APSF Workshop and EC Pierce Lecture Address Importance of Cognitive Aids

by Robert C. Morell, MD

On Saturday, October 11, 2014, the APSF/ASA sponsored the Ellison C. Pierce, Jr., MD, Patient Safety Memorial Lecture at this year’s Annual ASA Meeting in New Orleans, LA. Dr. David M. Gaba presented the timely topic, Competence and Teamwork Are Not Enough: The Value of Cognitive Aids. Dr. Gaba is associate dean for Immersive and Simulation-Based Learning and professor of Anesthesia at Stanford University School of Medicine and co-director of the Simulation Center of Innovation at the VA Palo Alto Health Care System. It was particularly poignant that Dr. Gaba gave the EC Pierce Memorial Lecture as Jeep Pierce was a mentor and close friend of Dr. Gaba’s for many years. Dr. Gaba’s experience as an innovator and expert in the fields of simulation and crisis management made this a fantastic educational experience for the hundreds of attendees at this timely lecture. Dr. Gaba pointed out the aviation analogies for emergency manuals and cognitive aids used by pilots and challenged anesthesia professionals to embrace the use of and training about these important tools. Dr. Gaba presented examples of how emergency manuals could assist in the recognition, diagnosis, differential diagnosis, considerations, and critical treatment steps of perioperative emergencies. He also gave examples of pitfalls that may occur with cognitive aids and strategies to mitigate these pitfalls, noting that not all possible events are included in a manual, that some events happen too quickly to utilize a manual, and the need to recognize the tradeoff between completeness and usability. Dr. Gaba’s take home points for his lecture and the subsequent workshop included the following:

• Anesthesiologists, Nurse Anesthetists and Anesthesiologist Assistants need cognitive aids—especially “emergency manuals” or “emergency checklists” because our memory is limited and fallible especially under stress and about uncommon and unexpected events.
• Emergency manuals help us with both diagnosis (figuring out what is going on) and treatment (what to do once we know what is going on). Failures of both types have been documented in real patient care and in simulations.

The Joint Commission Sentinel Event #53

Managing Risk During Transition to New Tubing (Small Bore) Connector Standards: What You Need To Know!

The Joint Commission issued Sentinel Event Alert #53 on August 20, 2014, to address safety concerns as the first phase of the change in the small bore connector standards, which began in the 4th quarter of 2014 and the 1st quarter of 2015 with enteral feeding tubes. Changes in epidural tubing connections will follow. Other connectors affected will involve intravenous connections, blood pressure tubing, and breathing systems. These standards were changed in response to recurring high severity patient safety events where different tubings were disconnected to the wrong infusion.

Ebola Virus: Resources for Health Care Providers

The recent treatment in the United States of several patients who contracted Ebola has highlighted the need for an organized and prepared response from hospitals and health care workers. Numerous professional societies have provided web links (below) for information on contact/isolation precautions for Ebola including the Centers for Disease Control, World Health Organization, American College of Surgeons, American Society of Anesthesiologists, American Association of Nurse Anesthetists, the American Hospital Association, the Joint Commission and numerous others. These links include:

http://www.cdc.gov/vhf/ebola/hcp/index.html
https://www.facs.org/ebola
http://www.aana.com/resources2/professional-practice/Pages/Ebola-Virus-Disease.aspx
http://www.who.int/csr/disease/ebola/factsheet-e.html
http://www.anesthesia.org/apa/newsletter/2014/New%20York%20Dis
http://www.ama-assn.org/ama/pub/category/9308

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APSF Newsletter guide for authors

The APSF Newsletter is the official journal of the Anesthesia Patient Safety Foundation. It is
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reviewed publication, and decisions regarding content and acceptance of submissions for
publication are the responsibility of the editors. Individuals and/or entities interested in
submitting material for publication should contact the editors directly at Morell@apsf.org and/or
Lee@apsf.org. Full-length original manuscripts such as those that would normally be submitted to
peer review journals such as Anesthesiology or Anesthesia & Analgesia are generally not
appropriate for publication in the Newsletter due to space limitations and the need for a peer-review process.
Letters to the editor and occasional brief case reports are welcome and should be limited to 1500
words. Special invited articles, regarding patient safety issues and newsworthy articles, are often
solicited by the editors. These articles should be limited to 2000 words. Ideas for such contributions
may also be directed to the editors. Commercial products are not advertised or endorsed by the
APSF Newsletter; however, upon occasion, articles about certain novel and important technological
advances may be submitted. In such instances the authors should have no commercial ties to, or
financial interest in, the technology or commercial product. The editors will make decisions regarding
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All submissions should include author affiliations including institution, city, and state, and a
statement regarding disclosure of financial interests, particularly in relation to the content of the article.

OSA Death and Near Miss Registry Opens

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President’s Report Highlights Accomplishments of 2014

by Robert K. Stoelting, MD

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

APSF believes that residual neuromuscular blocking drug-induced muscle weakness in the postoperative period is a patient safety hazard that could be addressed by objective monitoring of the effects of neuromuscular blocking drugs along with traditional subjective observations.

The peer review literature supports the conclusion that residual neuromuscular blocking drug-induced muscle weakness is more common in the postoperative period than often appreciated and this weakness may contribute to adverse patient events (delayed discharge from the PACU, need for tracheal reintubation, impaired oxygenation and ventilation [may be erroneously attributed to opioids], aspiration, pneumonia). Furthermore, the peer review literature supports the belief that addition of objective monitoring of the effects of neuromuscular blocking drugs to the traditional subjective observations will reduce the likelihood of unrecognized and clinically significant drug-induced muscle weakness in the postoperative period with resulting improved patient safety.

For these reasons, APSF is requesting that the American Society of Anesthesiologists (ASA) via its Committee on Standards and Practice Parameters (CSPP) consider “residual neuromuscular blocking drug-induced muscle weakness in the postoperative period” as a high priority for creation of a “neuromuscular blockade document” to present to the October 2015 ASA House of Delegates.

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

APSF believes that anesthesia professionals should demonstrate competence to use advanced medical technology before applying this technology to patient care. Anesthesia professionals have not generally been required to demonstrate their competence to use anesthesia technology to care for patients. In contrast, mandatory user training and/or demonstration of competence are currently required for clinicians who use devices including lasers, radiation emitting devices (fluoroscopy), some technology-based surgical procedures (carotid stents), and point-of-care laboratory devices. Demonstrating competency to use medical devices is consistent with safe patient care.

In October 2014, the ASA House of Delegates approved a recommendation to “endorse the key safety issues of training and education” as developed by the APSF Committee on Technology and approved by the Executive Committee (http://www.apsf.org/announcements.php?id=27). Over the next year, the ASA Committee on Equipment and Facilities will work in conjunction with APSF and in consultation with the ASA Committees on Economics, Surgical and Procedural Anesthesia, and Quality Management and Departmental Administration, the Society for Technology in Anesthesia and manufacturers to propose systems that are effective, efficient, economically viable, and accessible, to culminate in a report by the committee to the ASA Board of Directors in October 2015.

