

## Surgical Fire Injuries Continue to Occur *Prevention May Require More Cautious Use of Oxygen*



The conditions placing patients at risk for surgical fires on the body surface are well-defined:<sup>1-7</sup>

- Procedures involving the head, neck, and upper chest (above T5)
- Use of an ignition source (electrosurgical or electrocautery devices, laser) in proximity to an oxidizer-enriched (oxygen, nitrous oxide) atmosphere

Steps to decrease the likelihood of surgical fires on the body surface are well defined:<sup>1-7</sup>

- Determine if the patient is at risk for surgical fire
- Surgical team discusses the strategy for preventing and managing a surgical fire in a high risk patient
- Minimize the concentration of oxidizer (oxygen, nitrous oxide) near the surgical site
- Safely manage ignition sources
- Safely manage fuels (alcohol-based skin preps, drapes, oxygen masks, nasal cannulae, patient's hair).

Despite the fact that we know which patients are at risk for fire and understand how to prevent a fire, **SURGICAL FIRES CONTINUE TO OCCUR.**

A shocking and dramatic picture from the Fire Safety Video. Watch the whole video online at the APSF website home page—[www.APSF.org](http://www.APSF.org).

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# President's Report Highlights Accomplishments of 2011

As President of the Anesthesia Patient Safety Foundation (APSF), it is my privilege to report annually on the activities of the foundation during the past calendar year. The APSF was saddened by the passing of Ellison C. Pierce, Jr., MD, on April 03, 2011. Dr. Pierce was the founding president of the APSF, and without his vision and persistence the APSF would not have happened! The Ellison C. Pierce, Jr., MD, Patient Safety Memorial Lectureship has been established with the first lecture in October 2012 during the annual meeting of the American Society of Anesthesiologists.

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

## Postoperative Visual Loss Conference on September 12, 2012, in Phoenix, AZ

The APSF believes that increased awareness and understanding of risk factors associated with postoperative visual loss (POVL) is a timely patient safety topic. In this regard, the APSF is sponsoring a 1-day multidisciplinary conference to better define current information and understanding of "best practices" for patients at risk for POVL. Specific questions that will be addressed include

- Shared decision making (patient, surgeon, anesthesia professional)
- Who is "at risk"
- Informed consent (timing and by whom?)
- How is anesthetic and surgical management influenced?

If you are interested in attending this conference, please contact Dr. Stoelting at [stoelting@apsf.org](mailto:stoelting@apsf.org) for registration information.

## Research

The APSF Committee on Scientific Evaluation, chaired by Sorin J. Brull, MD, received 17 grant applications in 2011. In October 2011, the committee recommended funding the following 2 research awards to begin in January 2012:

Extubation Safety Quality Initiative Project – ESQIP

Miriam M. Treggiari, MD, PhD, MPH  
Department of Anesthesia, University of Washington  
APSF/ASA Endowed Research Award and Ellison C. Pierce, Jr., MD, Merit Award.

Enhancing Perioperative Safety through the Determination of Intraoperative Predictors of Post-Operative Deterioration

Jesse M. Ehrenfeld, MD, MPH  
Department of Anesthesia, Vanderbilt University  
APSF/Covidien Research Award and The Doctors Company Foundation Ann S. Lofsky, MD, Research Award

The total dollars awarded for these 2 grants was \$309,999.

In addition, the APSF is partially supporting the MOCA GRANT and has announced the Safety Investigator Career Development Award (\$150,000 over 2 years) to begin July 2012.

The APSF is the largest private funding source for anesthesia patient safety research in the world. Since the inception of the APSF grant program 522 grant applications have been received by the APSF. When the first grants were funded in 1987, funding for anesthesia patient safety was virtually unknown. Since 1987, the APSF has awarded 94 grants for a total of more than \$7,070,000. The impact of these research grants is more far-reaching than the absolute number of grants and total dollars, as the APSF-sponsored research has led to other investigations and the development of a cadre of anesthesia patient safety investigators.

## APSF Newsletter

The APSF Newsletter continues its role as a vehicle for rapid dissemination of anesthesia patient safety information with Robert C. Morell, MD, and Lorri A. Lee, MD, acting as coeditors. The circulation of the APSF Newsletter exceeds 94,000 recipients and is provided as a member benefit by the ASA, American Association of Nurse Anesthetists (AANA), American Association of Anesthesiologists Assistants (AAAA) and the American Society of Anesthesia Technologists and Technicians (ASATT) and the American Society of PeriAnesthesia Nurses (ASPAN).

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# Preventing On-Patient Fires in the Operating Room

From "Fire Safety," Page 41



In many of these fires, a common characteristic is the use of supplemental oxygen via an open delivery system, thus creating an oxidizer-enriched atmosphere in proximity to an ignition source. Anesthesia professionals have direct control over the delivered concentration of oxygen and the method of its administration.

The authors of this report propose that anesthesia professionals can contribute to the protection of patients at risk for surgical fires by **reassessing the administration of supplemental oxygen using the algorithm shown below.**

Preventing surgical fires is ultimately a team responsibility and depends on the surgeons, operating room nurses, and anesthesia professionals working together (*communication*) to identify patients at

risk and then following safety practices that have been clearly defined.<sup>6</sup>

*Robert K. Stoelting, MD, President, APSF (on behalf of the APSF Executive Committee)*

*Jeffrey M. Feldman, MD, Chair, APSF Task Force on Prevention and Management of Operating Room Fires*

*Charles E. Cowles, MD, Member, APSF Task Force on Prevention and Management of Operating Room Fires*

*Mark E. Bruley, BS, CCE, Vice President for Accident and Forensic Investigation. ECRI Institute*

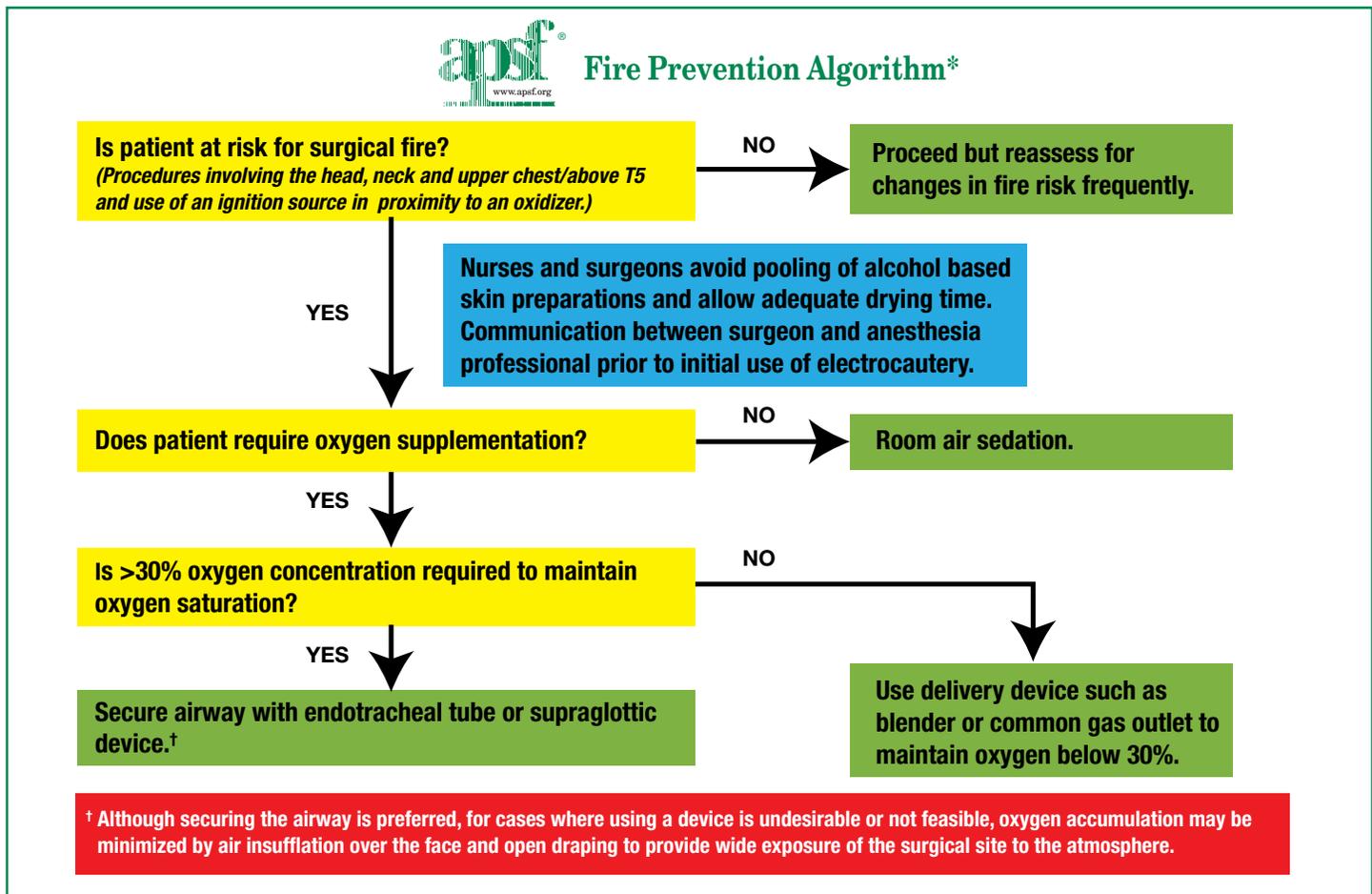
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4. Caplan RA, Barker SJ, Connis RT et al. Practice advisory for the prevention and management of operating room fires; A Report by the American Society of Anesthesiologists Task Force on Operating Room Fires. *Anesthesiology* 2008;108:786-801.

5. New clinical guide to surgical fire prevention. Health Devices. ECRI Institute. October 2009:314-332 ([www.ecri.org](http://www.ecri.org)).
6. Prevention and management of surgical fires (video). Anesthesia Patient Safety Foundation. 2010 ([www.apsf.org](http://www.apsf.org)).
7. Preventing surgical fires: collaborating to reduce preventable harm. Food and Drug Administration. October 2011 ([www.fda.gov/preventingurgicalfires](http://www.fda.gov/preventingurgicalfires)).

*\*The following organizations have indicated their support for APSF's efforts to increase awareness of the potential for surgical fires in at-risk patients.*

American Society of Anesthesiologists  
 American Association of Nurse Anesthetists  
 American Academy of Anesthesiologist Assistants  
 American College of Surgeons  
 American Society of Anesthesia Technologists and Technicians  
 American Society of PeriAnesthesia Nurses  
 Association of periOperative Registered Nurses  
 ECRI Institute  
 Food and Drug Administration Safe Use Initiative  
 National Patient Safety Foundation  
 The Joint Commission



# Dr. Stoelting Reports on Key Initiatives

## From "President's Report," Page 42

Important issues presented in recent editions of the *APSF Newsletter* included the report of the Board of Directors Workshop: 360° Assessment of the APSF, authored by Drs. Robert C. Morell and Lorri A. Lee, and Maria A. Magro, CRNA, and appearing as the lead article in the Winter 2011 issue. The Spring-Summer 2011 issue included an article entitled "Opioid Prescribing; Methadone Risk Mitigation" authored by Joan M. Christie, MD, and an article by Stephen E. Abram, MD, on "Avoiding Catastrophic Complications from Epidural Steroid Injections." The Fall 2011 *APSF Newsletter* included the proceedings of the APSF-sponsored conference on "Essential Monitoring Strategies to Detect Clinically Significant Drug-Induced Respiratory Depression in the Postoperative Period." This report was authored by Drs. Matthew B. Weinger and Lorri A. Lee. This same issue included a Dear SIRS article on reusable anesthesia breathing circuits by James M. Maguire, PhD, member of the APSF Committee on Technology. Drs. J. Paul Curry and Lawrence A. Lynn contributed an article entitled, "Threshold Monitoring, Alarm Fatigue, and the Patterns of Unexpected Hospital Death."

The "Question and Answers" and "Dear SIRS" (Safety Information Response System) columns in the *APSF Newsletter* provide rapid dissemination of safety issues related to anesthesia equipment in response to questions from readers. These columns are coordinated by Drs. A. William Paulsen (chair, APSF Committee on Technology) and Robert C. Morell (co-editor, the *APSF Newsletter*). The value of industry to anesthesia patient safety is reflected by these columns.

## Communication

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

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

APSF sponsored a panel entitled *Drug Errors You Must Avoid: Mishaps and Management* at the 2011 Annual Congress of the International Anesthesia Research Society. This panel was organized and moderated by Richard C. Prielipp, MD.

### Erratum:

The editors would like to apologize for omitting Dr. Jeff Jacob's name as the author of the letter to the editor, "Breathing Bag has Faulty Connection," that was published in Volume 26, No. 1 on pages 18 and 19 of this *Newsletter*.



Dr. Robert K. Stoelting, APSF President

## Fire Safety Video

More than 4,000 requests to receive the complimentary APSF fire safety video entitled "*Prevention and Management of Operating Room Fires*" have been received since the DVD became available in April 2010 (complimentary copies may be requested on the APSF website, [www.apsf.org](http://www.apsf.org)).

More than half the requests have come from registered nurses in their roles as safety educators in the operating room. The fire safety video emphasizes the appropriate use of supplemental oxygen for decreasing the risk of operating room fires. A survey to determine the impact of the APSF fire safety video on clinical practice has been conducted and the results are available on the APSF website ([www.apsf.org](http://www.apsf.org)).

The Food and Drug Administration has undertaken a fire safety initiative based on the initial role of the APSF and the ECRI Institute, bringing this safety issue to the forefront. A survey of recipients of the complimentary fire safety DVD is underway to determine how the DVD was used and its impact, if any, on clinical practice.

## Monitoring Strategies Conference

The *Conclusions and Recommendations* from the APSF-sponsored conference, *Essential Monitoring Strategies to Detect Clinically Significant Drug-Induced Respiratory Depression in the Postoperative Period* are available on the APSF website ([www.apsf.org](http://www.apsf.org)). The conference attendees agreed that monitoring oxygenation and ventilation should be available for all adult patients receiving opioids for pain management in the postoperative period.

## Annual Board of Directors Workshop

The annual APSF Board of Directors Workshop on October 15, 2011, entitled *Current Anesthesia Patient Safety Issues-Help Set the Priorities for Immediate Short-Term Resolution* included more than 700 attendees. A

unique feature of the workshop was the use of an audience response system. The answers to the questions posed using the audience response system are available on the APSF website ([www.apsf.org](http://www.apsf.org)).

