundation. Dr. Cooper is Associate Professor of Anesthesia, Harvard Medical School, Boston, MA, and the executive director of the Center for Medical Simulation. He is also executive vice president of the APSF.

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Report from the Chair: Education and Training Committee

"Committee," From Page 5

This is an ambitious guide to future action. Indeed, we hope it inspires you to help us achieve the mission of our Foundation, which is:

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

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

APSF Patient Safety Poll on the Website

Our future includes the just implemented APSF Patient Safety Poll on the home page of the website. We urge you to visit us at www.apsf.org monthly and register your opinion! This new survey instrument focuses on relevant, timely, "hot" topics, with the immediate availability of results to the participant. The Education Committee plans to organize new questions to be highlighted on a systematic as well as *ad hoc* basis. We encourage you to visit, vote, and get your voice heard!

SUMMARY

In summary, the **Committee on Education and Training** began its work concurrent with that of the foundation itself in 1986. Our goal then, as now, is to identify and disseminate educational/training information vital to patient safety. We are committed to this goal via the process of

- Determining the cause(s) of adverse anesthesia-related events
- Educating anesthesia providers on known causes and the ways in which to avoid them
- Disseminating national practice parameters designed to enhance quality anesthesia care
- Advocating for training protocols and simulation to enhance learning
- Participating in and promoting of safety research.

Please join us and participate in any the above forums. We are committed to build upon the legacy of the first 20 years of APSF success!

Dr. Prielipp is J.J. Buckley Professor and Chair of Anesthesiology at the University of Minnesota, Minneapolis, MN, and Chair of the APSF Committee on Education and Training.

Letter to the Editor**Percutaneous Coronary Interventions (PCI): Perioperative Antithrombotic Therapy and the Anesthesia Provider in 2007****To the Editor:**

The recent article in the *APSF Newsletter* regarding the perioperative management of patients with drug-eluting stents is timely, informative, and should be required reading for contemporary anesthesia practitioners.¹ Stenting with drug-eluting stents (DES) has become the most commonplace method of treating occlusive coronary disease, with 1 million stents placed each year. The Science Advisory in the editor's note is of special importance, advocating postponement of elective surgery for at least 1 year after DES placement, if possible, and emphasizes the acute need for very critical review of routine orders to hold aspirin or clopidogrel prior to surgery.² Such "routine policies" are misguided, as perioperative antithrombotic therapy should involve a comprehensive risk/benefit analysis regarding surgical bleeding vs. stent thrombosis, whereby the latter will typically remain the primary concern. The presented proposed strategy used at Wake Forest clearly emphasizes the dangers and complexities associated with effective perioperative management of patients presenting after coronary stent placement. It does provide one paradigm of antithrombotic management: continued aspirin therapy and bridging infusion of GP IIb/IIIa Inhibitors (GPI) and heparin. The Science Advisory itself indicates, however, that there are no data to date to support this GPI bridging therapy practice. This "Wake Forest Protocol (WFP)," like other published recommendations, leaves many additional and extremely pragmatic questions unanswered.²⁻⁶ Answers to these important questions are also unlikely to become "evidenced based," any time soon.

Pertinent questions remain: should surgical procedures in patients with coronary stents be undertaken only in tertiary centers with active interventional cardiology (>400 PCI/year as recommended by 2005 AHA/ACC guidelines⁷) and open heart programs with 24-hour availability (e.g., like Wake Forest)? How soon after surgery will repeat PCI be possible in the event of stent thrombosis in any given patient? Should patients for urgent surgeries be referred for management recommendations regarding percutaneous transluminal coronary angioplasty (PTCA)/bare metal vs. DES treatment to shorten intervals of mandatory antiplatelet therapy, if found in need of preoperative PCI? What procedures are associated with such excessive risk for surgical bleeding as to truly require discontinuation of thienopyridine? Further, should aspirin ever be discontinued (i.e., neurosurgical procedures)? What should be done with a patient with drug-eluting stents (DES) who presents for surgery after inappropriately discontinuing aspirin and thienopyridine therapy for several days in