Patient Safety and the Perioperative Surgical Home (PSH)

APSF held a consensus conference on this topic on Wednesday, September 3, 2014 (Royal Palms Resort and Spa, Phoenix, AZ). APSF believes that the model envisioned by the PSH will present opportunities for patient safety innovations based on standardization, increased use of protocols, better communication, and teamwork.

Implementing and Using Emergency Manuals and Checklists to Improve Patient Safety

APSF will sponsor an expert’s conference on this topic on Wednesday, September 9, 2015 (Royal Palms Resort and Spa, Phoenix, AZ). The conference will concentrate on the practical aspects of systematically implementing emergency manuals in perioperative settings. Experts on the development and production of emergency manuals will give guidance about key aspects of how to use emergency manuals with a focus on the process of implementation. The critical elements of implementation will be discussed in introductory presentations, followed by a panel discussion and facilitated breakout groups. The session will provide an interactive experience for attendees to learn about “how” to incorporate emergency manuals.

Those interested in attending should contact Dr. Stoelting (stoelting@apsf.org) for registration details.

See “President’s Report,” Next Page
APSF Panels Featured at both IARS and PGA Meetings

“President’s Report,” From Preceding Page

Research

The APSF Committee on Scientific Evaluation chaired by Steven K. Howard, MD, received 50 letters of intent and invited 8 investigators to submit completed applications for studies beginning January 1, 2015. In October 2014, the committee recommended funding 3 research awards totaling $450,000 (see page 51).

In addition, APSF supports a Safety Scientist Career Development Award (SSCDA) ($150,000.00 over 2 years) concluding in July 2015. In July 2014, APSF awarded a grant of $200,000 to evaluate the “implementation and performance” of the APSF Pre-induction Patient Safety (PIPS) checklist. Beginning in July 2015, APSF and AQA will co-sponsor a patient safety fellowship.

APSF is the largest private funding source for anesthesia patient safety research in the world. Since the inception of the APSF grant program, 735 grant applications have been received by APSF. When the level of financial support received 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.

Communication

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

Sorin J. Brull, MD, continues as the Patient Safety Section Editor for Anesthesia and Analgesia.

APSF-IARS Safety Panel


APSF-NYPGA Safety Panel

Robert K. Stoelting, MD, was joined by Drs. Jeffrey M. Feldman, Michael A. Olympio, and Lorri A. Lee for a panel entitled APSF Safety Initiatives: The Role of Educational Videos in Changing Clinical Practice on Monday, December 15, during the 2014 annual meeting of the NYPGA.

Prevention and Management of Operating Room Fires

Since its introduction in February 2010, more than 7,000 individual requests for a complimentary copy of the 18-minute educational DVD entitled Prevention and Management of Operating Room Fires (http://www.apsf.org/resources_video.php) have been received. In an effort to increase awareness for the potential of surgical fires in at risk patients, APSF has created a Fire Prevention Algorithm Poster and an OR Fire Prevention Flyer that are available for download from the APSF website (http://www.apsf.org/resources_safety.php).

The goal of the APSF Fire Prevention Algorithm to increase awareness of the risk of operating room fires was endorsed by ASA, AAAA, AANA, ASATT, American College of Surgeons, ASPAN, Association of periOperative Registered Nurses, ECRI Institute, Food and Drug Administration Safe Use Initiative, National Patient Safety Foundation, and The Joint Commission.

Medication Safety in the Operating Room

To date nearly 3,000 individual requests for the complimentary copy of the 18-minute educational DVD entitled Medication Safety in the Operating Room: Time for a New Paradigm (http://www.apsf.org/resources_video2.php) have been received.

Financial Support

Financial support to the APSF from individuals, specialty and components societies, and corporate partners in 2014 has been most gratifying. This sustained level of financial support makes possible the undertaking of new safety initiatives, the continuation of existing safety initiatives, and funding for anesthesia patient safety research. The level of research support is particularly dependent on the level of financial support received.

Online Donations

The link for online donations to APSF is http://www.apsf.org/donate.php. Contributions may also be mailed to the Anesthesia Patient Safety Foundation, 1061 American Lane, Schaumburg, IL 60173-4973.

Concluding Thoughts

APSF thanks retiring Board Directors Gerald Eichhorn, Walter Huehn, Kim Kraft, RN, and Michael O’Reilly, MD, and welcomes new directors Lynn J. Reed, CRNA, Shane Angus, AA-C, Heidi Hughes, Susan Carter, RN, Ana P. McKee, MD, and Shane Varughese, MD.

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 2015.

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)
1061 American Lane
Schaumburg, IL 60167-4973

or donate online at www.apsf.org
Culture Change May Be Needed To Effectively Implement Emergency Manuals

“Cognitive Aids,” From Cover Page

- Although there are a number of pitfalls to using cognitive aids, there are mitigating strategies available for all of them. The net benefit of using such aids very likely far outweighs the possible pitfalls and limitations.

Following Dr. Gaba’s lecture, the APSF sponsored the 2014 Board of Directors Workshop Competence and Teamwork Are Not Enough: Implementing Emergency Manuals and Checklists. Based upon the previous content presented in Dr. Gaba’s lecture, the workshop concentrated on the practical aspects of systematically implementing emergency manuals in perioperative settings. Experts on the development and production of emergency manuals gave guidance about key aspects of how to use emergency manuals with a focus on the process of implementation. The critical elements of implementation were discussed in introductory presentations, followed by a panel discussion and facilitated breakout groups. The sessions provided an interactive experience for attendees to learn about how to incorporate emergency manuals. The following objectives were intrinsic to the workshop:

- To be able to explain the value of emergency manuals to hospital leadership (anesthesia, surgery, nursing, administration)
- To be able to explain to others what is meant by each of the 4 elements to implementation of emergency manuals
- To know options for how to select a manual for their organization (adopt an existing one or create one de novo)
- To be prepared to address challenges from colleagues who are opposed to using a manual.

The workshop opened with an introduction by Jeffrey B. Cooper, PhD, APSF vice president and professor of Anesthesia at Harvard Medical School and founder and executive director of the Center for Medical Simulation. Dr. Cooper’s global perspective included admonitions that people should not expect the effective introduction of emergency manuals will be easy. Dr. Cooper also noted that it is relatively easy to just put emergency manuals in various locations where they may be needed; however, it is usually going to be very hard to get them to be used effectively. Clinicians should not underestimate the degree of culture change that is needed. The introduction of these tools can be an opportunity to help the culture change happen, and can be a reason to train together to facilitate effective implementation. As such, the process of introduction of emergency manuals is a great opportunity for good interactions and practice within the OR team. These interactions can promote a healthier safety culture.