## Medication Safety in the Operating Room Video

A complimentary copy of the 18-minute educational DVD, *Medication Safety in the Operating Room: Time for a New Paradigm* may be requested on line ([www.apsf.org](http://www.apsf.org))

## Financial Support

Financial support to the APSF from individuals, specialty and components societies, and corporate partners in 2010 has been most gratifying. This sustained level of financial support makes possible the undertaking of new safety initiatives, the continuation of existing safety initiatives, and funding for anesthesia patient safety research. The level of research support is particularly dependent on the level of financial support received.

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

## Concluding Thoughts

The APSF wishes to thank retiring Board of Directors members, Albert L. deRichemond, Thierry Leclercq, Susan R. Fossum, RN, Douglas M. Hansen, MD, and Robert A. Wise, MD, for their years of service.

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

Best wishes for a prosperous and rewarding year 2012.

Robert K. Stoelting, MD  
President

**The APSF continues to accept and appreciate contributions.**

*Please make checks payable to the APSF and mail donations to*

**Anesthesia Patient Safety Foundation (APSF)**

520 N. Northwest Highway  
Park Ridge, IL 60068-2573

## Future Patient Safety Initiatives Discussed at the APSF Board of Directors Workshop

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

Dr. Robert K. Stoelting, president of the APSF, and Dr. Robert A. Caplan, staff anesthesiologist and medical director of Quality at Virginia Mason Medical Center and clinical professor of Anesthesiology at the University of Washington in Seattle, WA, co-moderated the APSF Board of Directors Workshop entitled “Current Anesthesia Patient Safety Initiatives—Help Set the Priorities for Immediate Short Term Resolution” at the Anesthesiology 2011 meeting in Chicago, IL, on Saturday October 15, 2011. Opening introductory remarks were made by Dr. Stoelting and Dr. Mark A. Warner, president of the American Society of Anesthesiologists and member of the APSF Board of Directors, respectively. Dr. Caplan’s presentation followed these remarks and was entitled “What Do the Closed Claims Data Tell Us?” He presented data from the ASA Closed Claims Database highlighting the anesthesia areas with the highest proportion of medicolegal claims from 1990 or later. He discussed the most common damaging events in anesthesia claims and the areas with the highest severity injuries. Dr. Caplan noted that the ASA Closed Claims approach has been to identify recurring patterns of injury and provide suggestions for prevention, thus benefiting patients, anesthesia professionals, and insurers. He suggested we broaden the scope of future patient safety initiatives to include issues pertaining to surgeons and nurses as well. These initiatives should be embedded in our training programs so that future health care providers can “grow up” in a culture of patient safety. Dr. Caplan suggested that we should view risk management as risk reduction and provide a way to fail safely with redundancies built into the provision of health care. He felt that the most effective and efficient approach to improving patient safety is by identifying specific patient safety targets and measuring the effect of initiatives with pre- and post-intervention measurements.

Dr. David Gaba, professor of Anesthesia, associate dean for Immersive and Simulation-based Learning, Stanford University School of Medicine and staff physician, VA Palo Alto Health Care System, followed by discussing “How to Evaluate Targets for Safety Intervention.” He noted that most patient safety issues can be categorized as specific problems (phenotype), such as fire safety in the operating room, or deeper-level issues (genotype), such as teamwork and communication, production pressure, and developing a culture of safety. Dr. Gaba felt that specific issues may be more amenable to quicker resolution, but that they would have a high likelihood of recurrence unless we also work on the deeper level patient safety issues. He believed that both types of patient safety issues should be addressed simultaneously, and that deep problems would require sustained efforts and collaboration over decades with fundamental changes in health care organization and structure.



APSF Workshop speakers included (left to right): Dr. John C. Drummond, University of California, San Diego and VA Medical Center, San Diego, CA; Dr. Matthew B. Weinger, Vanderbilt University School of Medicine; Dr. Lorri A. Lee, University of Washington; Dr. David Gaba, Stanford University School of Medicine; Dr. Robert C. Caplan, Virginia Mason Medical Center and University of Washington; Dr. Mark A. Warner, ASA President and Mayo Clinic College of Medicine; Dr. Robert K. Stoelting, APSF President; Dr. Jeffrey M. Feldman, Children’s Hospital of Philadelphia and University of Pennsylvania School of Medicine; and Dr. Sorin J. Brull, Mayo Clinic College of Medicine.

Following these 2 overviews, 6 speakers each presented a specific patient safety issue and addressed the following 4 questions: 1) “Do we have evidence/agreement for the etiology of the problem?” 2) “Do we have evidence/agreement for the solution to the problem?” 3) “Does anesthesia have control/influence over introducing the solution to the problem?” and 4) “Do we have a way to measure the incidence for baseline and post-intervention data?”

A synopsis of the answers to these questions for each patient safety issue is presented in Table 1 below with more detailed answers at the following link: <http://www.apsf.org/announcements.php?id=11>.

Presentations and speakers included “Medication Safety in the Operating Room (Standardization, Technology, Pharmacy/Prefilled, Culture)” by Donald E. Martin, MD, Professor of Anesthesiology,

associate dean for Administration, Penn State University College of Medicine, Hershey, Pennsylvania; “Physician Hand-Offs—A Role for a Checklist?” by Matthew B. Weinger, MD, Norman Ty Smith chair in Patient Safety and Medical Simulation professor of Anesthesiology, Biomedical Informatics, and Medical Education, Vanderbilt University School of Medicine; “Cerebral Ischemia and Cerebral Perfusion Pressure (What is a Safe Blood Pressure?” by John C. Drummond, MD, Professor of Anesthesiology, University of California, San Diego, staff anesthesiologist, VA Medical Center, San Diego, CA; “Residual Effects of Neuromuscular Blockers into the Postoperative Period” by Sorin J. Brull, MD, FCARCSI (Hon) and professor of Anesthesiology, Mayo Clinic College of Medicine; “Fire Safety in the

See “Workshop,” Next Page

Table 1. Future Patient Safety Initiatives

Patient Safety Issue	Do we have evidence/agreement for the etiology of the problem?	Do we have evidence/agreement for the solution to the problem?	Does anesthesia have control/influence over introducing the solution to the problem?	Do we have a way to measure the incidence for baseline and post-intervention data?
Medication Safety in the OR	YES	INCONCLUSIVE	YES	YES
Hand-offs	YES	YES	YES	YES
Cerebral Ischemia and Cerebral Perfusion Pressure	INCONCLUSIVE	YES	YES	INCONCLUSIVE
Residual Neuromuscular Blockade	YES	YES	YES	YES
Fire Safety in the OR	YES	YES	YES	NO
Ischemic Optic Neuropathy	YES	YES	YES	YES

# Future Patient Safety Initiatives

## “Workshop,” From Preceding Page

Operating Room (Oxygen as a Drug in the Presence of an Unsecured Airway)” by Jeffrey M. Feldman, MD, MSE, Division Chief, General Anesthesia, Children’s Hospital of Philadelphia and clinical associate professor of Anesthesiology, University of Pennsylvania School of Medicine; and “Postoperative Visual Loss from Ischemic Optic Neuropathy After Spinal Fusion Surgery” by Lorri A. Lee, MD, associate professor, Department of Anesthesiology and Pain Medicine, University of Washington, Seattle, WA.

Following these presentations, the audience of approximately 700 Anesthesiology 2011 meeting attendees was polled using an audience response system (ARS) to help prioritize future patient safety initiatives. Of over 200 responses, 90% were anesthesiologists, and 89% had been in practice for more than 10 years. Of the audience members responding, personal (or a colleague’s) experience with these patient safety issues occurred in the following descending order: respiratory compromise from residual neuromuscular blockade (89%), adverse effects from medication errors (84%), adverse event related to a physician hand-off (68%), operating room fires related to supplemental oxygen use (49%), postoperative ischemic optic neuropathy (41%), and postoperative cognitive dysfunction following anesthesia in the beach-chair position (17%). The top 3 patient safety

issues that audience members selected as having evidence/agreement to the etiology and solution to the problem, as well as control/influence over introducing the solution to the problem, included fire safety in the operating room, medication safety, and residual neuromuscular blockade. The top 3 patient safety issues that members felt would improve patient safety without an increased investment in technology included hand-offs, residual neuromuscular blockade, and fire safety. Sixty percent of respondents believed that improvements in medication safety would require an increased investment in technology.

The session closed with Dr. Stoelting thanking the audience and speakers for their participation in helping prioritize patient safety initiatives for the future. He subsequently noted recent efforts that have been taken to improve patient safety on these issues including recent APSF workshops on medication safety and cerebral perfusion pressure in the beach-chair position, a special APSF research grant for the study of cerebral perfusion in the beach chair position, a recently released DVD sponsored by the APSF in conjunction with the ECRI Institute on prevention of fires in the operating room (available for download free on the APSF website [apsf.org](http://apsf.org)), the ASA Postoperative Visual Loss Registry and its associated recent multicenter case control study, and an ASA task force on the topic of hand-offs.

## 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.



APSF Sponsored Conference on Wednesday, September 12, 2012

## Postoperative Visual Loss—Who is at risk? What should we tell patients preoperatively? And, how should we manage their intraoperative care?

*Royal Palms Resort and Spa, Phoenix, AZ*

The APSF believes that increased awareness and understanding of risk factors associated with postoperative visual loss (POVL) is a timely patient safety topic. The goals of this 1-day multidisciplinary conference are to assure that current management reflects evolving information and understanding of “best practices” for patients at risk for POVL. Specific questions that will be addressed include:

- Shared decision making (patient, surgeon, anesthesia professional)
- Who is “at risk”
- Informed consent (timing of and by whom?)
- How is anesthetic and surgical management influenced?

Contact Robert K. Stoelting, MD at [stoelting@apsf.org](mailto:stoelting@apsf.org) for registration information.

# Clinical Experience with Capnography Monitoring for PCA Patients

by Ray R. Maddox, PharmD and Carolyn K. Williams, BSPHarm

In 2006 the ASPF first addressed the issue of drug-induced respiratory depression in the postoperative period,<sup>1</sup> and in June of 2011 convened its second conference to work toward mitigating and eventually eliminating this serious patient safety risk.<sup>2</sup> During the conference it was evident that there is a significant need for the anesthesia community to better understand and fully embrace the critical importance of continuous respiratory monitoring—particularly capnography in conjunction with, or as an alternative to, pulse oximetry when parenteral opioids are used in the postoperative period. Conference participants generally recommended pulse oximetry for all patients receiving PCA therapy, and capnography only for those receiving supplemental oxygen.<sup>3</sup>

Until recently capnography monitoring could only be used with intubated patients in the operating suite and intensive care unit (ICU). Most general-care clinicians are not as familiar with this type of monitoring as they are with pulse oximetry. In particular, the value of using capnography to measure not only respiratory rate (RR) but also end-tidal carbon dioxide (EtCO<sub>2</sub>) is not well recognized.

Overdyk et al. used both pulse oximetry and non-invasive capnography to continuously monitor 178 patients receiving PCA therapy. The incidence of respiratory depression as measured by oxygen desaturation was 12%, consistent with previous estimates.<sup>4</sup> However, the incidence of respiratory depression as measured by bradypnea was far greater than the 1 to 2% reported in the literature.<sup>5-7</sup> The use of continuous capnography monitoring yielded the following incidences: respiratory depression based on bradypnea, defined traditionally (≥1, two-minute or longer low-RR event [RR < 10 bpm]) was 58%; defined conservatively (≥1, three-minute or longer low-RR event) was 41%.<sup>4</sup>

Detection of a patient’s declining respiratory status before progression to respiratory depression can help avert undesirable outcomes and transfer to an ICU.<sup>8</sup> Because patients vary greatly in their response to opioids, patient status can change quickly, and traditional approaches to respiratory monitoring are less than optimal.

Current monitoring protocols typically require nurses to document the RR and less commonly the oxygen saturation (SpO<sub>2</sub>) value initially every 30 minutes, then as infrequently as every 2 to 4 hours.<sup>9</sup> The nurse’s presence may stimulate the patient, resulting in overestimation of the resting RR, which is often determined by manual respiration counts. Manual counts have been shown to be inaccurate when compared to capnometry.<sup>10</sup> Nurses usually are not available for continuous monitoring, and there is no automated alarm to alert nurses not in the room.

Even at a low RR, oxygen saturation is usually maintained.<sup>11</sup> Lethal hypercarbia is possible despite normal oxygen saturation.<sup>2</sup> As a result, pulse oximetry may fail to detect respiratory deterioration, particularly if a patient is receiving supplemental oxygen, which delays the progression of respiratory failure from bradypnea to apnea.<sup>11</sup> Thus, even continuous monitoring of heart rate and SpO<sub>2</sub> by pulse oximetry is not a substitute for monitoring RR, EtCO<sub>2</sub>, and apneic events by capnography.<sup>12</sup>

A growing body of literature shows that capnography is the earliest indicator of respiratory distress.<sup>8,13-16</sup> Earlier capnography systems required the patient’s trachea to be intubated, mostly limiting their use to critical care areas and the surgical suite. However, in 2004 the introduction of new technology made it possible to use capnography efficiently to monitor patients who are not intubated in general care nursing units. Nonetheless, problems have been encountered with using capnography in non-intubated patients such as compliance with use, dislodgement of devices, false or “nuisance” alarms, and restricted patient mobility. Some of these issues can be ameliorated with patient and clinician education as noted below.

In this article we describe how we determined that increased postoperative monitoring was needed; our process for determining what monitor(s) should be used; considerations that went into the cost-benefit analysis; how nursing staff was given significant process ownership; and patient outcomes achieved since introducing the increased monitoring.

## St. Joseph’s/Candler Health System, Inc.

St. Joseph’s Hospital and Candler Hospital, the main facilities of St. Joseph’s/Candler Health System (SJ/C) in Savannah, Georgia are 2 of the oldest continuously operating hospitals in the United States. Patient volume is 39,064 admissions annually with 644 beds. Staff includes 407 community-based, private practice physicians, 716 nurses, and 50 pharmacists. Interaction among staff and administration is characterized by a high degree of collaboration. SJ/C has the designation of “Magnet Hospital” from the American Nurses Credentialing Center. It is a medical teaching site for the Georgia Health Science University and is affiliated with several universities for the education of pharmacists, nurses, and other health-related disciplines.

### IV Infusion/PCA Safety Initiative

An article published in 2000 by the Institute for Safe Medication Practices (ISMP) detailing potential PCA-related medication errors<sup>17</sup> and completion of an ISMP Medication Safety Self-Assessment<sup>18</sup> in 2001 prompted the SJ/C Medication Error Team (pharmacists, nurses, respiratory therapists, risk managers, physicians, and others) to focus intensely on the

administration phase of the medication-use process and on IV medications.