anticipation of surgery? Should these patients undergo repeat stress testing prior to surgery? After what interval should antiplatelet therapy be reinstated? How long after DES placement should repeat stress testing occur? Does "patient compliance" affect this decision, and how can compliance be monitored? Should the cardiologist who placed the stent be personally involved in all perioperative agreements "between cardiology and surgery" as proposed in the WFP? What should occur in the event of disagreements? Why is "anesthesiology" not involved in the decision process, i.e., the perioperative physician? Should ALL stented patients undergo preoperative screening a week before scheduled surgery by an anesthesiologist in the pre-admission testing clinics to insure this complex coordinated care and eliminate "production pressures"? Surgeons will always fear bleeding. Production pressures are poorly combated in the holding area. How long after stent placement should this/any degree of concern persist and require strict assessments? What should be done if GPI or heparin allergy (i.e., heparin-induced thrombocytopenia) makes the WFP impractical and how is the "bridging therapy" optimally monitored and transitioned?

Aspirin and clopidogrel have elimination half-lives of 2-3 and 7.5 hours, respectively, while drug-exposed platelets are typically irreversibly affected, causing platelet inhibition until new, unaffected thrombocytes are produced.^{8,9} It is likely that perioperative administration of a titrated platelet infusion would typically correct drug-induced thrombasthenia caused by these agents, if antiplatelet drugs are last administered the morning prior to surgery and reduced to very low blood levels. While ABO identical or compatible units are preferred for transfusion, they are not required. In adults, ABO incompatible platelets may be used because the volume of plasma in the product is usually not clinically significant. Apheresis units may contain 350 mL of plasma, but passive transfer of antibodies rarely results in hemolysis.¹⁰ Thus, selective use of apheresis platelets in surgical patients from directed (i.e., spouse?) or proven repeat donor sources (repeatedly tested to further minimize infectious risks) may prove to be a viable alternative in elective patients who do not discontinue dual therapy prior to surgery and then actively display a need for functional platelets intraoperatively. An approach of this sort is not significantly different from autologous donation programs. This approach could allow for prospective intraoperative examination of bleeding tendency and "need to treat" for individual surgical procedures. It may also maximize stent-protective perioperative antiplatelet therapy, especially if these

patients are placed as first cases of the day. The role of platelet function testing is evolving as well. Clearly, emergent surgeries will continue to present, where antiplatelet therapy is addressed with random donor platelets. An apheresis program of this sort may lead to increased availability of apheresis platelet transfusions overall and specifically in emergent cases.

Guidelines from anesthesia specialists in France, Britain, and Canada provide additional useful information for rational decisions from the viewpoint of the member anesthesiology specialists, but are often discounted by surgical colleagues as "foreign."³⁻⁵ Unfortunately, there has been no attempt to develop such national guidelines by the American anesthesiology societies, and I would hope the APSF might champion this needed task, perhaps by first endorsing the Canadian Guideline and then via consensus development. This would offer opportunity to consider the multiplicity of perioperative eventualities, as well as educating and promoting needed specialty awareness to this very real and specific danger. Published recommendations from the conglomerate efforts of American non-anesthesiology specialists have left many anesthesiology-specific questions unanswered.^{1,2,6}

Often, production pressures overwhelm anesthesiologists and CRNAs when (institutional routine and) surgeons terminate antithrombotics inappropriately and push to do elective procedures.¹¹ The lack of clear and timely anesthesia specialty guidelines in the USA stands in stark contrast to other advanced countries.^{3,5} We, as the definitive "perioperative specialists" cannot fail to issue such practice-specific and important guidelines to underscore safe specialty practice, where controversy abounds and the dangers are real. Without specialty guidelines, we must, as individuals, continue to sort out and individually defend patient safety with logic alone, and often clearly without "evidenced-based proof." Personal experience repeatedly teaches that sudden cancellation of surgeries in recently stented patients based on "cutting edge knowledge" is often difficult, time consuming, and fraught with surgical and administrative animosity. Such difficulty mounts, especially when faced with "cleared for surgery" written on a prescription pad of a third-party internist or non-interventional cardiologist, consulted specifically to "clear for surgery." Furthermore, the importance of involvement of the stenting cardiologist and possibly hematologist appears paramount (and equally impossible when faced with a patient for a 7:00 am surgical start), given the complex and needed (and as yet

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All Stents Are Not Equal

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inadequately defined by outcome-based research) perioperative care, risk assessment, and the multiplicity of factors involved in stent thrombosis: All stents are not equal and not all cardiologists place stents! Problems are best anticipated and avoided, not solved. The APSF may be the best venue to address this issue at this time.