Dr. Gaba presented a summary of why emergency manuals are needed in perioperative care, which dovetailed quite nicely with his prior lecture and his take home points. Following Dr. Gaba, Sara N. Goldhaber-Fiebert, MD, presented a lecture pertaining to the basic principles of implementing of emergency manuals. Dr. Goldhaber-Fiebert is clinical assistant professor and co-director of Evolve simulation program at the Department of Anesthesiology, Perioperative and Pain Medicine at Stanford University School of Medicine. She was lead author along with co-author, Dr. Steve Howard, on the recent publication, “Implementing Emergency Manuals: Can Cognitive Aids Help Translate Best Practices for Patient Care During Acute Events?” that appeared in Anesthesia & Analgesia in 2013. Dr. Goldhaber-Fiebert offered the following take home points:

1. Training and familiarity are necessary to facilitate effective use.
2. Implementation can be facilitated by
   a. local champions and an interdisciplinary team
   b. leadership buy-in
   c. educational use and familiarity to enable clinical use
   d. resources for training
   e. using the ‘exclamation point’ model of implementation (Figure 1).

Figure 1. Exclamation point model of implementation for emergency manuals.


Following Dr. Goldhaber-Fiebert, Dr Paul Preston, safety educator for The Permanente Medical Group and a senior physician at the San Francisco Kaiser Foundation Hospital, presented, “What’s the right manual for your organization, group, or hospital?” Dr. Preston’s talk was on point and relevant to all of us, some of whom are in large academic organizations, as well as those of us in private practices, both large and small. Dr. Preston provided the following take home points germane to his lecture including:

1. There are no perfect lists, don’t take forever looking for them.
2. Strongly consider adapting what is already created to save time.
3. Make sure to allow time for testing these and training in the actual workplace. Doing so helps anesthesia providers decide which lists are best and most appropriate
4. Training and testing in the operating room environment is important because that is where the rescues truly happen.

See “Cognitive Aids,” Next Page
APSF Sponsors Conference on Patient Safety Opportunities and the Perioperative Surgical Home

by Mark A. Warner, MD, and Robert K. Stoelting, MD

On September 3, 2014, the Anesthesia Patient Safety Foundation (APSF) convened a multidisciplinary conference to examine the patient safety opportunities that might be associated with any number of perioperative surgical home models. The conference co-moderators were Drs. Mark A. Warner and Robert K. Stoelting.

Dr. Stoelting opened the conference by noting that 16 outstanding representatives of multiple medical specialties and health care organizations (Table 1) would provide their views and summarize their experiences related to coordinating care of surgical patients and the impact of that coordination on their safety. In essence, they would be discussing their perception of the perioperative surgical home concept and describing how they believed it may impact patient safety.

The room was packed with 114 attendees from a broad spectrum of health care providers, administrators, and representatives from various medical equipment and technology companies. Nearly three-quarters of the attendees were anesthesia providers, with one-third of those working in private practice settings.

Why Choose the Perioperative Surgical Home as a Topic?

This conference, focused on linking opportunities to improve patient safety across the perioperative continuum, was particularly appropriate given the origin of the perioperative surgical home concept. In

See “Surgical Home Model,” Next Page

Table 1: Speakers at the 2014 APSF Conference on Patient Safety Opportunities and the Perioperative Surgical Home

<table>
<thead>
<tr>
<th>Name</th>
<th>Organization/Position</th>
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<tbody>
<tr>
<td>George T. Blikie, MD</td>
<td>Chief Quality and Value Officer, Dartmouth-Hitchcock Clinic, Professor of Anesthesiology, Geisel School of Medicine</td>
</tr>
<tr>
<td>Brian J. Cammarata, MD</td>
<td>ASA Representative to the Council on Surgical and Perioperative Safety</td>
</tr>
<tr>
<td>Claire L. Chandler, AA-C</td>
<td>Clinical Anesthetist, Emory University Hospitals; Past President, American Academy of Anesthesiologist Assistants</td>
</tr>
<tr>
<td>Teo Forscht Dagi, MD</td>
<td>Professor, School of Medicine, Dentistry and Biomedical Sciences, Queen’s University Belfast and Harvard Medical School; American College of Surgeons</td>
</tr>
<tr>
<td>Franklin Dexter, MD, PhD</td>
<td>Director, Division of Management Consulting; Professor, Department of Anesthesia, University of Iowa</td>
</tr>
<tr>
<td>Richard P. Dutton, MD</td>
<td>Executive Director, Anesthesia Quality Institute; Chief Quality Officer, American Society of Anesthesiologists; Clinical Associate, Department of Anesthesia and Critical Care, University of Chicago</td>
</tr>
<tr>
<td>Nancy Foster</td>
<td>Vice President for Quality and Patient Safety Policy, American Hospital Association</td>
</tr>
<tr>
<td>Linda Groah, RN</td>
<td>Executive Director/CEO, Association of Perioperative Registered Nurses; APSF Board of Directors</td>
</tr>
<tr>
<td>David W. Larson, MD</td>
<td>Chair of Colorectal Surgery and Chair of Enterprise Practice Redesign, Professor of Surgery, and Director of Quality Cancer Care, Mayo Clinic</td>
</tr>
<tr>
<td>Ana Pujols McKee, MD</td>
<td>Executive Vice President and Chief Medical Officer, The Joint Commission</td>
</tr>
<tr>
<td>Bradly J. Narr, MD</td>
<td>Chair, Department of Anesthesiology, Mayo Clinic</td>
</tr>
<tr>
<td>Lynn J. Reede, CRNA, DNP, MBA</td>
<td>Senior Director, Professional Practice, American Association of Nurse Anesthetists</td>
</tr>
<tr>
<td>Warren S. Sandberg, MD, PhD</td>
<td>Professor and Chair, Department of Anesthesiology, Vanderbilt University School of Medicine</td>
</tr>
<tr>
<td>Michael P. Schweitzer, MD</td>
<td>Chair, American Society of Anesthesiologists, Committee on Future Models of Anesthesia Practice</td>
</tr>
<tr>
<td>Matthew B. Weinger, MD</td>
<td>Professor of Anesthesiology, Biomedical Informatics and Medical Education, Center for Research and Innovations in Systems Safety, Vanderbilt University School of Medicine</td>
</tr>
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</table>

Dr. Berry Shares Personal Experience with Sudden Cardiac Arrest

“Cognitive Aids,” From Preceding Page

At the conclusion of Dr. Preston’s lecture a panel discussion was held regarding when and how emergency manuals should be used, and a small group break-out session was held discussing values of the concept, how an example of a manual protocol would be practiced and used, as well as identifying challenges intrinsic to the implementation process.