- In October 2002 SJ/C implemented an advanced, modular IV medication-safety system for large-volume and syringe pumps that helped avert significant IV medication administration errors.<sup>8</sup> The need to improve PCA safety was underscored by the experience of 3 opioid-related events with serious outcomes in the preceding 2 years.
- The team recognized that safe use of PCA requires both correct pump programming and monitoring of patients’ individual respiratory response to opioids.<sup>8</sup> A 6-month beta test of new PCA and monitoring modules integrated with the existing IV safety platform was begun in June 2004. Beta testing revealed the difficulty of predicting which patients actually were high-risk, and that capnography, not pulse oximetry, provided the first indication of opioid-related respiratory depression.<sup>8</sup> As a result, the decision was made to require a capnography module for each PCA infusion and to use a pulse oximetry module for selected patients receiving PCA analgesics who have pre-existing co-morbidities. The patient selection algorithm developed at SJ/C is illustrated in Figure 1.<sup>9</sup>

## Technology

The modular intravenous (IV) medication-safety system combines large-volume, syringe, and PCA

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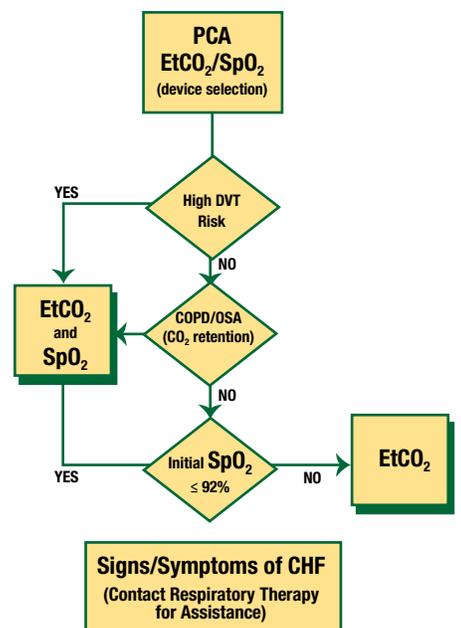


Figure 1. Patient monitoring - selection algorithm<sup>9</sup>

Source: Maddox et al. *Advances in Patient Safety: New Directions and Alternative Approaches*. Vol. 4. Washington: Agency for Healthcare Research and Quality; 2008:157-69. Used with permission.

# Improved Technology Interfaces Pulse Oximetry and Capnography with PCA pump

## From “Capnography,” Preceding Page

pumps with pulse oximetry and non-invasive capnography monitors on a single technology platform with a common user interface, which greatly increases ease of use and reduces possibilities for error (Figure 2). The system can be used reliably on both intubated and non-intubated patients, adult and pediatric patients, as well as patients receiving oxygen.

The non-invasive capnography system uses the filter line shown in Figure 3 to measure carbon dioxide in exhaled breaths in nose or mouth breathers. The “airway RR,” the most dependable measure of RR, is taken directly from measuring air movement in and out of the airway. In addition to RR, the system provides waveforms, exhaled EtCO<sub>2</sub>, and inhaled carbon dioxide (FiCO<sub>2</sub>) values.

An alarm, audible in the room and the hall, is generated whenever pre-established respiratory limits are exceeded. A nurse or respiratory therapist may respond to the alarm; patients may self-correct as a result of a physiologic response to the alarm, e.g. the alarm stimulates the patient to breathe during sleep apnea. The system provides up to 24 hours of PCA dosing history with corresponding time-based values from capnography and/or pulse oximetry monitoring. The trend data allow clinicians to better assess a patient’s response to PCA therapy and help provide an early warning of potential respiratory depression. When the PCA and monitoring modules are used as part of the overall system, if a patient falls below hospital-defined respiratory limits, the system’s unique



Figure 2. Modular IV medication safety system with PCA pumps and pulse oximetry and capnography monitors on a common technology platform. Source: CareFusion, San Diego, CA. Used with permission.

“pause protocol” automatically pauses the PCA infusion and deactivates the dose-request cord.

Initially the team programmed the system to generate an alert if a patient’s RR was  $\leq 10$  bpm or there was “no breath” for 30 seconds. In practice, this resulted in an unexpectedly high number of “nuisance” alarms. By analyzing extensive data retained in system memory, the team determined that changing the EtCO<sub>2</sub> parameter from 50 to 60 mmHg and resetting the RR from 10 to 6 would minimize nuisance alarms while maintaining patient safety. We confirmed these values and parameters in clinical practice as we

continuously monitored patients in the clinical environment. Settings can be adjusted if necessary based on patient requirements and physician order.

Patient mobility may be limited due to the presence of the PCA pump and monitoring module(s) on an IV pole, but we did not find that the cannula caused any additional limitation. Ambulatory patients infrequently require IV PCA and most often are receiving oral pain management.

## Implementation

The team recognized that for increased monitoring on the nursing units to be successful, this cultural shift needed to involve as many front-line clinicians as possible in the implementation. Physicians, nurses, pharmacists, and respiratory therapists worked together to develop policies and procedures, standardized PCA dosing forms, physician notification parameters, opioid drug libraries, routine order sets for SpO<sub>2</sub> and EtCO<sub>2</sub> monitoring, criteria for discontinuing monitoring and a reversal agent protocol. The use of supplemental oxygen was aligned with policies.

Having nurses involved at every step of preparation and implementation greatly increased the nursing staff’s knowledge of and willingness to use the new monitoring modules. Respiratory Care also needed to be part of the process, since respiratory therapists have an EtCO<sub>2</sub>/SpO<sub>2</sub> knowledge base, keen clinical assessment skills, ability to intervene and resolve potential respiratory emergencies, and are available around the clock.

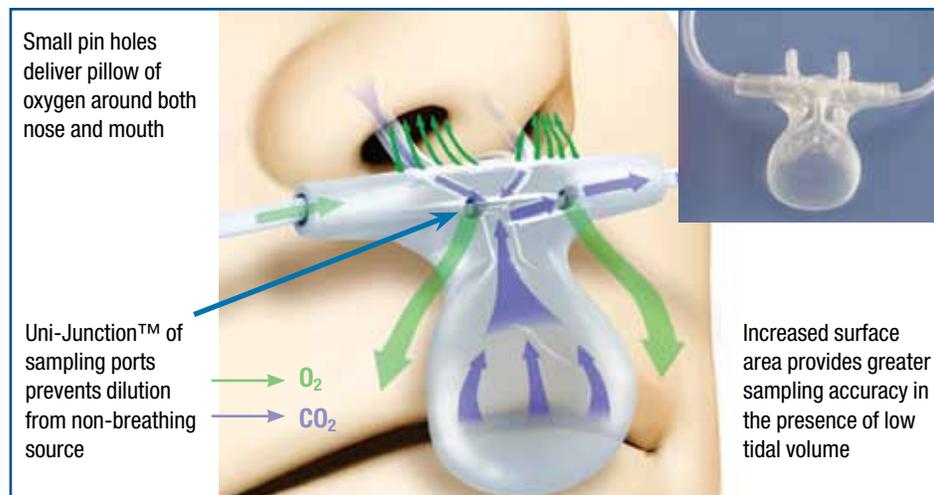


Figure 3. CO<sub>2</sub> sampling/O<sub>2</sub> delivery for non-intubated patients. Source: Oridion Capnography, Inc., Needham, MA. Used with permission.

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# Capnography Monitoring Helps Prevent Serious Adverse Outcomes

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## Education

Respiratory care and nursing with assistance from pharmacy developed a concise and basic program to introduce capnography monitoring into the general care nursing areas. Together, a clinical nurse specialist and the respiratory therapy education coordinator educated nurses and pharmacists on enhanced pain management, pulse oximetry and capnography monitoring. Education took place during staff orientation, annual competency assessments, and at the bedside. During implementation of capnography we discovered that patient education was a key component of a patient's understanding the importance of wearing the monitoring cannula, the reason for the alarms, and response when an alarm sounded. Education materials were provided for patients and families. When educated about the benefits of capnography monitoring before going to surgery, patients are more likely to accept wearing the filter line and do very well with postoperative monitoring.

## Clinical Practice

Hospital policy requires respiratory therapy to round on every PCA patient at least once every 12 hours. At each shift, the respiratory status of PCA patients is assessed by a therapist. The assessment includes an evaluation of the recorded trend analysis of RR, EtCO<sub>2</sub> waveforms, and any pulse oximetry results. Nurses consult respiratory therapists to assist with the assessment at any time during the shift when alarms indicate potential patient respiratory distress. Early identification of respiratory depression allows respiratory therapy to intervene before a patient's condition becomes serious, which saves time, helps increase the likelihood of a positive outcome, and allows existing staff to oversee more patients. If the nursing-respiratory team is unable to manage the patient or concludes that changes in medication, other therapy, or level of care may be necessary, the physician is contacted. The physician may change orders based on information provided and/or assess the patient at the bedside.

## Results

Since 2004 capnography monitoring for all patients receiving IV PCA opioid therapy has been required at SJ/C. As a result of the success of the monitoring process in patients receiving intravenous PCA, in 2006 the medical staff requested that capnography be implemented for patients receiving epidural PCA. This action was followed in subsequent years for patients receiving high-dose intermittent hydromorphone (>1 mg IV every 2 hours as needed) and for patients undergoing sedation in various types of invasive procedures. Figure 4 illustrates the distribution of PCA patient types over these years. During this period of time there

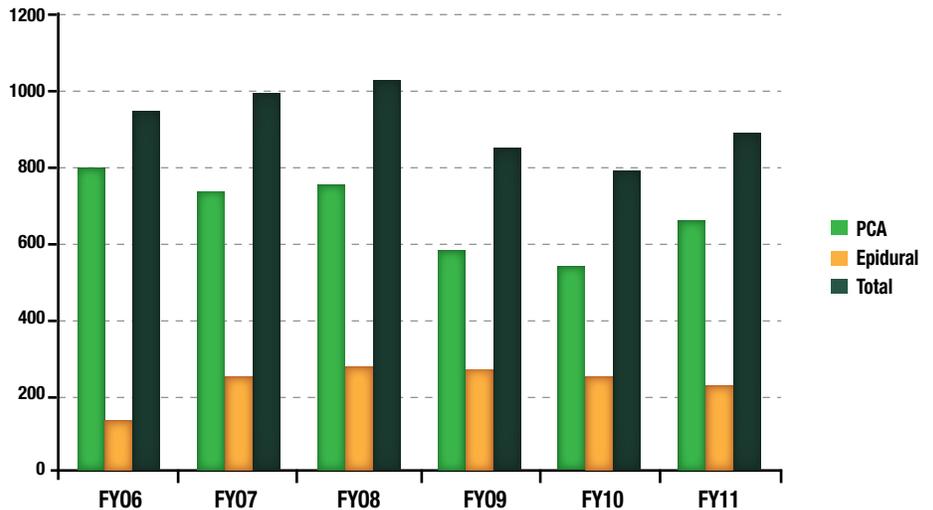


Figure 4. Volume of Patients: PCA & Epidural (n = 5,515)

Table 1. Examples of Programming Errors Averted After a Safety Alert Resulting in Avoidance of Adverse Medication Events Occurring between 2002 and 2007

Medication	Original Dose Programmed	New Dose Programmed After Safety Alert
Morphine PCA	30 mg/hr	1 mg/hr
Hydromorphone PCA	5mg PCA dose	0.5 mg PCA dose
Hydromorphone PCA	3 mg	1 mg
Fentanyl PCA	1 µg	50 µg

have been no PCA-related respiratory events with a serious outcome, i.e. no intubations, transfers to ICU, or deaths/brain damage in more than 5,000 patients receiving IV or epidural PCA. Additionally, none have occurred with monitored patients receiving hydromorphone via PCA or intermittent IV administration or patients receiving IV procedural sedation.

The monitoring system has alerted clinicians to the potential of declining respiratory function, and appropriate interventions have been made. We quickly discovered that the EtCO<sub>2</sub> alarm alerted nurses of respiratory depression as much as 2 hours earlier than the SpO<sub>2</sub> alarm did, especially in patients receiving supplemental oxygen. The concentration of EtCO<sub>2</sub> can rise even when a patient is breathing, if adequate air exchange / ventilation is not occurring, leading to CO<sub>2</sub> narcosis. As noted above, in the 2-year period immediately preceding the implementation of the capnographic monitoring system, 3 events with serious outcomes occurred in patients receiving PCA using traditional methods of monitoring—intermittent pulse oximetry and nursing assessments. Therefore, of the available alarm methods, the concentration of EtCO<sub>2</sub>

provided the earliest indicator of opioid-induced respiratory depression.

## Financial Return

There can be no adequate valuation of a life saved from preventing an adverse medication event. Nonetheless, it is important when possible to assess the potential of a new intervention to reduce the likelihood of serious outcomes and to determine the fiscal benefit of this reduction in the cost of health care. The decision in 2002 to replace the existing IV infusion pumps with “smart” modular IV safety systems, and then to add PCA, resulted in financial as well as patient safety benefits. A 5-year return on investment (ROI) was determined and previously reported.<sup>19</sup> This analysis evaluated the incremental cost of the intravenous safety system with PCA monitoring as compared to the cost of traditional infusion pumps. Disposable costs were also included in the analysis. Continuous quality improvement data accumulated in the system identified averted medication errors and PCA monitoring interventions.

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# Excellent Return on Investment with Capnography Monitoring

## From “Capnography,” Preceding Page

Over the 5-year period from 2002 to 2007, 558 expanded IV-safety systems helped avert 450 highest-risk IV medication errors (Table 1) and respiratory monitoring helped avert at least 35 PCA-related undesirable outcomes (Table 2), for a total of at least 471 preventable ADEs.<sup>19</sup> In 2006 the Institute of Medicine estimated the cost of managing a serious medication-related event to be \$8,750 per preventable ADE.<sup>20</sup> These errors, if not averted, would have resulted in potential expenses to SJ/C of \$3,970,296, not including potential litigation costs. Deducting the cost of averted outcomes/errors from the total purchase costs plus disposables yields a 5-year ROI of more than \$2.5 million.<sup>19</sup>

## Discussion

Clinical experience at SJ/C has confirmed that capnography monitoring is superior to SpO<sub>2</sub> monitoring in the detection of opioid-induced respiratory depression. In many cases, the capnography values were the only indicator of early onset of respiratory depression. Clinician assessments have been greatly enhanced with the availability of combined dosing and respiratory monitoring trend data, particularly for EtCO<sub>2</sub>. Nurses feel more comfortable in their ability to adequately manage patients' pain. The involvement of as many front-line clinicians as possible in the evaluation, selection and implementation of the new technology has been essential to successfully implementing and maintaining increased monitoring of patients receiving PCA therapy on the general care nursing units.