Paul M Kempen, MD, PhD
Pittsburgh, PA

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APSF Executive Committee Invites Collaboration

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

APSF Grant Applications Due June 18, 2007

\$150,000 Award Limits

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Stents, Stents, Everywhere—Now Even in the BRAIN!

by Richard C. Prielipp, MD, MBA, FCCM, Adnan I. Qureshi, MD, Steven J Haines, MD, and Vallabh Janardhan, MD

Myocardial stents (both bare metal and drug-eluting varieties) are widely utilized to prevent restenosis following percutaneous transluminal coronary angioplasty (PTCA) and coronary intervention (PCI). Indeed, by 1999 myocardial stents were inserted in 4 of every 5 patients undergoing PCI.¹ It now appears what is good for the heart may be good for the brain, too!

Atherosclerotic intracranial arterial stenosis is an important cause of stroke. The WASID (Warfarin Aspirin Symptomatic Intracranial Disease) trial, a double-blind, multicenter clinical trial, evaluated the benefits of best medical therapy (warfarin versus aspirin) in patients with symptomatic intracranial stenoses (50-99%). The primary end point was ischemic stroke, brain hemorrhage, or death from vascular causes other than stroke. During a mean follow-up period of 1.8 years (n=569), the primary end point occurred in 22.1% of the patients in the aspirin group and 21.8% of those in the warfarin group (hazard ratio, 1.04; 95% confidence interval, 0.73-1.48; P=0.83).²

Because medical treatment of symptomatic intracranial stenosis carries a high risk of stroke, neuro-interventionalists (interventional neurologists, endovascular neurosurgeons, and interventional neuroradiologists) are finding increasing application for stents in cerebral vessels with symptomatic severe stenoses that are refractory to best medical therapy. The main goal of the angioplasty and stent placement is to improve blood flow. Some of these lesions may manifest symptoms only after they become extremely tight, and even relatively minor corrections in the degree of stenosis may improve symptoms and outcomes. Flow is proportional to the fourth power of the vessel's radius. This means that the flow is approximately doubled when the radius is increased by 20% or the diameter by 10%, so that small increases in the luminal diameter may result in large increases in the flow.

The Wingspan™ stent (Figure 1) is placed via Gateway™ PTA balloon catheter system (Boston Scientific Corporation, Fremont, CA), which is approved to increase cerebral artery lumen diameter in patients with intracranial atherosclerotic disease (>50% stenosis that is refractory to medical therapy).

The Wingspan™ bare metal stent is manufactured in diameters from 2.5-4.5 mm, and in lengths from 9-20 mm. The device is inserted by neuro-interventionalists via intra-arterial catheters across stenotic lesions using biplane fluoroscopy for

sentinel vessel identification and localization (Figure 2). The patients may require deep MAC sedation or general anesthesia during the procedure depending on individual circumstances and interventional protocols.

Clinical experience with the new cerebral stents is relatively limited. A prospective, multi-center, single arm trial of 45 patients at 12 interventional centers evaluated the safety and feasibility of the current stent system. These patients had a mean age of 66 ± 8 years, with 96% having a neurological history of stroke and 29% a history of TIA. The 3 most common sites for stent placement were the vertebral artery (29%), the middle cerebral artery (22%), and the carotid petrous artery (11%). All patients successfully underwent balloon angioplasty to dilate the lesion, and a stent was then deployed across the dilated lesion in 44/45 patients (98% success). Potential adverse events include intimal dissection, stent migration, misplacement, or thrombosis, vessel perforation, or rupture. Subsequent, single center series have validated these results.³ Actual results of this pilot study are shown below:

Major Endpoints (30 days)	Total Evaluable Patients = 44	
	Number	%
Death or ipsilateral stroke (<i>same hemisphere as lesion</i>)	2	4.5
Major ipsilateral stroke	2	4.5
Death	1	2.3

Of special note, metal stent implantation causes endothelial injury with inflammation, rendering both the stent and affected vessel highly thrombogenic for a prolonged period.^{4,5} Thus, anti-platelet therapy with aspirin and clopidogrel is required for 4-12 weeks after cerebral stent placement. Adjunctive antiplatelet medication is crucial in preventing local stent thrombosis, major stroke, and death.^{5,6} Current recommendations for patients with bare metal stents include dual antiplatelet therapy with aspirin and clopidogrel, continued for at least 4 and up to 12 weeks to allow complete endothelialization of bare metal stents (BMS). Thus, anesthesia providers must be aware of patients presenting with cerebral stents and the status of antiplatelet therapy during this vulnerable period. Indeed, these complex issues parallel myocardial stents recently reviewed by Newsome et al.⁷