Finally, Dr. William R. Berry, MPH, FACS, and principal research scientist at the Harvard School of Public Health as well as chief medical officer for Aridane Labs, shared his expertise regarding overcoming the cultural barriers. Dr. Berry’s highly personal approach included his own story of being a survivor of sudden cardiac arrest. Dr. Berry offered these take home points for our participants and readers of this Newsletter:

- Training to improve teamwork and communication can help us deliver better care in every crisis.

This workshop was extremely well received and will likely have a significant impact on the participants. Our readers are highly encouraged to seek out and consider the implementation of cognitive aids that are becoming increasingly available. The Stanford Emergency Manual is an excellent starting place and is but one of the downloadable manuals (see http://emergencymanual.stanford.edu/). For further resources and links see the global site www.emergencymanuals.org.

Dr. Morell is the Senior Co-editor of the APSF Newsletter, a member of the APSF Executive Committee, and a private practice anesthesiologist in Niceville, Fl.
Survey of Attendees Demonstrates Complexity of Perioperative Surgical Home

“Surgical Home Model,” From Preceding Page

2000, leaders from the APSF, American Society of Anesthesiologists (ASA), and the American Board of Anesthesiology (ABA) met in San Francisco to discuss opportunities to improve patient safety through expansion of anesthesia practices in collaboration with surgical and medical specialties, nursing, and other health care providers. A basic tenet of the meeting was the recognition that the dramatic improvements in patient safety from the previous 2 decades had primarily involved important changes to intraoperative care and management of anesthetized patients. The nearly exponential rate of decrease in intraoperative catastrophes during the preceding period had slowed. There was growing recognition that further major advances in patient safety would require multidisciplinary teams working together across the full perioperative period.

That remarkable meeting triggered changes over the next decade that ultimately resulted in 1) a new definition of the expectations of ABA-certified anesthesiologists; 2) modified anesthesia training requirements for residents that expanded their experiences in general medical and pediatric care, preoperative medicine, critical care, and pain management; and 3) support for the perioperative surgical home concept by the ASA, government agencies, and others.

The APSF reasoned that it is now time to explore how the perioperative surgical home and its various models may assist anesthesia providers in their quests to further improve safety of surgical and procedural patients. For the purposes of this report, the term “surgical” will be used to refer to patients undergoing any surgery or diagnostic/therapeutic procedure.

What Is the Perioperative Surgical Home?

In describing the perioperative surgical home concept, the speakers noted that it is essentially a patient-centered, systematically-designed care pathway of the entire perioperative continuum. Inherent within the concept are several key attributes: 1) although focused on patients, it also must be user-centric to ensure that teams will be engaged and participate; 2) teamwork consisting of collaboration between multiple disciplines is essential; 3) standardization of clinical processes and patient expectations must be integrated; and 4) data collection processes and metrics must be established to document improvements in patient safety, satisfaction, and outcomes as well as cost-effectiveness and efficiency (value) of care.

Lessons Learned

A number of the speakers gave useful examples of how the perioperative surgical home concept has been successfully piloted in their institutions and described the lessons that they had learned:

• There must be a deliberate, multidisciplinary perioperative system design, “Decision (to operate) to discharge.”

• The design must be applicable to small as well as large hospitals.

• Nurses and pharmacists, in their roles as the primary implementers of clinical pathways and protocols, are vital team members and must be fully engaged in planning, executing, and assessing the care model.

• Specific focus on the sickest patients is crucial as they often are the patients who fall outside of standardized care pathways.

The speakers also provided attendees with a few unique pearls of wisdom:

• Preoperative patient assessment and optimization is important, especially regarding setting patient expectations for what they will experience: “If they know what to expect, there is a greater chance that patients will be satisfied.”

• Since a major expense in perioperative care includes re-admissions, “Ensure efficient, safe, and durable discharges.”

• When starting out, “Engage (your colleagues), communicate, standardize, communicate, coordinate, communicate, and then communicate some more.”

• Ensure that the hospital or health system engages in the perioperative surgical home, then “Either lead the effort or contribute and add value.”

• And finally, paraphrasing Woody Allen, “Remember, 80% of success is showing up—be involved; be a leader.”

Interesting Attendee Responses

An audience response system was used to pose questions to the attendees during the conference. (http://www.apsf.org/announcements.php?id=33). Their responses suggest that while most believe that the perioperative surgical home concept will be able to improve patient safety, especially reduction of perioperative complications (e.g., deep venous thromboembolism, surgical site infections, and pneumonias), there is still confusion, concern, and some degree of skepticism about the acceptance and sustainability of the concept.

Improved Patient Safety

• Nearly 9 in 10 attendees believed that “the perioperative surgical home concept can improve patient safety and outcomes through better coordination of care.”

• More than 9 in 10 attendees agreed that “the perioperative surgical home concept will contribute to patient safety by promoting improved multidisciplinary communication, teamwork, and attention to patient-centered care.”

• Three-quarters of attendees felt strongly that the ‘main driver’ of the perioperative surgical home concept is to deliver a better patient experience and outcome at a lower cost.

Acceptance and Sustainability

• Two-thirds of attendees did not believe that “the perioperative surgical home concept will gain widespread acceptance.”

• Two-thirds of attendees expressed concern that “surgeons will not be full participants in the perioperative surgical home model.”

• One-third doubted that “hospital facility leaders will recognize the value of the perioperative surgical home concept for improving patient safety.”

• Nearly all attendees agreed “the perioperative surgical home concept will require creation of alternatives to traditional fee-for-service finances” if it is to be successful.

• And sadly, nearly 8 in 10 attendees worried that “demand for efficiency and production by hospital facility leaders may overwhelm patient safety concerns.”

Role and Training of Anesthesia Professionals

• Two-thirds of attendees believed that “anesthesia professionals are best positioned to lead the perioperative surgical home concept so as to facilitate standardized care in partnership with surgical and nursing colleagues.”

• All attendees agreed that if the perioperative surgical home concept gains acceptance, “training programs will have to change.”

Summary

Clearly attendees believed that perioperative patient safety can be—and should be—enhanced by deliberately and systematically designing care pathways that optimize patients preoperatively, manage them perioperatively with teams of health care professionals who work collaboratively, and reduce complications and re-admissions. The impact of the perioperative surgical home concept will need to be tracked with excellent data systems and analyzed carefully to ensure that patient safety, outcomes, and satisfaction are consistently improving.

A looming, occasionally overwhelming message from speakers and attendees was that the perioperative surgical home concept remains to be proven effective at improving patient safety, reducing expenses, and increasing patient satisfaction. Thus, the acceptance and sustainability of this concept remains suspect. The ASA’s learning collaborative of the perioperative surgical home may provide information on the value of various models as well as examples of best—and ineffective—practices. Proponents will need to show how the perioperative surgical home concept can be monetized to support interest in the changes that will be necessary to sustain it long-term.