Our experience suggests that the use of capnography monitoring on ALL patients who receive PCA can reduce the incidence of adverse events from IV opioids in the postoperative setting. Selected patients should also receive continuous pulse oximetry monitoring. In the future it may be possible to more effectively utilize continuous electronic respiratory monitoring of postoperative patients. However, as the APSF has stated, maintaining the status quo while awaiting newer technology is not acceptable.

Health care providers involved in perioperative care need to fully appreciate the risk of drug-induced respiratory depression in patients receiving PCA therapy. Preventable deaths and anoxic brain injury from unrecognized opioid-related sedation and respiratory depression remain a serious and growing patient safety concern. The actions taken at SJ/C help mitigate these risks.

Based on this experience, we believe there is a pressing need for the anesthesia community to consider carefully the growing body of evidence and experience that points to capnography monitoring as providing the earliest indication of opioid-related respiratory depression.<sup>8,13-16</sup> Continuing research and development will undoubtedly lead to even better approaches to protecting the labile patients under our care. However, there is no need to wait. Careful use of the knowledge and technology we have now can do much to help realize the

Table 2. Avoidance of PCA-related Undesirable Outcomes: Examples

**Case 1 – Postop arthroplasty.** Patient awake but groggy according to nurse. EtCO<sub>2</sub> alarming. Further assessment indicated respiratory depression due to undiagnosed sleep apnea and opioid administration. PCA discontinued and patient placed on oral pain medications. Patient diagnosed with chronic sleep apnea exacerbated by obesity and opioid administration.

**Case 2 – Postop total hip.** Respiratory therapist giving treatment down the hall. Heard pump alarm. Responded and found patient with RR = 4 and EtCO<sub>2</sub> = 58. Patient was easily stimulated and encouraged to deep breathe. Patient on PCA demand but no doses of PCA had been administered. Determined to be respiratory depression associated with medications administered in surgery and post-anesthesia care unit (PACU).

**Case 3 – s/p subtotal colectomy.** Patient on hydromorphone PCA for severe pain. Patient transferred to a medical/surgical unit from critical care. Upon assessment, nurse noted respiratory rate of 9 and EtCO<sub>2</sub> of 47. MD contacted and continuous dose PCA was discontinued. Monitor values reset to increase sensitivity and earlier alarm after event. Pain was managed and patient improved.

vision that “No Patient Shall Be Harmed By Opioid-Induced Respiratory Depression.”

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Dr. Maddox discloses that he has received speaking honoraria from both CareFusion and Oridion; however he has no financial interest in either of these companies. Ms. Williams has no financial disclosures.

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# LIFEBOX: Promoting Patient Safety Around the World

Patient safety during anesthesia is a high priority in the western world, but it is an even more urgent issue in developing countries, where anesthesia-related mortality is often appallingly high. So many issues could be addressed in order to improve safety in resource-poor settings that it is hard to know where to begin. The availability of a pulse oximeter in every OR in the world would be a good start—and one program aims to do exactly that. The *Lifebox* program originated with several anesthesia organizations, and is supported by the WHO. It is described by some of the program initiators in the accompanying article.

## Lifebox

Reports of anesthesia and surgery practice in resource-poor parts of the world commonly include accounts describing shortages of personnel, equipment and drugs, limited access to surgical care, and patients who present late with high severity of disease.<sup>1</sup> Not surprisingly, outcomes from anesthesia in these settings are often poor—in some parts of the world, anesthesia-related mortality is 100- to 1000-fold greater than in the USA.<sup>2</sup>

What can clinicians from the UK and USA do to support our colleagues working under such difficult conditions? Clinicians from the USA have been involved in anesthesia outreach for many years and the ASA recently established the Committee on Global Humanitarian Outreach (GHO) to support the American Society of Anesthesiologists' vision of improving global anesthesia practice and outcomes. GHO encourages volunteerism, supports anesthesiology education and training in low-income settings, and advocates for long-term partnerships and collaborations between organizations with a common mission.

The World Health Organization (WHO) also has begun to consider the issue of surgery as a public health issue. Around 234 million operations are performed each year and these are associated with 1 million deaths and 7 million serious complications, half of which are likely to be preventable.<sup>3</sup> Under the leadership of Atul Gawande, MD, renowned surgeon, writer and public health researcher, the WHO developed the WHO Surgical Safety Checklist to help teams work more effectively together. When piloted in a variety of settings, the checklist resulted in a greater than 30% reduction in mortality and morbidity. Backed by these findings, it is being introduced as a routine measure in many countries.<sup>3</sup>

One of the requirements of the checklist is that a pulse oximeter be used during surgery. This simple, non-invasive monitor was introduced into practice in the early 1980s; it transformed the ability of anesthesia professionals to monitor their patients and quickly spread to every area of the hospital. Without doubt millions of lives have been saved due to the widespread introduction of pulse oximetry.

For colleagues working in developing countries the situation is very different. Many are working without access to pulse oximeters and are required to monitor their patients with a precordial stethoscope and a finger on the pulse. There are significant price barriers to the introduction of pulse oximeters, and (as is frequently the case in the developing world) difficulties in replacing components such as probes and

batteries often lead to a very short lifespan of the device. Recently it has been estimated that at least 70,000 operating rooms do not have a pulse oximeter,<sup>4</sup> but the overall need for oximeters in health care is much greater. All areas of the world where resources are in short supply are affected.

Recently Atul Gawande in partnership with the Association of Anaesthetists of Great Britain and Ireland (AAGBI), the World Federation of Societies of Anaesthesiologists (WFSA), and the Harvard School of Public Health formed a new charity, Lifebox ([www.lifebox.org](http://www.lifebox.org)), which aims to promote the use of the WHO Surgical Safety Checklist in developing countries and also to make available a good quality pulse oximeter for use in operating rooms anywhere in the world.

Following a tender by the WFSA, a contract was awarded to Acore Technology Limited Taiwan to supply a pulse oximeter that exceeds the WHO specifications and is particularly suited to the difficult conditions found in low-income settings. This oximeter can be purchased or donated via the Lifebox website and sent to any clinician or non-profit hospital in low- or low-middle income country for only \$250. Replacement probes are only \$25 and include a universal finger probe (for ages 1 year to adult) and reusable infant wrap-around finger probes. The oximeter is robust, high quality, battery- or mains-powered and has a monitor with an audible tone, waveform and adjustable alarms. (More details are available on the Lifebox website—all enquiries welcome!)

Lifebox works to ensure that pulse oximeters are only delivered to clinicians or hospitals that have completed appropriate screening. Our favored way to distribute pulse oximeters is to work through locally based clinical colleagues who will help us undertake training in the use of pulse oximetry and the WHO Surgical Safety Checklist. Additionally, local clinicians are often able to help with customs clearance and further distribution within the country.

In July 2011 the AAGBI donated 80 pulse oximeters to colleagues working in Uganda, and a team travelled from the UK to deliver the oximeters and provide checklist training at Mbarara University Teaching Hospital. The Lifebox team has been following up the students and oximeters, and we have been delighted to hear about the many critical incidents identified and lives saved with the device. The checklist also is proving useful where it is taken up, but there is more work needed on this, as is the case in our own hospitals!

Lifebox would welcome donations to purchase oximeters and also partnerships in hospitals in



countries where oximetry is not used. Our target is to ensure no patient undergoes anesthesia without a pulse oximeter, and no surgery is undertaken without the use of the WHO surgical checklist. This will bring us another step closer to fulfilling the APSF dictum that no patient shall be harmed by anesthesia. Can you help us?

*Dr Iain H Wilson*  
President AAGBI and Lifebox Trustee

*Dr Isabeau Walker*  
AAGBI Executive and Lifebox Trustee

*K A Kelly McQueen, MD, MPH*  
Chair, American Society of Anesthesiologists, Global Humanitarian Outreach

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# Anesthesia Patient Safety Foundation

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# APSF Grants 2012 Awards

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

The application process continues with an electronic, online submission format that was introduced in 2005. The applications, as well as all the required attachments, are uploaded to the new redesigned APSF website ([www.APSF.org](http://www.APSF.org)), a process that facilitates the application review by members of the Scientific Evaluation Committee, improves the timeliness of responses to queries, and facilitates transmission of reviewer feedback to the applicants. The Scientific Evaluation Committee members continue to modify and perfect the electronic application and review process.

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

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

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

contributor to anesthesia patient safety. It is the hope of the APSF that this award will inspire others toward her ideals and honor her memory.

For the year 2011 (projects to be funded starting January 1, 2012), 2 grants were selected for funding by the APSF Scientific Evaluation Committee (for names of committee members, please refer to the list in this issue). The APSF Scientific Evaluation Committee members were pleased to note that they reviewed a total of 17 applications in the first round, 8 of which were selected for final review at the American Society of Anesthesiologists’ (ASA) Annual Meeting in Chicago, IL. As in previous years, the grant submissions addressed areas of high priority in clinical anesthesia. The major goal of APSF funding is to stimulate the performance of studies that lead to prevention of mortality and morbidity due to anesthesia mishaps. A particular priority continues to be given to studies that address anesthetic problems in healthy patients, and to those studies that are broadly applicable and promise improved methods of patient safety with a defined and direct path to implementation into clinical care. Additionally, the APSF is encouraging the study of innovative methods of education and training to improve patient safety, and methods for the detection and prevention of medication errors.

The APSF Scientific Evaluation Committee convened during the ASA Annual Meeting on October 15, 2011, in Chicago for evaluation and final selection of the proposals. Of the 8 finalists, the members of the APSF Scientific Evaluation Committee selected the following applications:



**Jesse M. Ehrenfeld, MD, MPH**

*Assistant Professor of Anesthesiology and Biomedical Informatics, Vanderbilt University, Nashville, TN.*

Dr. Ehrenfeld’s Clinical Research submission is entitled *“Enhancing Perioperative Safety Through the Determination of Intraoperative Predictors of Post-Operative Deterioration.”*

**Background:** Post-surgical deterioration necessitating unanticipated ICU transfer is common and is associated with worse patient outcomes. Although the morbidity and mortality attributed to anesthesia is low, large numbers of patients experience adverse postoperative events in spite of the availability of advanced monitoring technologies. In fact, 7-27% of post-surgical and trauma patients have inpatient clinical deterioration that is specifically associated with adverse events and worse outcomes, including pulmonary complications, shock, cardiac failure, and hemorrhage. In a recent national survey of surgical Medicare inpatients with serious treatable complications, “failure-to-rescue” occurred in 9.6% of patients and was an independent predictor of death. Suboptimal management of airway, breathing, circulation, oxygen therapy and monitoring occurred in a majority of severely ill patients prior to their transfer to an intensive care unit (ICU). However, failure to rescue really consists of 3 parts: failure to anticipate [increased risk of deterioration], failure to detect [an evolving problem], and failure to treat. This proposal addresses the first of these elements required to prevent harm to post-surgical patients.

**Aims:** The overall goal is to identify intraoperative risk factors for clinical deterioration in the immediate postoperative period defined as transfer to an ICU within 48 hours of admission to a post-surgical floor after a surgical procedure. Relatively healthy, post-surgical and trauma patients continue to suffer potentially preventable adverse events, in spite of the availability of advanced monitoring technologies. The investigators hypothesize that certain intraoperative physiologic markers (e.g., heart rate variability, vasoactive drug use patterns) portend poor outcomes in the immediate postoperative period. Pilot data from Vanderbilt identified 422 surgical patients who were discharged from the PACU to a surgical floor, and then transferred to the ICU within 48 hours of their departure from the operating room (OR). These patients had a 50% increased relative risk of death at 30 days compared to a matched group of patients who did not have postoperative deterioration. Having previously validated a risk-stratification score for major complications or death within 30 days (the Surgical Apgar Score), the investigators now propose to identify risk factors for deterioration in the immediate postoperative period. This work is enabled by the availability of high-resolution physiologic data and new advanced pattern recognition algorithms.

**Implications:** A validated risk score will ultimately allow the investigators to: 1) identify patients who are at risk for postoperative deterioration; and 2) design and evaluate both intraoperative and postoperative interventions to decrease the incidence of postoperative deterioration and prevent harm to post-surgical patients.

**See “2012 Grants,” Next Page**

## APSF Grants 2012 Awards for Predictors of Postoperative Deterioration and Development of an Extubation Algorithm

### "2012 Grants," From Preceding Page

In addition to receiving the requested funding of \$149,357 for his project, Dr. Ehrenfeld's application was designated as the **APSF/Covidien Research Award**.

Dr. Ehrenfeld is also the recipient of **The Doctors' Company Foundation Ann S. Lofsky, MD Research Award**, which consists of an additional, unrestricted grant of \$5,000.



**Miriam M. Treggiari, MD, PhD, MPH**

Associate Professor, Department of Anesthesiology, Adjunct Associate Professor of Neurological Surgery and Epidemiology, University of Washington, Seattle, WA.

Dr. Treggiari's Clinical Research project is entitled "*Extubation Safety Quality Initiative Project, -ESQIP.*"

**Background:** Patient safety surrounding tracheal extubation represents an area for significant practice improvement in the intensive care unit (ICU). In a cohort study, the investigators have previously observed that nearly 20% of mechanically ventilated, critically ill patients required reintubation during their hospitalization, and the need for tracheal reintubation was associated with higher mortality, length of stay, and higher hospital costs compared with those patients who never required tracheal reintubation. While the occurrence of difficult intubation and airway-attributed complications were similar for initial and subsequent intubation, airway difficulty encountered during reintubation was associated with higher mortality. With appropriate planning, the majority of tracheal extubations can be carried out in a fashion that maximizes the safety of the procedure and prevents adverse events. Recently, the use of a pre-intubation checklist consisting of 10 bundle components significantly reduced the occurrence of cardiac arrest or death, severe cardiovascular collapse, and hypoxemia occurring within 60 minutes of emergency intubation in the ICU. The logical next step to improve the safety of tracheal extubation is to implement a planned extubation strategy in the context of a quality improvement initiative.

**Aims:** The purpose of this proposal is to determine if the use of a standardized airway management algorithm at the time of tracheal extubation reduces the occurrence of serious complications, improves

patient outcomes, and reduces the incremental cost incurred in the event of failed extubation.

**Implications:** Few recommendations are available on the approach to tracheal extubation in spite of the observed high frequency of potential complications. An important step in the understanding of these adverse events is to evaluate a systematic approach to tracheal extubation. This strategy has the potential to greatly improve airway management, resulting in improved patient outcome and safety.