In summary, anesthesia providers should be aware of increasing insertion of metal stents throughout the circulation, including the cerebral circulation. Current trends suggest we will see increasing frequency of neuro-interventional procedures including

intracranial angioplasty/stenting. The need for post-procedure antiplatelet therapy is significant, and will likely mirror that noted for myocardial bare metal stents.^{5,6}

Richard C. Prielipp, MD, MBA, FCCM is the J.J. Buckley Professor and Chair of Anesthesiology; Adnan I. Qureshi, MD, is a Stroke and Interventional Neurologist and Professor of Neurology; Steven J Haines, MD, is a Professor of Neurosurgery; and Vallabh Janardhan, MD, is a Stroke and Interventional Neurologist and Assistant Professor of Neurology, Neurosurgery, and Radiology at the University of Minnesota in Minneapolis, MN.

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Figure 1: The Wingspan™ stent.

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Stents, Balloons, Microwares Treat Cerebrovascular Disease

“Stents” from Preceding Page

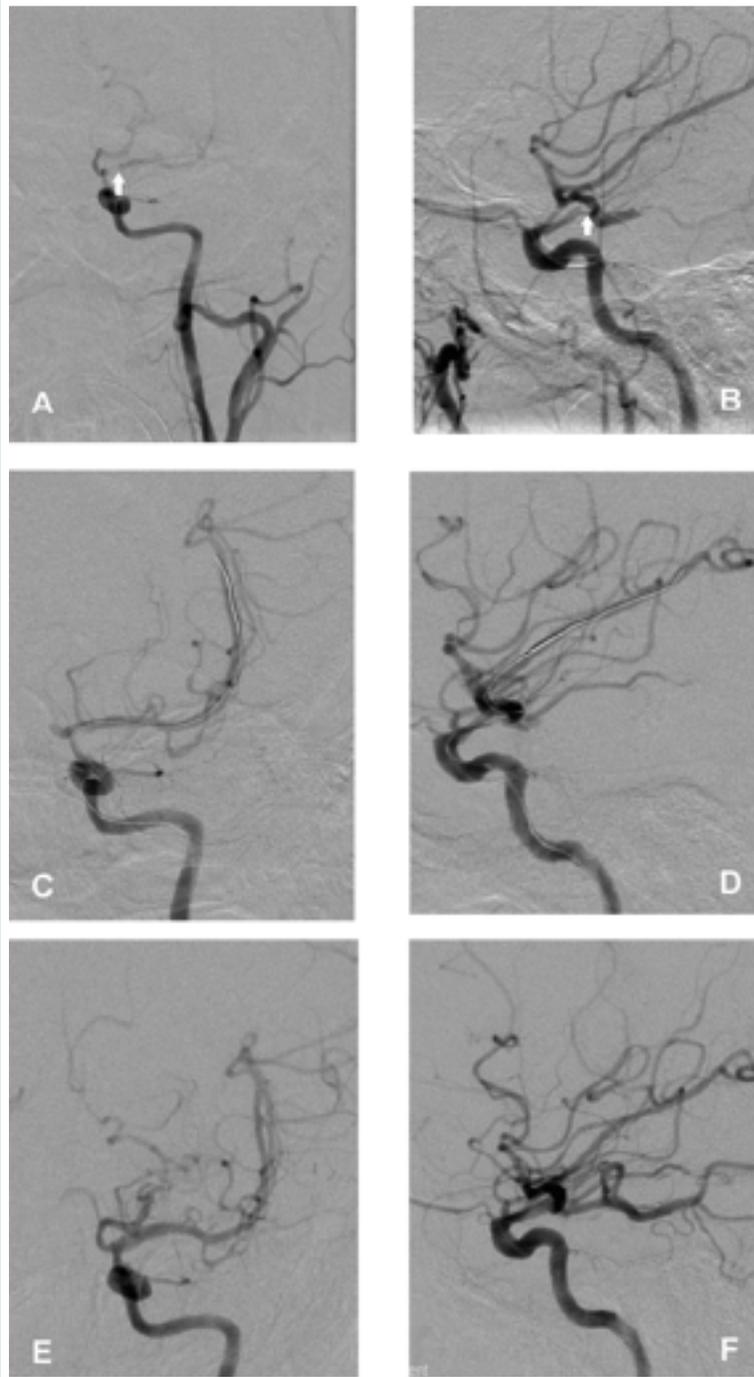


Figure 2: These two figures demonstrate successful dilation of a >90% stenosis in the left middle cerebral artery of a 53-year-old woman who had been having multiple left hemispheric TIAs (mini-strokes) while on maximal medical therapy. After balloon angioplasty, a Wingspan™ stent (radiographic markers denote the proximal and distal boundaries) was inserted to optimize the vessel lumen. Figures 2A and 2B show the >90% stenosis in the proximal M1 segment of the left middle cerebral artery (white arrows). Figure 2A is in the anterior-posterior projection (front view), and Figure 2B is in the lateral projection (side view). Figures 2C and 2D show the balloon catheter and microwire across the stenotic lesion and how the vessels have improved in size post-angioplasty. Figures 2E and 2F show the final result post-balloon angioplasty and Wingspan stent placement with no residual stenosis in the left middle cerebral artery.

Simulation Summit Held

by Elizabeth H. Sinz, MD

The March 2007 issue of the journal *Simulation in Healthcare* carries a full report (and editorial) concerning a first-of-its-kind Simulation Summit convened by the Society for Simulation in Healthcare (SSH) in November 2006. This Summit had the goal of fostering dialogue among stakeholders interested in a robust future for simulation in healthcare. Fifty-five individuals participated, representing the leadership of 33 organizations including specialty societies, regulatory bodies, and industry.