Should various models of the perioperative surgical home concept prove effective at reducing expenses and improving patient safety, a key question will then be, “Which patient safety issues are the most effectively improved and have the greatest impact on patient outcomes and satisfaction?” That question and subsequent discussions, debates, and trials that study the best approaches to improving patient safety across the broad continuum of perioperative care will undoubtedly be the focus of future APSF efforts.

Dr. Warner is Professor of Anesthesiology at the Mayo Clinic in Rochester, MN.

Dr. Stoelting is the President of the APSF.
E.C. Pierce, Jr., MD, Award for Best Scientific Exhibit

James Tse, MD, PhD, Rose Alloteh, MD, and Syviana Barsoum, MD, et al. were awarded the E.C. Pierce, Jr., MD, Award for the best scientific exhibit at the 2014 American Society of Anesthesiologist meeting in New Orleans, LA. Their exhibit was entitled “A Simple TSE-Alloteh Nasal CPAP/CF Mask/Circuit to Improve Nasal Ventilation and Oxygenation in OSA Patients during Intraoperative Sedation and Induction of General Anesthesia.” The authors highlighted an easily assembled infant face mask with fully inflated air cushion, which was secured over the nose with head straps and connected to an anesthesia circuit with either CPAP or BiPAP mode using the pressure support ventilator mode.

Announces the Procedure for Submitting Grant Applications

Deadline to Submit the Letter of Intent (LOI) for an APSF Grant Award to Begin January 1, 2016 Is:
March 2, 2015 (5 Pm Est)

http://www.apsf.org/grants.php

• LOI will be accepted electronically beginning January 21, 2015.
• The maximum award is $150,000 for a study conducted over a maximum of 2 years to begin January 1, 2016.
• Based on the APSF’s Scientific Evaluation Committee’s evaluation of these LOIs, a limited number of applicants will be invited to submit a full proposal.
• Investigators will be notified of the status of their LOI electronically on Thursday, May 15, 2015.
Drug Shortages in the U.S.—A Balanced Perspective

by Daniel S. Orlovich, PharmD, and Richard J. Kelly, MD, JD, MPH

In 2012, Congress passed the Food and Drug Administration Safety and Innovation Act (FDASIA) granting the FDA more authority regarding drug shortages. The legislation, in part, mandated that manufacturers notify the FDA of potential discontinuations or interruption in the manufacture of drugs used to prevent or treat serious or life-threatening diseases. Within the first year after passage of the legislation the number of notifications to the FDA increased 6-fold. This bill also gave the FDA authority to expedite reviews and inspections to help mitigate drug shortages.

In 2013 the FDA issued its Strategic Plan for Preventing and Mitigating Drug Shortages. It had 2 goals. The first was aimed at further mitigation of drug shortages. The second was to develop long-term prevention strategies. The former targeted improvements to the FDA’s current mitigation activities for existing or imminent shortages. The latter concentrated on the root causes of shortages to better understand and eventually anticipate future drug shortages.

These measures have had an effect on the number of reported drug shortages. According to data from the University of Utah Drug Information Service, the number of new drug shortages per year from 2005 to 2011 had increased more than 5-fold, culminating in a maximum number of new drug shortages being reported in 2011. Since that time, there has been a downward trend that has resulted in more than a 50% reduction in new drug shortages through 2013. A review of these drug shortages show that certain classes of medications, sterile injectable drugs in particular, comprise the majority and have caused specialties such as anesthesiology to be especially vulnerable. And, while there has been a decrease in the number of new drug shortages, the number of existing drug shortages from 2012 to 2013 has increased slightly (Figure 1).

Figure 1: Drug Shortages in US: Prevented Shortages2 vs. New Shortages5 vs. Average Total Shortages.

For more information, see “Drug Shortage,” Next Page

Cited Factors in Successful Prevention of Drug Shortages

1. Strong Quality Systems that lead to compliance with manufacturing regulations
2. Documented corporate goal to avoid drug shortages
3. Strong Quality Systems track record and Current Good Manufacturing Practice Inspection History
Balanced Perspective Needed to Understand U.S. Drug Shortages

“Drug Shortages,” From Preceding Page

4. Corporate Goals Tagged to Drug Shortage Prevention

5. Ability to Quickly React to Drug Shortages

6. Strong Relationship With Regulatory Authorities

7. Strong Communication Link With Regulatory Authorities

8. Dedicated Resources Focused on Preventing Drug Shortages

9. Incentives Tied to Preventing Drug Shortages


The FDA is also a major stakeholder in the drug shortage problem. In order to be more responsive about drug shortages, the FDA has upgraded its drug shortage website to include a searchable database with therapeutic categories that allows subscribers to receive RSS feeds specific to an area of practice as well as the planned future development of a smartphone application to make the information more readily available. The FDA has also begun to include notices from pharmacists and other health care professionals who report price increases for drugs sold by third parties on the “gray market.” While the FDA can mandate reporting of drug shortages, it has no authority to regulate the quality of manufacturing. To address this problem, according to Stephen King, the public affairs specialist at the Center for Drug Evaluation and Research, the FDA is exploring ways to incentivize and prioritize manufacturing quality.

Professional organizations have also been active in addressing drug shortages. The American Society of Anesthesiologists is committed to the implementation of the drug shortage provisions of the FDASIA and working with stakeholders and the FDA to prevent and mitigate drug shortages. The American Society of Health-System Pharmacists (ASHP) most recently collaborated with the Assistant Secretary for Preparedness and Response to develop a resource for managing critical shortages of IV fluids. During a recent national shortage of 0.9% injectable sodium chloride, the ASHP conducted a survey and found that 75% of the respondents reported the product to be in short supply. The ASHP conveyed this information to the FDA and other health care organizations and encouraged conservation efforts that included patient triage and dosage changes.

Anesthesiologists, Nurse Anesthetists and Anesthesiologist Assistants are integral to the fight against drug shortages. The ASHP has developed a Drug Shortage Team Reporting Form on its website for health care professionals to provide valuable information regarding the sense of urgency and the magnitude of drug shortages that may affect patients at the point of care.

Hospitals, as institutions that reward manufacturers with their business, are also active stakeholders in the fight against drug shortages. Presently, drug suppliers are not required to list where a drug has been made or which factory manufactured it. Hospitals, therefore, cannot be assured either of the drug’s quality or the consistency of its supply. Dr. Erin Fox, the director of the University of Utah Drug Information Service, believes hospitals may purchase more drugs from manufacturers when they are assured of a steady supply and a high quality product.

One such measure that may improve transparency and influence ordering patterns is the Drug Quality and Security Act (DQSA) signed by President Obama in November 2013. The DQSA will require all pharmaceutical drugs to have a complete list of transaction information whenever the drugs are bought or sold. Starting in July 2015, hospital pharmacies will have to reject drug products without an accompanying transaction history. In addition, within the next 4 years drug manufacturers must add serial numbers to all drugs packaged, and within the next 10 years the industry must implement electronic codes to track medications that travel from the manufacturing facility to hospital pharmacies.