In addition to receiving the requested funding of \$149,997 for the project, Dr. Treggiari's application was designated as the **APSF/American Society of Anesthesiologists (ASA) Endowed Research Award**, made possible by an unrestricted, \$150,000 grant from the American Society of Anesthesiologists.

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

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

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

## ANESTHESIA PATIENT SAFETY FOUNDATION (APSF) 2013 GRANT PROGRAM

*Announcing Guidelines for Grant Applications to be Selected on Saturday, October 13, 2012 (ASA Annual Meeting), and Scheduled for Funding Starting January 1, 2013*

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

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

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

### ANTICIPATED 2012-2013 NAMED AWARDS

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

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# Scientific Papers Address Patient Safety

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

Over 1,700 abstracts were presented at the 2011 American Society of Anesthesiologists annual meeting in Chicago, Illinois. As in previous years, a number of these abstracts examined issues directly related to patient safety. This brief review will highlight several abstracts discussed at the meeting.

## Patient Handover Communication



Mark et al. from the Durham VA Medical Center, North Carolina, performed a review of the literature on postoperative patient handovers (A1528). Twenty-three articles identified factors leading to poor handover communication, while also providing recommendations for improving the handover process. Some factors identified for ineffective handovers were poor teamwork and communication, patient instability on arrival, unclear procedures, technical errors, unstructured processes, interruptions and distractions, lack of central information repositories, and nurse inattention. Some of the broad recommendations included standardizing the transfer of care and training in team skills and communication. Bready et al. from UTHSC, San Antonio, Texas, devised an 18-element checklist and performed a process improvement study over a 4-month period. With education and implementation of the checklist, the rate of communication of essential elements improved from 50% at baseline to 98% post-implementation (A1530). Greulich et al. from UT Southwestern Medical Center in Dallas, Texas, designed a handoff checklist for patient transfers from the operating room to the intensive care unit (A1529). After a 20-week study period, the average provider satisfaction following implementation increased by 51% from baseline measures. The average time to complete the checklist was  $11 \pm 4$  minutes. Central line associated blood stream infections fell from 2.9/1000 catheter days to zero in the 5 months following implementation. Further studies are needed to investigate and identify best practices in postoperative patient handovers (A1528).

## Database Studies and Perioperative Complications

Several institutions utilized database information to examine factors that may be associated with perioperative complications. Mehta et al. from the University of Washington in Seattle reviewed 85 claims for cautery-related surgical fires from 7031 total surgical claims over a 23-year period. Cautery related fires increased from <1% in 1985-1994 to 4% of all surgical claims in 2000-2008. Ninety-six percent of fires occurred in high risk procedures (which were not defined by authors) and 84% of fires occurred during sedation (A1722). Investigators (A435) performed a cross-sectional study to identify cases of maternal cardiac arrest among admissions for delivery from 1994-2006 utilizing the Nationwide Inpatient Sample (NIS) of the Healthcare Cost and Utilization Project. Six hundred and ten women arrested during 7,503,155 admissions for delivery (an event rate = 1:12,300). Women who experienced an arrest had the following co-diagnoses in descending order of frequency: hypertensive disorders of pregnancy, postpartum hemorrhage, antepartum hemorrhage, amniotic fluid embolism (AFE), cardiomyopathy, anesthetic complications, sepsis, aspiration pneumonia, venous embolism, stroke, trauma, myocardial infarction (MI), pulmonary edema, magnesium toxicity, local anesthetic toxicity, status asthmaticus, anaphylactic shock, and vascular catastrophes. Cardiac arrest secondary to antepartum hemorrhage, MI, AFE, stroke, embolism, trauma or vascular catastrophe was associated with low survival rates (from 46 to 0%) (A435). Roth et al. (A716) from the University of Chicago, utilized the NIS database to examine trends in obstetric anesthesia complications in the US from 1993-2008. While the total number of pulmonary, cardiac, or CNS complications appeared to be decreasing (958 to 376), the number of diagnoses that were other or unspecified complications has increased significantly (4,159 to 16,138). The database did not identify the nature of these other or unspecified complications.

Another study (A415) examined closed claims associated with epidural and spinal anesthesia in non-obstetric surgical cases (1990-present). Of 6894 claims, 443 were associated with spinal or epidural anesthesia in the surgical setting. While most of the injuries were temporary (45%), 37% were associated with death and brain damage. Sixteen percent of injuries were associated with permanent nerve injury. The 4 most common causes for injury were block technique (primarily with nerve damage), neuraxial associated cardiac arrest, dural puncture, and high spinal epidural block. Sviggum et al. (A416) at the Mayo Clinic performed a retrospective cohort study to investigate whether peripheral nerve blocks for upper extremity joint surgery (UEJS) increased the risk of peripheral nerve injury (PNI). Out of 3044 patients who underwent UEJS, 53 cases of PNI were identified (1.7% incidence). A multivariate analysis suggested that peripheral nerve blockade was not

associated with PNI (OR=0.72; 95% CI 0.39 to 1.32). Those patients who developed PNI had complete neurologic recovery in 62% of cases, while 34% of cases experienced partial recovery.

Some authors investigated risk factors for reintubation, prolonged intubation, and postoperative respiratory complications. Investigators (A549) performed a case-controlled study to identify the incidence of tracheal reintubation and associated risk factors. The authors reviewed medical records of 58,854 anesthetic cases in a tertiary care hospital in Thailand over a 5-year period. The reintubation rate was 1.86 per 1000 intubations. Risk factors identified were height, preoperative anemia, preoperative hypoalbuminemia, preoperative hypokalemia, site of operation (airway and cardiac), non-official time (4:30 pm – 8:30 pm), operation time > 3 hours, and use of any muscle relaxants. Friedman et al. from New York Presbyterian-Columbia University Medical Center in New York, performed a retrospective study to identify risk factors for prolonged intubation (> 24 hours) after multi-level spine surgery (A1502). A multivariate analysis suggested that longer anesthetic times ( $677.8 \pm 102.5$ min) and more blood product administration ( $1799 \pm 1924.8$ cc) were associated with prolonged intubation times. Henneman et al. from the Massachusetts General Hospital reviewed 57,100 surgical cases requiring intubation during a 4.5 year period to investigate whether neuromuscular blockade (NMBA) is associated with adverse postoperative respiratory events. Results suggested that NMBA was associated with an increased risk of hypoxic events after extubation (OR-1.49 95% CI: 1.36-1.62), and an increased risk of reintubation/unplanned ICU admission (OR-2.12 95% CI: 1.71-2.63). The use of neostigmine was independently associated with an increase in hypoxic events (OR-1.09 95% CI: 0.98-1.21). Neuromuscular monitoring was documented in only 50% of patients receiving intermediate-acting NMBA (A437). The relationship between anesthesia time and risk for postoperative pulmonary complications (PPC) in patients undergoing general anesthesia for orthopedic surgery was examined in abstract #1498. Out of 162,247 discharges, 8,966 patients developed a PPC (5.53%). This study suggested that a 15-minute interval increase in anesthesia time was associated with an 8% increased risk of PPC, a \$974 increase in average total hospital cost and 3.1 hours in mean total length of stay.

Rohrbaugh et al. from the University of Pittsburgh (A235) examined 13,512 cases of shoulder surgery in the beach-chair position (99% performed under interscalene block and propofol sedation) over a 9.5-year period. The authors identified 37 total adverse events. All of these events were rare (occurred in < 0.07% of cases) and included emergency airway intubation, acute respiratory distress without need for intubation, seizures, persistent nerve injury, CNS injury (or stroke within 24 hours of surgery), cognitive dysfunction, headache,

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# Topics Include “Triple-Low” and Postoperative Delirium

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myocardial infarction, dysrhythmia, hypotension, drug reaction, or unexpected admission. Investigators examined 136,371 moderate-high risk surgical patients over a 5-year period to determine whether postoperative troponin I values predict 30-day in-hospital mortality (A1578). Among 9516 cases where troponin I levels were measured, 912 patients had troponin elevations. Approximately 80% of troponin I elevations occurred during the first 3 postoperative days. Forty-two percent of all deaths were associated with elevations in troponin levels.

Gan et al. from Duke University Medical Center performed a retrospective database study of 18,961 non-cardiac surgical procedures to investigate whether “Triple Low,” (low bispectral index (BIS), low mean arterial pressure (MAP), and low anesthetic concentration) increases postoperative mortality (A1574). The authors suggested that the “triple low” combination was associated with a 2.5-times increased risk of 1-year mortality compared to those patients with normal values. Investigators (A003) reported patient experiences with awareness who had general anesthesia and those that had not received general anesthesia (GA). Among 183 patients who had enrolled in the Registry with awareness experiences from 1990 or later, most respondents had psychological sequelae related to awareness regardless of anesthetic type (88% receiving GA, 65% receiving non-GA). Patients in both the non-GA and GA groups reported paralysis even when the medical records indicated that neuromuscular blockade was not given. The authors suggest that improved communication and education may help patients who are not receiving GA understand that some degree of patient awareness should be expected. Bhavani et al. (A1024) at the Cleveland Clinic performed a retrospective review of all patients undergoing spine surgery from 1995-2010 at their institution to identify the incidence and associated risk factors for postoperative visual loss. Out of 2532 potential controls, 6 cases of visual loss were identified. Cases with visual loss had a significantly greater blood loss ( $P=0.002$ ) and a greater amount of red blood cells transfused ( $P=0.006$ ). No other intraoperative risk factors were identified.

## Postoperative Delirium

Several abstracts this year addressed the incidence of and associated risk factors for the

development of postoperative delirium (POD) and cognitive dysfunction (POCD). Investigators (A1617) utilized a large database of inpatient surgical discharges (Premier Perspective Database®) to examine the incidence, risk factors, and cost related to postoperative cognitive complications (POCC). Of 1,043,647 inpatient surgical discharges, 1% of the patients had a diagnosis of POCC. Episodes of POCC were associated with a significant increase in hospital mortality, mean total cost, and mean length of stay. The risk of developing POCC was associated with male gender, Caucasian, diseases of the Charlson comorbidity index, emergency admissions, ICU stay, and general anesthesia. Brewbaker et al. from Wake Forest University School of Medicine performed a retrospective study to determine the prevalence of postoperative delirium (POD) among patients undergoing hip fracture repair. Out of the 72 patients included in the review, 22 patients (30.6%) showed strong evidence of POD (A1527). Abstract #1497 evaluated the influence of delirium on mortality and quality of life 6 months after carotid endarterectomy. This prospective observational study evaluated 70 patients admitted to the post-anesthesia care unit; delirium was assessed using the Intensive Care Delirium Screening Checklist (ICDSC). Seventeen percent of the patients developed POD. Mortality rates at 6 months were higher for patients with POD (25% vs. 3%,  $p=0.023$ ). However, POD did not influence quality of life at 6 months after surgery. Wagner et al. from Vanderbilt University examined 200 consecutive patients from the Cardiovascular Intensive Care Unit (CVICU) to determine the prevalence and risk factors associated with the development of delirium. The overall prevalence of delirium was 26%. The duration of delirium was  $0.5 \pm 1.1$  days. Risk factors associated with an increase rate of delirium included use of statins, dexmedetomidine, benzodiazepines, and physical restraints (A088). Another study investigated the incidence and risk factors related to POD (A083). Out of 775 adult patients admitted to the post-anesthesia care unit (PACU), 128 patients developed POD (18.9%). Patients with delirium were more severely ill, had longer hospital and PACU stays, and had higher mortality rates. Independent risk factors for delirium included age, ASA physical status, emergency surgery, and the total amount of FFP administered during surgery (A083).

Chapman et al. (A1516) from Duke University performed a prospective study of 1274 patients undergoing non-cardiac surgery to determine whether obstructive sleep apnea (OSA) predisposes patients to postoperative cognitive dysfunction (POCD). The incidence of POCD in this study was 35%. A multivariate analysis suggested that age > 50 years old was a predictor of POCD at hospital discharge and 3 months after surgery. A BMI > 35 was also a predictor of POCD at one week. Subjects who had a positive STOP-Bang questionnaire (suggestive of those with OSA) had higher 1-year mortality. However, the study could not definitively conclude whether there was an association between OSA and POCD. Behrends et al. from UCSF in San Francisco,

California, utilized an internal database in older patients undergoing major non-cardiac surgery to determine whether blood transfusion was associated with early POD in the elderly (A1090). Of 577 patients examined for POD on postoperative day 1, 31.9% developed POD. A multivariate regression analysis suggested that age and blood transfusion were independent risk factors for early POD in older patients. Larger amounts of transfusion were associated with a further increase in the risk of developing early POD.

## Use of Etomidate & Outcomes

Sunshine et al. from the University of Washington performed a retrospective study involving 824 mechanically ventilated patients to determine whether etomidate administration is associated with an increase risk of hospital mortality in the critically ill (A089). After adjusting for age, gender, simplified acute physiology score (SAPS II), the relative risk (RR) of death among etomidate recipients was 20% higher than that of patients given an alternative agent. Another study (A638) analyzed 329 postoperative cardiac surgical patients who had a cortisol level and/or corticotrophin (ACTH stimulation test) drawn during a 2-year period. Adrenal insufficiency occurred in 43.4% of patients, and etomidate was given to 57% of the patients. Etomidate use was associated with a significant increased risk of adrenal insufficiency (53.7% of recipients vs. 29.4% of non-recipients). In a multivariate analysis, etomidate was the only independent risk factor for developing adrenal insufficiency (OR-3.05).

## Obstructive Sleep Apnea (OSA)

Several abstracts investigated perioperative issues facing patients with OSA or at risk for OSA. Sharma et al. (A1501) from the University of Buffalo, New York, reviewed 3,593 patients undergoing surgery under general anesthesia and indentified 306 patients who were at high risk for OSA (HR-OSA). During the postoperative period, HR-OSA patients had a higher incidence of hypoxia, reintubation, and postoperative use of CPAP. This group also had a longer PACU/ hospital length of stay and had an increase in overall postoperative complications. Mehta et al. from the Toronto Western Hospital, (A223) performed a systematic review of the literature to define the incidence of postoperative complications in patients with OSA versus those without the disease. Of the 12 studies selected, 10 reported significantly higher postoperative complications in OSA patients than those without OSA. Mehta et al. also performed a retrospective study to determine the long-term health benefits of screening patients for OSA in a preoperative clinic (A038). The investigators contacted 156 patients, and 82% of these patients had OSA established by polysomnography. Sixty-nine percent of these patients were prescribed continuous positive airway pressure (CPAP), but only 45% of these patients were compliant with using CPAP. The CPAP compliant patients had a greater reduction in medication dosage for

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# Patient Safety Themes Stand Out in ASA Meeting Exhibits

by John H. Eichhorn, MD

Both the Scientific and the Technical Exhibits at the October American Society of Anesthesiologists (ASA) Annual Meeting in Chicago featured anesthesia patient safety as a significant component theme. The scheduling of the exhibits at the meeting reflected the new ASA meeting compressed format in that the Exhibits opened Saturday, October 15, at 11 am and closed Monday, October 17, at 3 pm. New and recurrent patient safety concerns were presented throughout the Exhibits along with proposed technical and educational safety improvement strategies.