The SSH chose to hold the Summit both because of its mission to lead the facilitation of excellence in multidisciplinary simulation-based healthcare education, practice, and research, and its vision to move simulation into the mainstream of healthcare. Participants at the Summit worked diligently and collaboratively. The group first defined “simulation” in its diverse forms, then reviewed the ways that it could be used to improve patient care. Through facilitated small group discussions, a consensus was reached on the key issues that must be addressed to advance the field.

This forum provided a starting point for increased collaboration and cooperation within the healthcare simulation community and with external stakeholders. The use of simulation has exploded recently, leaving many groups to work independently toward achieving what is essentially a common goal. Fostering both collaboration and healthy competition will provide efficient and effective means of achieving the success desired by all who share the goal of improved patient safety through diverse applications of simulation-based techniques. Future summits will build on the items outlined in the report to incorporate new ideas and facilitate ongoing progress.

Dr. Sinz is an Associate Professor of Anesthesiology, Critical Care Medicine, and Neurosurgery and Director of the Simulation Development and Cognitive Science Laboratory with the Office of Educational Affairs at Pennsylvania State University College of Medicine and Penn State Hershey Medical Center in Hershey, PA.

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Letter to the Editor

The Icarus Effect: The Influence of Diluent Warming on Dantrolene Sodium Mixing Time

To the Editor:

The idea of adjusting temperature to impact the solubility of a substance is hardly revolutionary. The mythical tale of Icarus serves as a testament to the ancient Greek's understanding of the sophisticated nature of physics by illustrating the relationship between temperature and the corresponding state of matter. Through a study we conducted in an operating room environment, we were able to demonstrate a significant reduction in the time from the start of mixing to the ability to administer intravenous (IV) dantrolene sodium. In a simulation of real world conditions, with equipment common to the operating room environment, a randomized, controlled, single-blind study was conducted dividing 16 dantrolene sodium vials into 2 equal groups, a warm group (41°C) and an ambient temperature group (22°C). By the use of an IV fluid warmer at 41° C, primed using a 1-liter bag of preservative-free sterile water, attached to a 60-ml syringe via a 3-way stopcock, the diluent was aspirated and injected directly into each dantrolene sodium vial.