Pharmacies, too, play an integral role in addressing drug shortages. The University of Utah Health Care system is an example of what can be done: alternative drugs are purchased when available; proactive plans are developed; pharmaceutical drug needs are prioritized; physicians and anesthesiology professionals are educated about alternatives; and physicians are kept informed about current and impending drug shortages. About a quarter of hospital pharmacies directors report that they have added at least one full-time position in order to manage and ameliorate drug shortages.

Looking to the future, more information is needed from patients about how drug shortages affect them. A reporting system for patients, similar to the FDA’s post-marketing surveillance program, may provide valuable information. In addition, pharmacies, physicians and anesthesiology professionals, and professional organizations can reach out to patients to assess how drug shortages have affected their health and safety. Finally, identification of locations most affected by drug shortages may help to focus efforts to address new and ongoing drug shortages.

Drs. Orlovich and Kelly are both with UC Irvine Health, Orange County, CA. Neither author has financial conflicts of interest to report.

References


The APSF’s mission statement explicitly includes the goal to improve continually the safety of patients during anesthesia care by encouraging and conducting safety research and education. Since 1987, over $8 million has been provided to investigators for patient safety research and the field of anesthesiology continues to be a shining example in health care in this area.

In 2014, the APSF Scientific Evaluation Committee transitioned the process of applying for funding to a Letter of Intent (LOI) submission and review followed by select invitation for full proposal submission to investigators with the highest scoring LOIs. This year the Committee also utilized new online grant management software for investigator submissions of LOIs and full proposals and subsequent review by Committee members. The APSF investigator-initiated grant program had 50 LOI submissions and the Committee invited the top scoring 8 for full proposals. The 8 full proposals were reviewed and scored prior to more widespread adoption. The additional economic costs associated with the treatment of POD exceed $4,000 per patient resulting in an estimated total annual cost in the U.S. as high as $152 billion.

The etiology of POD is multifactorial involving a complex interaction between a vulnerable patient and precipitating factors in the perioperative period. Unmodifiable patient risk factors include age, comorbidities, and preoperative cognitive status. A preoperative geriatrics consultation using a multimodal intervention focused on improving modifiable risk factors such as sleep disorders, fluid balance, pain control, and medication management has been shown to decrease POD by approximately one-third. However, there are also intraoperative factors under the control of anesthesia providers that can be modified in an attempt to further reduce the overall incidence and severity of POD.

Aim: The objective of this study is to determine if the incidence and severity of POD can be reduced by optimizing general anesthesia management in elderly patients undergoing surgery for repair of a hip fracture. The hypothesis for the study is that optimization of blood pressure, cerebral oxygenation, and depth of anesthesia will decrease the severity and duration of POD. To evaluate this hypothesis, we will randomize patients to either a standard or an optimized anesthetic technique. After surgery, patients will be evaluated with the confusion assessment method and the delirium rating scale to determine...
Teams from University of Missouri, Harvard, and Yale Receive Grant Awards

“Grant Awardees,” From Preceding Page

mine the incidence and severity of POD. The results of the study are intended to enhance patient safety by identifying a general anesthetic technique that can be used by both academic and private practice anesthesia providers to decrease the risk of POD associated with hip fracture surgery.

Implications: At the present time, the only strategy proven to minimize POD is a proactive geriatric consultation utilizing a combination of both pharmacological and non-pharmacological strategies in the perioperative period. If optimization of intraoperative anesthesia care minimizes POD and improves postoperative outcomes, anesthesia providers will become integral members of the perioperative surgical home team for patients requiring surgical intervention for hip fractures. If successful, optimized anesthesia care will result in significant reductions in the economic and societal costs associated with POD. Data from this study may also be used to develop multicenter clinical trials to support and validate the optimized anesthesia management protocol.

Funding: $150,000 (January 1, 2015 – December 31, 2016). This grant was designated as the APSF/ American Society of Anesthesiologists (ASA) Endowed Research Award.

Jodi D. Sherman, MD
Assistant Professor, Department of Anesthesiology, Yale, School of Medicine, New Haven, CT

Dr. Sherman’s clinical research project is entitled “Environmental and Public Health Impacts of Anesthesia Alternatives.”

Background: Pollution is a hidden and ignored patient safety issue. The U.S. health care sector is a significant contributor to national emissions to air, water, and land. Anesthesia, in particular, is a resource intensive specialty; however, the human disease burden stemming from its pollution is as yet unquantified. Life Cycle Assessment (LCA) is an internationally standardized, science-based approach to quantify emissions and multiple environmental and public health impacts of a product or process over its entire life span, from extraction of natural resources, to material production, device manufacturing, transport, use, and disposal. The study objective is to use LCA to estimate the greenhouse gas emissions directly and indirectly attributable to anesthetic alternatives, to identify opportunities to reduce disease burden stemming from pollution, and improve safety for public health.

Aims: The large global warming impacts of inhaled anesthetics, particularly compared to intravenous propofol, are established. However, there are various additional drugs and devices used in different anesthetic approaches, and whether there is a significant environmental burden that equates to anesthetic approaches is presently unknown. Dr. Sherman’s group will perform a complete inventory of common drugs and devices utilized for the delivery of anesthesia at Yale-New Haven Hospital for a representative surgery (elective ankle) for which multiple safe anesthetic pathways potentially exist: regional plus sedation, general inhaled, general intravenous, combined regional and general inhaled, and combined regional and general intravenous anesthetics. Next, a Life Cycle Inventory will be performed to determine direct and indirect “cradle-to-grave” material inputs for each medical item through manufacturer reporting, industry databases, literature review, and through destructive testing. LCA modeling will then quantify standard environmental pollution and public health impacts for the anesthetic approaches, to translate these inventoried physical flows into measures of environmental change or damage along established impact categories. Finally, Dr. Sherman will estimate national impacts by extrapolating results for each anesthetic pathway through case-totals estimated through the National Anesthesia Clinical Outcomes Registry and the Multicenter Perioperative Outcomes Group databases. The primary endpoint is global warming potential expressed as carbon dioxide equivalents. In addition, secondary endpoints will include 8 other standard categories of environmental and human health outcomes, so relevant tradeoffs can be considered.

Implications: Patient safety ought to include concern for the health and safety of future generations. Should choices exist between safe anesthetic alternatives, the results of this research can aid clinicians to make informed decisions that are safer to the health of the community while maintaining the highest assurance of patient care. Once the LCA for standard drugs and devices is complete, any institution can use the results to identify critical areas to target improvements. Further, the methodology can be applied to any specialty and throughout several scales within health care to identify opportunity for efficiencies, and so anesthesiology as a specialty can continue to serve as a leader in advancements in patient safety.

Funding: $150,000 (January 1, 2015-December 31, 2016).