## Widespread Scientific Safety Subjects

In the Scientific Exhibits, safety-related topics varied widely, from some with the greatest impact to others that might appear somewhat mundane, but that still represent everyday hazards persisting as threats to patients. Also, high-fidelity simulation was featured as an integral part of more exhibits than ever before.

Several exhibits displayed educational programs aimed at anesthesia professionals and intended to improve patient outcomes, such as in caring for morbidly obese patients or children with congenital vascular or lymphatic malformations of the head and neck causing difficult airway situations. Likewise, there was emphasis on practitioners learning to use ultrasound guidance for initiating regional anesthesia, either for placing neuraxial blocks in one exhibit or thoracic paravertebral blocks in another.

One educational exhibit from the University of Florida featured 2 newly developed simulators—one for skin prepping and the other for central venous

catheter (CVC) placement. The CVC simulator was stimulated by a “learning need” demonstrated by an above-average incidence of pneumothorax as a complication of CVC placement. The device has a 3-D component on the monitor screen showing strikingly realistic neck/chest anatomy that incorporates the same type of technology that puts the yellow first-down stripe on the TV image of a football field. The practice needle the student inserts into the mannequin has a sensor on the tip with 6 degrees of freedom so it is mapped in 3-D space by what is essentially radar inside the mannequin, and the needle is shown on the monitor screen passing through the realistic depiction of the internal anatomy. The screen can be moved so only the instructor can see where the needle is going, or turned so the student can also see and correlate tactile with visual senses. Further, the software allows modifications of the anatomy, such as depicting a very obese patient. Another exhibit, from Japan, featured a “knowledge simulator” with dramatic 3-D video images (requiring battery-powered glasses) of relevant anatomy, such as for a brachial plexus block.

Airway management issues, as always, were featured prominently. A technique for nasal intubation using a bougie through the nose and a video laryngoscope in the mouth was demonstrated. A new technique for topicalization of an airway in preparation for awake intubation utilizing a fiberoptic bronchoscope involved a “mucosal atomizing device” that was offered for trial on willing exhibit visitors. A review and update of Rush University’s formal resident training program in advanced airway management was offered at a well-attended exhibit booth. A recurrent Cleveland Clinic exhibit on airway innovation featured a new version of their oral airway

design with continuous suction capability, intended to reduce aspiration danger. Also, repeated from last year was the sealed sterile plastic sheath (with both a lens and a suction port orifice at the distal end) that fits over a fiberoptic bronchoscope with the intention of keeping it sterile inside the sheath during use – thus reducing the time involved in turning over the scope between uses, which is intended to increase dramatically the availability of this critical tool.

An exhibit from the University of Pittsburgh addressed the risk of bleeding complications from placing peripheral nerve blocks in patients receiving thromboprophylaxis. Over a period of 9 years, more than 15,000 blocks were placed without observation of any significant bleeding complications.

An excellent example of high-fidelity simulation was exhibited in a presentation from Johns Hopkins that recreated a remarkably dramatic explosive airway fire that can occur when a surgeon uses an electrocautery to incise a trachea containing 100% oxygen.

Safe medication practices in the OR were emphasized in an exhibit from Emory University regarding breaches in correct techniques of safe medication utilization involving, for example, sterility of IV medications and also the reuse of “single-use” vials allegedly to reduce cost, waste, and environmental burden. Results of an anonymous survey about exactly what anesthesia professionals really do in the operating room in day-to-day practice were cited as the stimulus demonstrating the need for the teachings in this exhibit.

An intriguing dual-purpose exhibit from Boston Medical Center was awarded the APSF’s E.C. Pierce, Jr., MD, Award for the best safety-themed Scientific Exhibit. The presenters created a simple sensor with a force transducer that is intended to demonstrate with “stop-light” type signals in real time that cricoid pressure is being performed correctly. In addition, the exhibit was offered as a demonstration of how it is possible to use readily available inexpensive resources to facilitate the translation of a clinical idea for new technology into a working prototype of an invention, thus encouraging more innovation in biomedical devices.

## Safety Spirit Also Shines on Technical Side

In the Technical (commercial) Exhibits at the ASA meeting, both the usual presentations as well as a few new displays with patient safety implications were exhibited.

As customary, airway management and safety issues were prominent in the displays. (As often stated in this report, the induction of deep unconsciousness and muscle relaxation before genuine confirmation that a patient’s airway can be comfortably managed and accessed is still [even with all the recent attention and device development] one of the least



Members of the APSF award the Ellison C. (“Jeep”) Pierce Best Scientific Exhibit in Patient Safety at the ASA meeting on Sunday, October 16th, 2011 in Chicago, IL. Photo displays award recipients Christopher Connor, MD, PhD and Eddy Feliz, MD from Boston Medical Center, Boston, MA. Also pictured are: Robert Stoelting, MD, APSF President, and APSF Education Committee members Maria Magro, CRNA; Richard Prielipp, M.D., FCCM; Tricia Meyer, PharmD; Deb Lawson, Certified Anesthesiologist Assistant. The authors developed a simple electronic prototype device to assist in accurate performance during application of cricoid pressure for clinical practice and learning during simulation of Rapid Sequence Intubation (RSI).

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## New Airway Devices, Improved CO<sub>2</sub> Absorbent, Capnography Monitors, Medication Safety, and Simulators Focus of Patient Safety Exhibits

### “Exhibits,” From Preceding Page

improved and most dangerous things anesthesia professionals do.) Video laryngoscopes have proliferated greatly and were featured prominently throughout the exhibit hall with heavy promotions. There were many varieties of sizes and shapes, and also models having several different placements for the new improved-resolution video screens. A large assortment of blades was available, including sets with bright color coding for different sizes. In another exhibit, a new version of standard blades for direct laryngoscopy was promoted as significantly improving the operator's view of the larynx as the blade has 2 different bulbs, an L.E.D. bright white light and a separate UV light. In photographs and the exhibit demonstration, this combination of lights gave clearer, more nuanced visualizations with greater detail and no incandescent glare. A new design of laryngeal mask airway was shown that does not have an inflatable cuff, but rather a circumferential outer edge made of a soft gel-like substance that is meant to conform easily to the pharyngeal wall. Another exhibit again featured laryngeal mask devices with pressure indicators incorporated on the cuff pilot tube to help prevent excessive pressure on the pharyngeal wall that could conceivably cause structural damage of several types.

A genuine advance in “airway” devices was a new type of Magill forceps manufactured by a small Florida company. This instrument has unique features. The arms open in a vertical rather than horizontal axis, and there are no traditional jaws at the distal end (the ones with the sharp serrated edges that often puncture an endotracheal tube cuff during nasal intubations). Rather, there is a metal ring that separates into top and bottom semicircles, allowing the operator to grasp the tube tip firmly and easily with no danger to the cuff and guide the tube into the larynx.

Another new airway tool that has potential special application in ICU patients intubated for extended periods, as well as for acute patients in the OR, was a special catheter intended to clean out the lumen of an endotracheal tube with an inflatable cuff that has an action analogous to that of a Fogarty catheter pulling out a clot from a clogged artery. This could relieve an acute obstruction from a mucus plug or simply clean out accumulated intraluminal secretions that are reducing airway compliance. The periodic prophylactic removal of “biofilm” inside the tube is suggested by the manufacturer to help prevent ventilator-associated pneumonia in ICU patients.

A new exhibit featured a different type of CO<sub>2</sub> adsorbent that is not pebble-like granules of the traditional chemicals but, rather, is a solid lithium-based micropore cartridge that is fitted inside the standard absorber head where the granules usually go. It was claimed that this type of device does not absorb volatile anesthetic gases as the granules do, thus reducing

total agent use and also promoting significantly faster wash-in and wash-out of inhalation anesthetics. The claim was that this cartridge is much slower to desiccate (reducing the potential for Monday-morning carbon monoxide production) and has much less potential for toxic compound A production. The used cartridges are intended for return to the manufacturer for recycling and reuse in making more cartridges.

With all the recent emphasis from the APSF and other groups on the dangers of narcotic-induced post-operative hypoventilation/respiratory depression, it is logical that manufacturers responded with special efforts to highlight monitoring products designed to detect problems and sound an alarm before patient injury occurs. Several versions of face-mounted sampling devices for expired CO<sub>2</sub> detection were shown, including an update of the original dual nasal/oral sampling cannula with an appendage that looks like a small spoon hanging down over and in front of the patient's mouth to capture mouth-breathing expired CO<sub>2</sub>. A version of the traditional “venti-mask” O<sub>2</sub> face mask now includes an internal catheter sticking down into the inside of the mask that connects to the capnograph sampling line. Another type of approach was an acoustic sensor that is affixed to the neck to “listen” for the rate and qualities of inspiratory sounds that can be automatically analyzed to diagnose central and/or obstructive hypoventilation. A corollary in another exhibit was a bite block intended for use in upper GI endoscopy that now includes both a port for supplemental O<sub>2</sub> insufflation and another port for capnographic sampling for ventilation monitoring.

Medication safety in the OR was touted by the various exhibitors of premixed IV medications and also of various labeling systems, including those that will automatically read the barcode on a medication ampule/vial and then print an appropriate label (including date, time, and operator) on the small printer affixed to the side of the anesthesia machine that can be immediately applied to the just-filled syringe of that medication.

The various devices that use infrared light to outline subcutaneous veins so as to facilitate intravenous cannulation have evolved with more configurations, including hand-held, floor-standing, and side-mounted varieties. One model has an “inverse” mode that is intended to illuminate veins below skin of darker colors.

The panoply of other displays that were offered by multiple manufacturers as promoting patient safety included several types of products that have been presented previously, including ultrasound devices for both vascular access and nerve block placement, infusion pumps with new algorithms and “safer” programming protocols, patient warming devices (particularly this year more fluid warmers), various

temperature monitoring techniques (including for brain temperature), and, of course, information management systems that both create highly legible anesthesia records that are more defensible if challenged and also capture maximum demographic and financial information intended to enhance practice revenue generation.

Finally, one of the great bright spots of the Technical Exhibits was the proliferation of high-fidelity simulators of various shapes and sizes intended to teach and help perfect techniques in a multitude of anesthesia procedures. Complementing the familiar mannequin simulators was the addition of several new “virtual reality” type computer-based simulators, particularly ones offering training in placement of regional anesthesia blocks, in some ways similar to at least the idea of the simulator described above in the Scientific Exhibits that teaches CVC placement. It certainly was interesting to walk down an exhibit aisle and see an attendee with a large elaborate video visor on gesturing into thin air (including sometimes extensive “body English”) with the motions of performing a regional anesthetic. Perhaps this is a harbinger of things to come.

Overall, patient safety persisted as a distinct focus among both types of exhibits at the 2011 ASA Annual Meeting. This emphasizes both continued success in improving anesthesia patient safety and also the significant challenges yet remaining.



Dr. John H. Eichhorn, Professor of Anesthesiology at the University of Kentucky, Founder of the APSF Newsletter (Editor until 2002), and Consultant to the APSF Executive Committee, shakes hands with the Opening Session speaker for Anesthesiology 2011, Dr. Atul Gawande. Dr. Gawande is an Associate Professor, Harvard School of Public Health, and Associate Professor of Surgery, Harvard Medical School, and New York Times best-selling author of numerous books on improving patient safety.

## Letter to the Editor

# Propofol (Diprivan®) and Clevidipine (Cleviprex®) and Potential Look-Alike Concern

### To The Editor:

CRNA Duerr-Trebilcock points out that all that is white is not necessarily propofol (*APSF Newsletter*, Fall 2011). The pretender in question is the surgical lubricant Rotaglide®. However, a much more potentially dangerous pretender is clevidipine (Cleviprex®). Since clevidipine, a calcium channel antihypertensive, is, like propofol, formulated in a lipid emulsion, it too appears milky white (Figure 1). Since it is a potent antihypertensive, clevidipine is much more likely to be in a hospital formulary and perhaps find its way into the operating room or other procedural areas. This potential danger was initially brought to the attention of Veteran Affairs Hospitals by the VA National Pharmacy Benefits Management Services (PBM) in 2009. I believe the medical profession in general should be made aware of this as well.

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Figure 1

A photo of a typical propofol vial (above) and photos of Cleviprex (below).



Department of Veterans Affairs Veteran Health Administration (VHA)  
Pharmacy Benefits Management Services (PBM) & Medical Advisory Panel (MAP)  
VA Center for Medication Safety (VAMedSAFE)

## NATIONAL PBM COMMUNICATION · April 30, 2009

### *Propofol (Diprivan®) and Clevidipine (Cleviprex®) and Potential Look-Alike Concern*

- Propofol (Diprivan®) is an intravenous (IV) sedative agent used in the induction and maintenance of general anesthesia, monitored anesthesia care sedation, procedural sedation, and sedation for mechanical ventilation (See Figure 1).
- Clevidipine (Cleviprex®) is an IV calcium-channel blocker used to treat peri-operative hypertension as well as acute, severe hypertension (See Figure 2).
- Both are milky white solutions that are infused intravenously.
- Both are available in small glass bottles and used in the intensive care unit (ICU)/operating room (OR)/emergency department (ED) settings.
- Due to the above similarities, a concern of potential “look-alike” confusion between the 2 products has been raised.
- Patients may be at risk for suffering significant harm due to the acute situation(s) in which the patient would be receiving these medications.
  - Unsuccessful sedation resulting in rapid awakening, as well as anxiety, agitation, and resistance to mechanical ventilation could result if a patient did not receive their intended dose of propofol. If a patient receives propofol instead of clevidipine without a protected airway, the patient could suffer from respiratory depression or arrest.
  - Uncontrolled blood pressure could result if a patient did not receive their intended dose of clevidipine. If a patient receives clevidipine instead of propofol without an elevated blood pressure, hypotension could result.
- Staff must be informed of potential look-alike confusion between Propofol and Clevidipine (Cleviprex®).
- Pharmacy must store Propofol (Diprivan®) and Clevidipine (Cleviprex®) in separate areas in the pharmacy. [Clevidipine (Cleviprex®) vials should be refrigerated at 2-8°C (36-46°F). Vials in cartons may be stored at temperatures up to 25°C (77°F) for no greater than 2 months.<sup>1</sup> Propofol (Diprivan®) should be stored between 4-22°C (40-72°F).<sup>2</sup>]
- Pharmacy must create a warning system for staff to notify of potential look-alike confusion between Propofol and Clevidipine (Cleviprex®) (e.g., computer alerts during the ordering/verifying process and/or warning stickers on packaging).
- Drug/syringe used must be verified with the name of the drug on the prescription.