Chartrand¹ was the first to suggest the use of an IV fluid warming device to facilitate dantrolene sodium reconstitution. A comparison of our investigation with the work of Mitchell and Leighton,² and that of Quraishi et al.,³ validates the notion that warmed diluent hastens dantrolene sodium solubility, although the methodologies developed to reach this conclusion contrast on several levels. Mitchell and Leighton examined this concept; however, their study included only 1 data point at 5 different temperatures between 20°C and 40°C. Although they determined the presence of a linear relationship between diluent temperature and solubility, their study lacked the power to adequately support the significance of their findings. After the data were collected for the present study in May 2006, Quraishi et al. published their report with similar findings. Quraishi et al. mimicked Mitchell and Leighton's results and claimed their data were collected under clinical conditions. Interestingly, they emptied all of their sterile water vials into a sample



Figure 1. Dantrolene sodium solubility

cup prior to mixing the dantrolene sodium. This task devours precious time, challenges aseptic technique, and fails to replicate actions that might take place during a malignant hyperthermia (MH) crisis. They also incorporated warming closets to heat their sterile water. Many of these devices are not intended to warm IV fluids, and we cannot recommend them for use in this application. In addition, neither of the study designs in the aforementioned investigations incorporated blinding of the observing party.

Our use of an adequate sample size and a methodology for warming the diluent with materials common to the operating suite and readily available to the anesthesia provider (warmed diluent [41° C] versus ambient temperature [22° C]), hastened the time of aqueous solubility of dantrolene sodium (Figure 1). The mean time to particulate-free dantrolene sodium solution suitable for IV injection with the warm diluent was 58.88 seconds compared to 93.87 seconds for the ambient temperature group (p<0.001). Data suggest a time savings of about 35 seconds per vial when the diluent is warmed to 41°C.

The time needed to mix an appropriate number of dantrolene sodium vials to successfully treat MH necessitates the assistance of multiple providers during a crisis. The time-savings afforded by

mixing dantrolene sodium with warmed diluent versus ambient temperature sterile water for 1 and 3 mixers is summarized in Table 1. The results demonstrate the Icarus effect, the crucially important relationship between the effect of temperature and the corresponding state of matter. Warming the aqueous diluent hastened the development of a clear and particulate-free dantrolene sodium mixture suitable for IV injection, freeing precious manpower time for other life-saving measures.

The manuscript from this study was recently published in the April issue of the AANA Journal.⁴ This letter is written to disseminate this information in the event someone experiences a MH crisis, and to promote patient safety that may improve patient outcome. A practical method, using a reliable and safe warming device readily available to the anesthesia provider, and ubiquitous to the operating room environment, speeds the time to administration of dantrolene sodium, potentially reducing morbidity and mortality associated with MH. Perhaps our research, in addition to the work of Mitchell and Leighton and Quraishi et al., will lay the groundwork for changing MH treatment protocols, and help further reduce morbidity and mortality.

Donna Landriscina, CRNA, MSNA
Richmond, VA

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Table 1. Dantrolene Mixing Time by Dose and Diluent Temperature

Dantrolene Dose	2.5 mg /kg		10 mg /kg	
	A Diluent	W Diluent	A Diluent	W Diluent
*Time / seconds	94 seconds	59 seconds	94 seconds	59 seconds
Number of Vials	9 vials	9 vials	36 vials	36 vials
1 Mixer / minutes	14 minutes	9 minutes	56 minutes	35 minutes
3 Mixers / minutes	5 minutes	3 minutes	19 minutes	12 minutes

A = Ambient (22° C), W = Warmed Diluent Temperature (41° C)

*Comparative Study Results, Mean Times

Letters To The Editor: **Medication Labels Need Practical Standards**

To the Editor:

Dr. Foster gave an excellent review on the history, current status, and future for drug labeling in the operating room. I would like to express a personal concern regarding the labeling issue. While I strongly believe that labeling of syringes is critical to patient safety, I am concerned that in an age of over-regulation, rules devoid of common sense may be placed upon us by the regulating and accreditation bodies. Few would argue that unlabeled syringes pose a potential danger to patients. Propofol may be an exception since no other medication in the operating room is similar in appearance. (However, even propofol should be labeled if anything is added to it.) Even an unlabeled syringe does not seem unreasonable in a dire emergency when left in the vial from which it was drawn up, if discarded soon afterwards. But the potential for catastrophic iatrogenic patient injuries is tremendous if the syringe is not labeled with the contents and concentration of the medication. Imagine administering succinylcholine thinking that it is midazolam! However, should an anesthesiologist have to worry about being cited by a regulating body or an accreditation organization because the syringes at his side are not timed, dated, and initialed by the physician who drew them up? Would criticism be warranted if the syringe were not labeled as to the concentration of medication when only one standard concentration is available? Common sense would dictate that any medication that is altered in concentration, available in different concentrations, or has other medications added to it must be labeled as to content and

concentration especially if the anesthesiologist will not be in attendance for 100% of the case. But should we be cited if we did not record for example, that the concentration of fentanyl was 50 µg/ml when that concentration is the only concentration offered in the institution? I agree with the premise that concentration changes should be recorded on a nonstandard label to prevent the assumption by a different caretaker that the medication is a standard concentration.