Dr. Howard is an Associate Professor of Anesthesia at Stanford University School of Medicine and Chair of the APSF Committee on Scientific Evaluation.
Obstructive Sleep Apnea Death and Near Miss Registry Opens

by Karen L. Posner, PhD, and Norman Bolden, MD

The Obstructive Sleep Apnea (OSA) Death and Near Miss Registry opened in May 2014 and is now accepting case reports. The goal of this new registry is to identify recurring patterns or themes underlying death or adverse events suspected to be related to obstructive sleep apnea with an ultimate aim of risk prevention and improved anesthesia patient safety. The Registry seeks to obtain a large number of case reports to achieve these goals.

OSA or sleep-disordered breathing is present or suspected in many patients presenting for anesthesia care. Patients with OSA are at risk for difficult airway management and opioid-induced respiratory depression. The postoperative risks may extend for a number of days as regular sleep patterns are re-established. The American Society of Anesthesiologists Practice Guidelines for the Perioperative Management of Patients with Obstructive Sleep Apnea recommend screening of patients with characteristics associated with OSA in advance of their procedure so an appropriate perioperative management plan can be developed. Screening does not provide a diagnosis, and anesthesia professionals continue to face challenges in developing perioperative plans weighing risks and benefits of perioperative care choices for patients with signs or symptoms of OSA but lacking a definitive diagnosis. Transfers of care postoperatively present additional challenges in providing appropriate continuity of care for these patients, adding the risk of perioperative care plans falling through the cracks as patients are transferred to unmonitored settings or discharged to home.

Some initial cases submitted to the OSA Registry exemplify the complexity of perioperative management of OSA patients. In one case of a patient diagnosed with OSA preoperatively, the patient’s CPAP was not used postoperatively, continuous monitoring was not in place, and signs of respiratory depression were missed by the floor nurse. In another case the patient’s history of OSA was assessed by the anesthesia provider, who developed an appropriate perioperative care plan. With a change in shift postoperatively, the patient’s OSA history was overlooked, pain management protocols were changed, and continuous monitoring discontinued. The patient was found non-responsive less than 1 hour after the last nursing check. Both of these OSA-related adverse events occurred on the night following the surgical procedure.

These cases illustrate themes in perioperative risks for OSA patients related to patient management and monitoring that, while perhaps obvious to many, were clearly not obvious to all of the health care professionals involved in the care of these patients. A broad sample of adverse events will create opportunities to identify additional risks in patient identification and management that may drive initiatives to prevent such adverse events in the future.

The OSA Death and Near Miss Registry is the culmination of a multi-year planning process started by a committee of the Society for Anesthesiology and Sleep Medicine (SASM). The current SASM OSA Death and Near Miss Registry Committee includes Norman Bolden, MD (chair), Dennis Auckley, MD, Kenneth Barchenb, MD, Jonathan Benumof, MD, Frances Chung, MBBS, David Hillman, MD, Frank Overdyk, MD, Satya Krishna Ramachandran, MD, and David Samuel, MD. The Anesthesia Closed Claims Project and its Registries, part of the Anesthesia Quality Institute (AQI), has teamed with the SASM committee to implement the Registry, provide technical assistance, and serve as a repository for Registry data. The Anesthesia Closed Claims Project will also serve as a source of Registry case reports obtained through collection of closed anesthesiologist malpractice claims throughout the United States. Karen L. Posner, PhD, and Karen B. Domino, MD, MPH, are leading the effort on behalf of the Anesthesia Closed Claims Project/AQi. The project offices are currently housed at the Department of Anesthesiology and Pain Medicine at the University of Washington in Seattle. The case report form includes significant clinical detail. Due to its length and complexity, and data confidentiality concerns, electronic case reports are not an option at this time. Case report instructions and forms are available on the OSA Death and Near Miss Registry website: http://depts.washington.edu/asaccp/projects/obstructive-sleep-apnea-osa-death-near-miss-registry.

Cases must meet specific inclusion criteria:
1. Patient age 18 years or older at time of event
2. Event occurred in 1993 or later
3. Event or outcome occurred in 1993 or later
4. One of the following events suspected to be related to OSA or sleep-disordered breathing is present or suspected in many patients presenting for anesthetic care: OSA

• Unanticipated death suspected to be related to OSA
• Brain injury (diagnosed by a neurologist) suspected to be related to an adverse event related to OSA
• Event or outcome suspected to be related to OSA:
  – Urgent/Emergent transfer to ICU from general ward due to respiratory distress
  – Respiratory arrest (prolonged apnea not responsive to vigorous stimulation)
  – Code Blue or ACLS protocol

Case reports do not contain identifiers for patients, providers, or institutions, so they represent anonymous data. In order to protect anonymity, case reports are not linked to their source. No link is maintained between individual case reports and the person submitting the report, in order to further protect the confidentiality of the case report system and those generously sharing their cases with this project. Questions about case submission and confidentiality should be directed to Dr. Posner at posner@uw.edu or by telephone at (206) 616-2630.

Karen L. Posner, PhD, is a Research Professor, Department of Anesthesiology and Pain Medicine, University of Washington, Seattle, WA.

Norman Bolden, MD, is an Associate Professor, Case Western Reserve University, Department of Anesthesia, MetroHealth Medical Center, Cleveland, OH.

Disclosure: The authors have no financial conflicts in relation to the content of this article.

Reference:
Improving Anesthetic Safety in Low/Middle Income Countries: A Different Challenge

by Patricia Livingston, MD, and Marcel Durieux, MD, PhD

The mission of APSF is "to improve continually the safety of patients during anesthesia care by encouraging and conducting: (1) safety research and education, (2) patient safety programs and campaigns, and (3) national and international exchange of information and ideas." Whereas we focus mostly on improving anesthetic safety in the U.S., work being done in other settings fits the APSF mission statement perfectly. This article describes 2 papers published recently about anesthetic safety improvement in Rwanda.

ANTS in Africa

Rwanda, a small and densely populated country in East Africa, has about 15 anesthesiologists for 12 million people. All physician anesthesiologists work at a few university-associated teaching hospitals. In about 40 district hospitals throughout the country, technicians, who have no more than 3 years training after high school, provide all anesthesia services. They work in geographic isolation and have virtually no opportunity for continuing education. Cesarean deliveries form the majority of procedures in district hospitals, and maternal mortality is estimated at 340 deaths per 100,000 live births in Rwanda (the U.S. number is about 19*). Suboptimal anesthetic management plays an important role in this: an observational study in a Rwandan district hospital found that pre-anesthetic assessment was omitted in 95% of patients and general anesthesia with an unprotected airway was given in 84% of patients. Overall, in sub-Saharan Africa one-third of perioperative mortality for cesarean section is considered attributable to anesthesia factors.