### References

1. Cleviprex package insert. Parsippany, NJ: The Medicines Company; 2008 Aug.
2. Diprivan package insert. Wilmington, DE: AstraZeneca; 2005 Aug.

### Actions:

**Facility COS:** Forward this document to all appropriate providers who prescribe/use/handle this agent (e.g., providers, nurses and technicians who work in the ICU/OR/ED settings, including contract providers, etc.). In addition, forward to the Associate Chief of Staff (ACOS) for Research and Development (R&D). Forward to other VA employees as deemed appropriate. Report completion of actions to the Facility Director.

**ACOS for R&D:** Forward this document to Principal Investigators (PIs) who have authority to practice at the facility and to your respective Institutional Review Board (IRB).

## Scientific Papers Explore Fluid Loading for PONV Prophylaxis and Risks of OSA, Preoperative Elevated Hgb A1C, and Smoking Cessation

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comorbidities than the non-compliant group. Eight percent of the study population had long-term health benefits from OSA screening and compliance with CPAP (A038). Abstract A224 investigated whether postoperative oxygen therapy can improve oxygen saturation without worsening OSA. Out of 168 patients, 58% were on oxygen therapy on the first postoperative night. Compared with those without O<sub>2</sub> therapy, those that had oxygen applied had a significantly higher SpO<sub>2</sub> and a lower oxygen desaturation index. Those patients who had oxygen therapy also experienced a lower time percentage with SPO<sub>2</sub> < 90% (CT90). However, the average duration of apnea/hypopnea episodes was longer in the patients who had O<sub>2</sub> therapy.

### Miscellaneous

Kawashima et al. (A186) from Wakayama Medical University in Japan performed a systematic review to investigate the anti-emetic effect of perioperative fluid loading on postoperative nausea and vomiting (PONV). Eight randomized controlled studies (851 patients) were selected. Results suggested that perioperative fluid loading of crystalloids (1000 ml or more) improved PONV (OR-0.48) and reduced the use of anti-emetics when compared with control groups. Subramaniam et al. (A787) from the Beth Israel Deaconess Medical Center in Boston, MA, enrolled 986 patients undergoing cardiac surgery in a prospective observational trial to investigate whether a preoperative hemoglobin A1C (HbA1C) level may be associated with postoperative glycemic variability and adverse outcomes. A multivariate analysis suggested that the HbA1C  $\geq$  6.5 gm/dl was associated with a higher risk of perioperative complications (OR-1.7). Glycemic variability was also significantly greater in the HbA1C  $\geq$  6.5 gm/dl. Lastly, Abrishami et al. from the University of Toronto, performed a meta-analysis to determine the minimal period of smoking cessation before surgery that could reduce postoperative pulmonary complications (PPC)

(A227). While 62 articles were analyzed, only 13 papers (15,297 patients) reported results on different times of smoking cessation. Results suggested that short-term smoking cessation prior to surgery (2-4 weeks) was not associated with an increased risk of PPC when compared to current smokers. However, smoking cessation for > 4 or 8 weeks was associated with a 23-47% decreased risk

This brief review summarized only a small number of abstracts on patient safety presented at the 2011 Annual Meeting. This is not an endorsement of the methods, results, or conclusions of any particular abstract. To view other abstracts on patient safety, or to obtain further information on the abstracts discussed in this review, please visit the Anesthesiology website at [www.anesthesiology.org](http://www.anesthesiology.org).

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### Letter to the Editor

## Reader Stresses Use of Multimodal Analgesia to Decrease Risk of Opioid-Induced Respiratory Depression

### To The Editor:

We read with interest the article covering the Proceedings of the “Essential Monitoring Strategies to Detect Clinically Significant Drug-Induced Respiratory Depression in the Postoperative Period” Conference, published in the Fall 2011 *APSF Newsletter*. We agree that prevention of opioid-induced respiratory depression (OIRD) is an unmet medical need and an ongoing national patient safety issue. We commend strategies outlined in the conference; however, we are concerned that the focus to prevent OIRD is too heavily weighted on monitoring. There was limited mention of techniques to minimize or avoid the use of opioids by utilizing multimodal treatment protocols. We write this letter to remind our colleagues of the importance of multimodal treatment modalities to prevent OIRD.

Monitoring of adequate oxygenation and ventilation is the cornerstone of OIRD detection and timely treatment. However, the limitation of monitoring is that it may not prevent the problem. In keeping with Benjamin Franklin's old adage, “An ounce of prevention is worth a pound of cure,” we believe that more emphasis should be directed toward opioid-minimizing strategies and multimodal therapies. Utilizing opioid-sparing drugs as part of multimodal pain management and administering the smallest opioid dose necessary are key to OIRD prevention.<sup>1,2</sup> There are several non-opioid therapies that can reduce the amount of opioids consumed and therefore decrease opioid-related adverse events.<sup>3</sup> Several new non-opioid therapeutics have recently been FDA-approved including intravenous acetaminophen (Ofirmev<sup>TM</sup>), intravenous ibuprofen (Caldolor<sup>®</sup>), diclofenac liquid capsules (Zipsor

<sup>®</sup>), nasal ketorolac (Sprix<sup>®</sup>), and DepoFoam<sup>®</sup> bupivacaine (EXPAREL<sup>TM</sup>), a long-acting local anesthetic with analgesic effects up to 72 hours, that should be considered for perioperative treatment to reduce opioid use.

In summary, we believe that multimodal opioid-sparing or minimizing strategies should not be forgotten, and emphasized alongside adequate monitoring as key strategies in the prevention of OIRD.

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Disclosure: Dr. Marwah has received consulting fees and has stock options in Pacira Pharmaceuticals, the manufacturer of EXPAREL, which is mentioned in his letter.

# Reducing Risk of Epidural-Intravenous Misconnections

Michael Block, MD, Russell J. Horn, MD, Mark D. Schlesinger, MD

*Disclosure: The Department of Anesthesiology, Hackensack University Medical Center, Hackensack, NJ, received an educational grant from Smiths Medical, Inc., for participation in the clinical trial of the CorrectInject® system, which is currently under 510(k) review.*

## Background

Medication errors are leading causes of preventable harm in hospitals.<sup>1</sup> Device misconnections leading to wrong route medication administration have attracted worldwide attention in patient safety.<sup>2</sup> These incidents are believed to occur more frequently than reported since visible harm (which drives reporting) does not always result.<sup>3</sup> Nevertheless, reports in the medical and lay press<sup>4</sup> highlight that wrong route medication errors persist despite mitigation efforts and have catastrophic consequences in a broad range of clinical settings.

The Joint Commission's Sentinel Event Alert Number 36 (April 2006), cites 9 cases of tubing misconnections involving 7 adults and 2 infants. Deaths occurred in 8 of these instances and 1 resulted in permanent loss of function.<sup>3</sup> The Institute for Safe Medication Practices (ISMP) reports numerous misconnection errors between peripheral and central venous infusion routes, neuraxial routes (epidural and spinal), enteral feeds, and bladder irrigation systems.<sup>5</sup> Since 1985, 13 cases of inadvertent intrathecal administration of intravenous vincristine have been reported in the United Kingdom (U.K.) resulting in 10 deaths and 3 cases of permanent paralysis.<sup>6</sup> Misconnections involving accessory devices such as tubing used for noninvasive blood pressure cuffs, oxygen delivery and sequential compression devices are described as well.<sup>7</sup> The US Pharmacopeia, the largest information source of tube misconnection related errors, has received 1600 reports of epidural to central or peripheral intravenous misconnections since 1999.<sup>8</sup>

In the Labor and Delivery setting, recurring injuries and deaths due to epidural intravenous misconnections have been reported in the United States (U.S.) and United Kingdom (U.K.). In one article, 2 cases of intravenous magnesium sulfate infusions inadvertently administered epidurally within 2 months are reported.<sup>9</sup> In another high profile case report, maternal death resulted from the accidental spiking and infusion of an epidural solution (mistaken for an antibiotic) into an intravenous line of a patient that did not have an epidural at the time.<sup>10</sup> These traumatic errors have also led to career ending disciplinary action against providers, loss of reputation for hospitals, and growing public distrust of the health care system.<sup>10</sup>

The universal presence of Luer connection systems in functionally different types of medical equipment is the leading common root cause of misconnection/wrong route administration incidents. Originally designed for attaching hypodermic needles and syringes, these traditionally inexpensive and easy to use

[push (slip) or screw (lock)] male-female configurations enable the direct connection of unrelated medical devices. In other words, "If it *can* happen, it *will* happen."<sup>3</sup> A single patient may interface with up to 40 Luer-containing devices during a hospitalization.<sup>7</sup> Concern has risen for Labor and Delivery units since medications are concurrently administered to the same patient by physicians (anesthesiologists) and nurses at separate points in care. To date, interventions predominantly aimed at modifying clinicians' practices (policy changes, re-education, dual signatures, equipment relocation, enhanced labeling) have been implemented in response to misconnection incidents. Patient safety experts regard the effectiveness of these interventions in preventing harm as "weak."<sup>8</sup> Furthermore, these changes potentially undermine efficiency without added safety benefits (prevention of harm) and may contribute to hazardous workarounds. Equipment redesign such as the installation of Luer-incompatible fittings on epidural administration components (syringes, catheter adapters, bacterial filters, infusion tubing, reservoir hubs) has been widely advocated by patient safety experts as a "strong" intervention. In 2002 Lanigan outlined a reconfiguration model for all potential risk points in epidural administration systems, yet emerging technology has been slow to appear.<sup>8</sup> Active legislation in the U.K. (effective April 1, 2012) and in the U.S (California, effective January 2014) will prohibit the use of Luer connectors in neuraxial administration systems.<sup>11,12</sup>

An August 2010 report by the National Patient Safety Agency (U.K.) outlines the current manufacturing activity of Luer alternative components for neuraxial systems. These predominantly relate to spinal devices (needle hubs, syringes, manometers). For epidural systems, several types of epidural needles and loss of resistance syringes with unique safety connectors are in development. In the United States, an epidural safety system, the CorrectInject® System was evaluated at 4 clinical sites and is presently awaiting 501k clearance from the FDA. The following describes the system and the current experience in clinical practice.

## Technical Description

The system consists of several unique components:

For the purpose of the clinical evaluation, 3 packaging configurations were available:

1. The CorrectInject® Safety System which includes CorrectInject® Catheter Connector with Cap, CorrectInject® Infusion Adapter, CorrectInject® Filter, CorrectInject® Syringe, CorrectInject® Filter Straw, CorrectInject® White Transport Cap (Figure 1).
2. The CorrectInject® Infusion Set which includes CorrectInject® Infusion Set Adapter and White Transport Cap.
3. The CorrectInject® Syringe Kit which includes CorrectInject® Syringe, CorrectInject® Filter Straw and White Transport Cap

## Study Methods

A clinical evaluation by users of the CorrectInject® epidural safety system was initiated at 4 U.S. hospitals. The objectives were to determine the system's: 1) clinical acceptability and 2) perceived effectiveness for preventing wrong route medication administration into the epidural space. Compatibility of CorrectInject® connectors with other devices (syringe pumps, cassette infusion pumps) was also included in the evaluation. An open-labeled, prospective, controlled study was conducted at 4 clinical sites across the United States from September 2009 until July 2010. The protocol sample size called for 200 device uses for epidural administration. Eligibility for participation included obstetrical, surgical, or pain management patients undergoing epidural administration techniques. Data collection involved the completion of a 9 item questionnaire—"case report form" (CRF) following each use of the CorrectInject® device. Five questions pertained to ease of use and two to error prevention. Included was a rating scale of 1 (very simple) to 5 (very complicated) for ease of use. Space for comments and suggestion was also provided. At the completion of the

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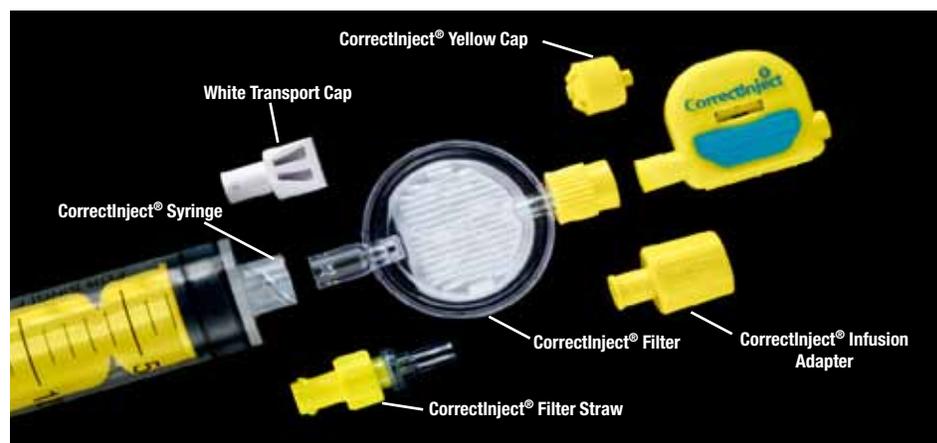


Figure 1. The CorrectInject® Safety System that includes CorrectInject® Catheter Connector with Cap, CorrectInject® Infusion Adapter, CorrectInject® Filter, CorrectInject® Syringe, CorrectInject® Filter Straw, CorrectInject® White Transport Cap. All resins and colorants used for the CorrectInject® Epidural Safety System are FDA medically approved materials.

# Few Difficulties With Epidural-Specific Connector

## “Reducing Risk,” From Preceding Page

trial, participating clinicians at each site completed a 16 item system evaluation survey. Ten of these items related to ease of use and 6 to prevention of error. Questions were in “yes/no” format. Responses were entered into an Excel database by the clinical trial coordinator. Monitoring of the study included on-site visitations, and telephone and email contact by the Smiths Medical clinical trial coordinator. Site initiation training included protocol review and instructions for use. Routine monitoring visits were conducted during the trial period and a closeout meeting took place at the completion of the investigation. Inventory of remaining stock kits were collected and returned at that time and final data sheets collected and entered into the database for analysis.