Patient safety regarding drug administration depends both on a system which reduces errors, i.e., vial and syringe labeling, and a compulsive practitioner who establishes and maintains safe habits, especially pertaining to drug administration. This includes careful examination of the vial before drawing up medicine as to content and integrity, labeling of the syringe, checking the label before inserting it into the IV tubing, and double-checking as the syringe is placed back on the cart. There is no substitute for this compulsive attitude and the establishment of safe habits in the practitioner. Bar-coding may help the system, but the actions of the practitioner are paramount.

It is my hope that the Anesthesia Patient Safety Foundation will encourage the JCAHO and others to establish practical standards with respect to drug labeling in the operating room, so they do not institute onerous and unrealistic "standards" on all of us.

*John Beauregard, MD
Washington, DC*

Zero Tolerance May Be Unrealistic

To the Editor:

I read with interest the many articles in the winter 2006-2007 issue of *APFS Newsletter* regarding respiratory complications from opioid administration. Recommendations should be practical and applicable in a typical hospital setting. But it is unrealistic to have a policy of "zero tolerance" as some have suggested. Any intervention carries risks; even if a perfect respiratory monitor is discovered some patients will still experience adverse events due to both known and unknown factors.

Furthermore, any monitor employed should be convenient for the patient, as otherwise it will be associated with low to no compliance, and have a low false-positive alert system so as to not condition the providers to ignore the warning signs. Dr. Caplan's closed claims analysis of cases involving postoperative PCA and neuraxial narcotics identified the care to be inappropriate in half of the cases, thereby suggesting that adherence to the existing guidelines might immediately cut the complication rates by half. More important than any monitor is knowing your patients, educating them, and having their support. Having guidelines in place and adhering to them through education and monitoring should be the cornerstone of the effort to reduce complications from opioid use. The bar should not be set so high as to make it impractical or impossible to administer any narcotics, as uncontrolled pain is associated with its own set of adverse events.

*Babak Roboubi, MD
Washington, DC*

Anesthesiologist/Mother Shares Labor Epidural Perspective

To the Editor:

I am an anesthesiologist and the mother of 5 children. My husband is also an anesthesiologist. After reading the letter in the Fall 2006 *Newsletter* from Tami Maloney, wife of an "anesthesia professional," I felt compelled to respond. Mrs. Maloney's assertion that "anesthesiologists are at the beck and call of couples who do not prepare" adequately for childbirth is simply wrong. Mrs. Maloney extols her experience of having 4 vaginal deliveries without any pain medication. While that certainly is her right, I would not offer this "option" as being the gold standard of childbirth preparation for my patients.

I had 5 vaginal deliveries in 7 years and had a labor epidural with each one (1998, 1999, 2001, 2003, and 2005). However, the labor epidural with my first child had minimal to no effect in diminishing my labor pains. Despite preparing both physically and mentally for my delivery, the pain was intense

and overwhelming. The entire experience was a blur. The other 4 deliveries were pain-free and manageable. I was able to interact with the hospital staff, my husband, and especially our new baby without the pain and fatigue to cloud my thoughts.

With so many options for pain control available today, it makes no sense to see painful, medication-free childbirth as a badge of honor. Getting physically and mentally prepared does not remove the severe pain but merely helps one deal better with it. We are lucky to have so many choices regarding pain intervention in this modern society. Most people would not consider having dental work or passing a kidney stone without some form of medication. Similarly, women requesting pain relief during childbirth should not be viewed as failures.

As an anesthesiologist who has labored 5 times, I do not think that learning to deal with labor pain is a viable option for most expectant mothers. Anesthesiologists are trained to tailor the myriad of pain relief

options to each individual case. We are at the beck and call of our laboring patients to make them more comfortable if they should request our services—not to pass judgement on how well they have prepared for delivery during their pregnancies.

*Laura Wolf, MD
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20th Anniversary of the APSF

Past, Present, Future



- ▲ Report of the Committee on Technology
- ▲ Report of the Education and Technology Committee
- ▲ Newsletter Revisited
- ▲ President's View of the Future

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