## Results

A total of 202 CRFs were collected from participating sites. 97% of CorrectInject® system usages involved obstetric patients; the remainder involved acute postoperative epidural pain management (Figure 2).

The majority (91%) of epidural administrations were combined bolus and infusion pump techniques as shown in Figure 3.

## Case Reports

There were 15 reports of technical difficulties with the CorrectInject® system (Figure 4) with 2 occasions of bypassing the system with the replacement of a standard Luer type connector (Figure 5).

Two such cases involved emergent situations. In one scenario the CorrectInject® connector was noted to

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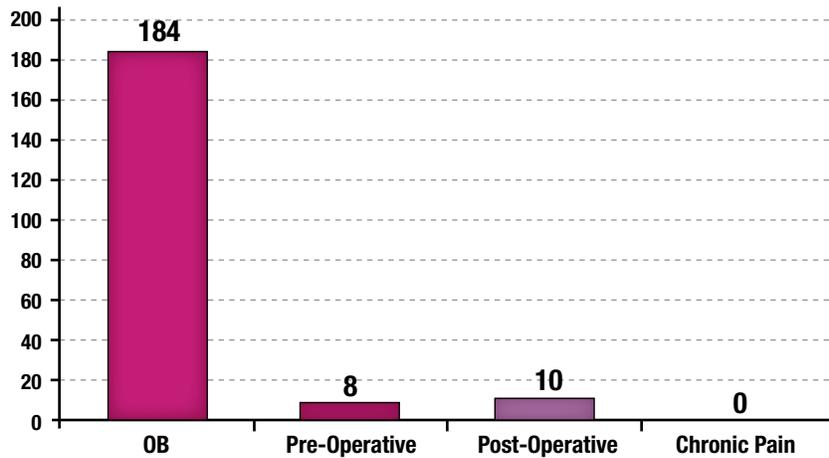


Figure 2. Epidural Indication.

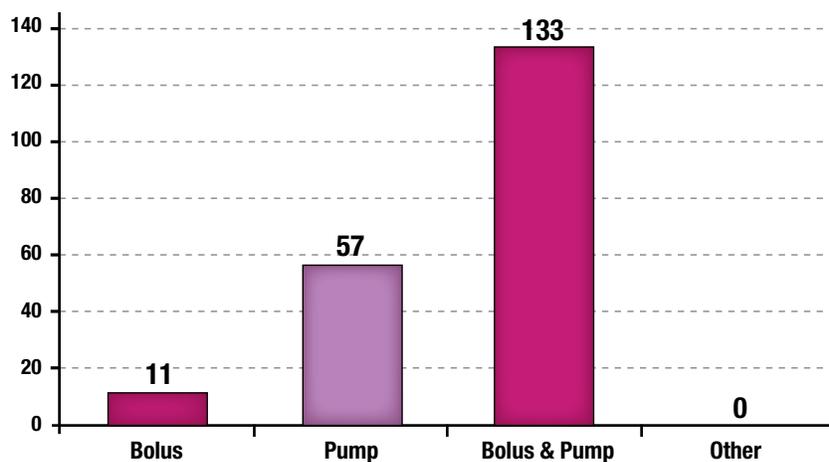


Figure 3. Medication Administration.

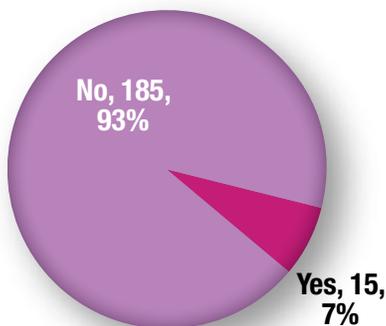


Figure 4

■ Yes ■ No

Did you experience any technical difficulties with the system?

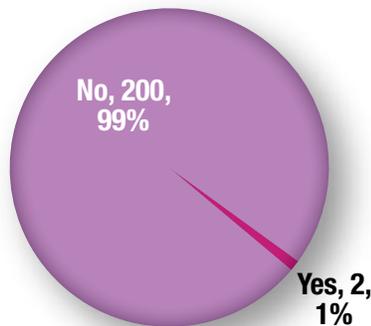


Figure 5

Were you required to circumvent the system and replace the CorrectInject® connector with a standard connector?

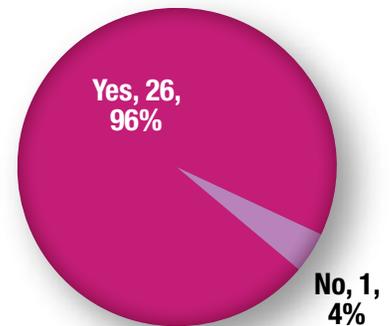


Figure 6

Do you believe the CorrectInject® system may reduce accidental connection to other Luer type connectors on other administration systems?

# Operator Satisfaction With Epidural-Specific Connectors

## “Reducing Risk,” From Preceding Page

be missing upon patient arrival to the operating room. In the other, an urgent epidural bolus was needed with a pre-filled Luer-type syringe with anesthetic medication. In both circumstances, the CorrectInject® epidural connector was replaced with a standard connector. Additional comments referred to the nature of how individual components are packaged and clinician preference for CorrectInject® syringes of different sizes.

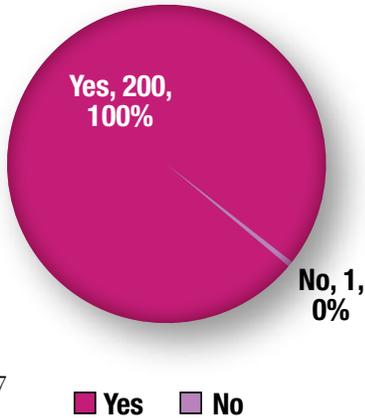


Figure 7

**Do you feel having the connector color coded yellow helps with the identification of this product as an epidural system?**

### System Evaluation:

In 99% of cases, clinicians felt that the CorrectInject® system protects against inadvertent administration of non-epidural medications into the epidural space, while 96% felt the system protects against inadvertent epidural medication to non-epidural routes such as intravenous (Figure 6).

Yellow color coding on the CorrectInject® connector was felt to be an effective identifier for epidural use by 99% of respondents (Figure 7).

The weighted mean score for ease of use was 2.4. In 86% of cases, a score of 3 or below was given (Figure 8). Furthermore, perceived difficulty with the system significantly declined by up to 50% at each site over time (Figure 9).

### Summary

System redesign, rather than clinician practice changes, is an efficient and effective intervention against tube misconnections leading to wrong route medication administration.<sup>8</sup> The findings of this clinical trial demonstrate the perceived safety benefits and clinical suitability of the device in settings with high utilization of epidural pain management techniques (obstetric and pain management epidural bolus/infusion techniques). Given the favorable “learning curve” illustrating the acceptability of the new system, ease of integration into clinical practice can be anticipated. Specifically, molding of the non-Luer

On a scale of 1-5, how would you rate the ease of set-up and use of the CorrectInject® system with this patient?

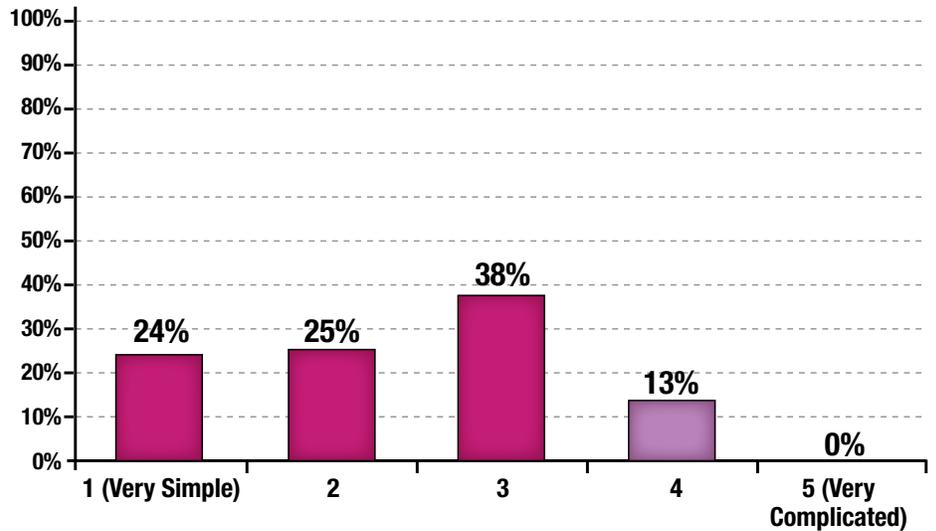


Figure 8

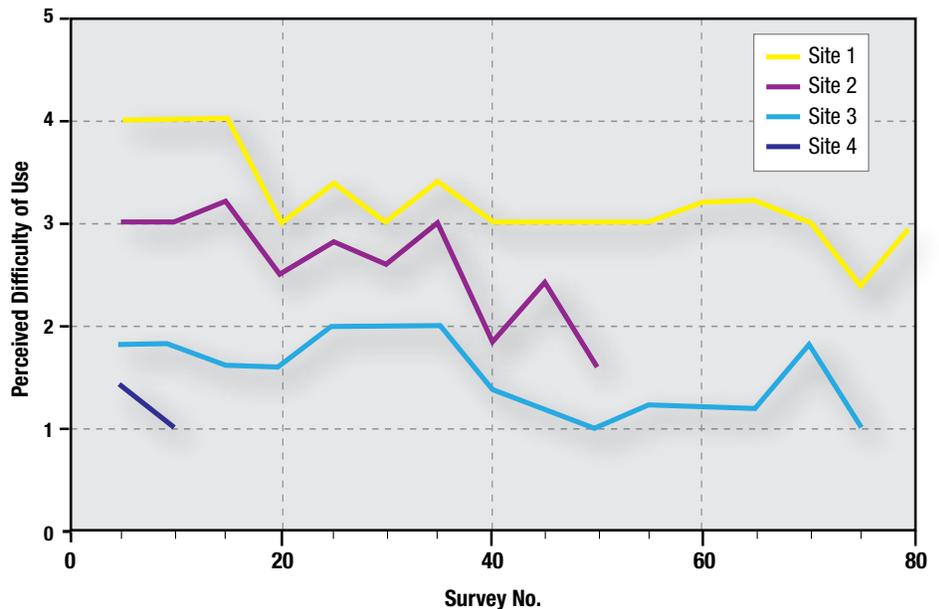


Figure 9

adaptor into the infusion tubing during manufacturing would achieve incompatibility with intravenous tubing without required attachment by the clinician. Furthermore, future safety goals could aim for universal storage of epidural solutions in designated, unique containers rather than storage in intravenous bags. This may have prevented the patient fatality involving the accidental spiking of an epidural reservoir, mentioned above. Like the pin index system in anesthetic gas delivery, Luer-incompatibility offers a universal<sup>14,15</sup> technological solution that is widely advocated to combat this highly underestimated, “persistent and potentially deadly” root cause of patient harm.

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## Letter to the Editor

# Creating a Safer Environment in the Operating Room

### To the Editor:

Operating room personnel are at risk for needle-stick injuries and consequently blood acquired infections.<sup>1</sup> Anesthesia personnel use all kind of needle devices (safety and non-safety intravenous catheters and hollow needles) and are cautious during the cannulation of a vein and artery. They are also educated about discarding the stylet of the intravenous catheter in a box for sharp objects. Recently, an anesthesiologist provided services in 3 operating rooms. He washed his hand between each room. After leaving the last room, he felt "something" under his shoe (Figure 1). Besides some tape and an electrocardiographic lead, there was also a non-safety intravenous catheter stylet attached to the sole of the shoe. Perhaps operating room personnel should also check their shoes between rooms and use intravenous catheters with safety measures designed to reduce the incidence of needle sticks.

Alfonso Casta, MD  
Boston, MA 02115

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Figure 1. The stylet (Needle) is noted in the sole of the shoe.

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### "Reducing Risk," From Preceding Page

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## Q &amp; A

## Regulations for Back-Up Anesthesia Machine Availability?

### Q Dear Q&A,

We have recently had an anesthesia machine malfunction and are trying to determine if there is a standard that requires a backup, functioning anesthesia machine to be available. When our machines were all replaced several years ago, we acquired an extra machine "just in case"; however, that machine has been scavenged for parts, having been idle for over 5 years.

*Michelle H Barker, CRNA, DNAP  
Asheville, North Carolina*

### A Dear Reader,

The Committee on Technology is unfamiliar with any regulations or standards that require a "spare" anesthesia machine to be available to a suite of operating rooms. We recognize that this is both a safety issue and an economic issue. Imagine that such a regulation existed and was applied to an outpatient surgical center with 2 operating rooms. A spare machine may be cost prohibitive, not just to purchase, but to maintain. One approach might be to develop a protocol specifying how to manage a catastrophic failure of an anesthesia machine during a surgical procedure.

In a suite of operating rooms the protocol could involve "borrowing" an anesthesia

machine from another room that is not in use (during the day or after hours). If the catastrophic failure occurs at a time when no spare machine is available a protocol might include

- Using the spare oxygen tank in the room.
  - Supply oxygen to disposable face mask if the patient is breathing spontaneously.
  - Switch to manual ventilation using a self-inflating breathing bag if the patient is not spontaneously breathing.
- Obtaining a transport monitor if patient monitoring is an integral part of the machine.
- Instituting Total Intravenous Anesthesia (TIVA).
- Closing the room after the case is finished until a fully functional anesthesia machine is available.
  - MAC cases could be considered for a room without an anesthesia machine; however, the ever present risk of complications and needing to convert to a general anesthetic may preclude this option.

The cost of a spare machine should be considered and weighed against lost revenue from closing an operating room for the day or longer that it may take for a biomedical equipment

technician to obtain the parts, repair the machine, completely evaluate the machine operation, and place it back in service.

A spare machine in the operating room environment that is not functional is inappropriate if it has been scavenged for parts. This machine should not remain near the ORs where it could be mistaken for a functional machine. If the anesthesia machines are supported by an in-house clinical engineering department, they should maintain the spare machine in functional form if they are going to leave it within the operating room area. If they are going to remove a part to fix another machine, the machine should live in the clinical engineering department until it is in completely functional according to the manufacturer's specifications.

While a standard that requires a spare anesthesia machine be available in the event of a catastrophic machine failure does not exist, an economic argument may be made that it is a cost savings to have and maintain a spare machine rather than lose the revenue from closing the room for a day or two until the machine may be fixed.

Alternatively, a protocol could be developed for managing the patient safely in the event of a catastrophic failure of an anesthesia machine during a procedure.

### The APSF Committee on Technology

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.

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

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