A group of Rwandan, Canadian, and U.S. anesthesiologists set out to provide safety training. This was not an easy proposition, for both logistical and cultural reasons. Approaches to education must be culturally informed, or they will likely fail. The group therefore performed an assessment of Anesthetists' Non-Technical Skills (ANTS)—something not previously done in low/middle income countries. Through observation and interviews, they identified recurring themes that prevented providers from practicing safely. Communication, a key concept in ANTS, was found to be influenced in Rwanda by lack of resources and a formal hierarchical structure. The former led to persistent frustration, but also induced resignation to being without adequate supplies; the latter led to a fear of speaking up for safety. It is obviously difficult to maintain safety standards when critical equipment or drugs are routinely missing, and cultural barriers prevent one from voicing concern about unsafe situations.

These findings indicated that educational efforts to improve safety in the country should include training in leadership and communication skills, encouraging both role definition and speaking up for patient safety.

The SAFE Course

These concepts were subsequently applied to an educational safety initiative for anesthesia technicians to improve obstetric anesthesia practice in Rwanda. The model used was the Safer Anaesthesia From Education (SAFE) course, a 3-day refresher course developed by the Association of Anaesthetists of Great Britain and Ireland. Topics include essential obstetric anesthesia knowledge and skills, management of critical events (such as airway difficulties, hemorrhage and preeclampsia), and non-technical skills. Training-of-trainers (TOT) is embedded in the course, in order to allow subsequent courses to be given without outside support. Given the constraints identified in the ANTS study, it was clear that simply delivering educational material would not likely change habits. To ensure new knowledge would be incorporated into practice, a framework known as the Knowledge-to-Action cycle was used. Its basic premise is that learners are more likely to implement new knowledge if they perceive it relevant to their needs and appropriate to their context. Thus, the SAFE course, adapted to Rwanda circumstances, featured active hands-on learning, dialogue between participants and mentors, as well as discussions around enablers and barriers to practice change.

Ninety technicians, representing about half of the Rwanda district hospitals, participated in the course and 26 trainers were invited for TOT. Needs assessments were conducted with participants to ensure their priority topics would be well covered. Immediately before the course, a full-day workshop was held to reflect on current practice: experiences, positive and negative, were explored to identify areas of strength and weakness. During the course itself, mentors assigned to geographic regions met with small groups of participants from that area to start a program known as the Anesthesia Practice Network (APN). The purpose of APN is to support participants in practice change after the course and to reduce their sense of isolation.
Esophageal Injury During Radiofrequency Catheter Ablation for Atrial Fibrillation: Can It Be Prevented?

by Steven Greenberg, MD, FCCP and Jose Nazari, MD

Dear Q&A,

What are the patient safety and anesthesia practice implications of actively cooling the esophagus during atrial fibrillation ablations under general anesthesia?

Sam Moore, CRNA

Dear Mr. Moore,

Thank you for your inquiry. There are several potential unproven preventative measures to reduce the risk of esophageal injury. None of the present modalities are substantiated by a significant amount of quality evidence. Here is some general information regarding this important topic.

Esophageal Injury During Radiofrequency Catheter Ablation For Atrial Fibrillation: Can It Be Prevented?

Atrial fibrillation (AF) is the most common arrhythmia affecting patients around the world today. There is a 9% prevalence among those greater than 80 years old. Treatment modalities such as Radiofrequency Catheter Ablation (RCA) have become a conventional and successful way to manage symptomatic patients with drug-resistant paroxysmal and refractory AF. One worldwide survey reported that over 20,000 AF catheter ablation procedures were performed between 2003-2006. The effectiveness rate of this procedure has been reported at 60-90%. AF catheter ablation creates lesions around the pulmonary vein ostia to isolate and subsequently eliminate AF triggers. Extensive RF ablation of the posterior aspect of the pulmonary ostia and left atrium may result in damage to nearby structures such as the esophagus. Significant thermal injury can lead to the relatively common phenomenon of esophageal ulceration (6-26%) or the rare event known as atrioesophageal fistula (0.015%-0.04%). The latter complication typically results in a greater than 75% mortality rate.

Several reports suggest that the incidence of esophageal injury is higher in patients undergoing procedures with general anesthesia vs. monitored anesthesia care secondary to higher temperatures achieved with general anesthesia. The following review will discuss the controversies surrounding the strategies that seek to reduce these unwanted complications.

Several untested measures may potentially reduce the risk of esophageal injury. None of the present modalities are substantiated by a robust amount of quality evidence. Pre-procedure assessment of the esophageal position in relation to the left atrium by CT/MRI scanning may be helpful to identify those patients at higher risk for esophageal injury (e.g., the closer these structures are to one another the higher the risk of injury). The following potentially preventative methods can be instituted during catheter ablation: limiting energy delivery on the posterior wall of the left atrium (LA), esophageal cooling/insulating techniques.

LET monitoring is also a commonly employed method for reducing esophageal injury. Several studies suggest that lower LETs may result in a lower incidence of esophageal injuries. The LET must be in close proximity to the RF site in order to accurately detect higher risk situations. Suboptimal positioning of the LET monitor may result in esophageal injury despite acceptable LETs. Lastly, the LET may fix the esophagus into one position, thereby promoting contact with the LA wall. Cardiologists may use electroanatomical mapping systems to visualize the distance between the catheter tip and the esophagus as well as the location of the LET monitoring tip site. Even with LET monitoring, esophageal injuries can still be seen in up to 26% of patients.

Several temperature probes have been created to monitor temperature. The deflectable esophageal device has been reported to be more effective than other probes as it can be placed very close to the ablation site. Alternatively, the multi-thermocouple esophageal temperature probe has 3 thermocouples that can measure esophageal temperature at 3 different sites. A recent study of 100 patients undergoing RF ablation for AF compared these 2 monitoring devices. The incidence of mild to moderate esophageal injury (between 20-30%) was nearly identical in both groups. More devices are being developed to more accurately monitor temperature to subsequently reduce the risk of esophageal injuries.

See “Q&A,” Page 58

Photos of esophageal ulcerations resulting from ablation procedures without luminal esophageal temperature monitoring in 4 separate patients.
Anesthesia Patient Safety Foundation

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Esophageal Injury Can Lead to Deadly Complications

“Q&A,” From Page 55

Another potential preventative strategy is mechanical manipulation of the esophagus during catheter ablation. This maneuver displaces the esophagus away from the posterior wall of the LA. Esophageal injury can be achieved to minimize esophageal injuries by two approaches. A fluid filled balloon catheter can be directly placed into the oblique sinus to displace the esophagus away from the LA, thereby protecting it. This approach is rarely used because it is invasive and patients are susceptible to bleeding and infection. Alternatively, a cooling solution (e.g., saline) may be introduced through an oral or nasogastric tube when the LET reaches a certain threshold (typically >39°C) to reduce esophageal injury. A recent observational study of 318 consecutive patients undergoing catheter ablation for AF suggested a benefit with esophageal cooling (with 10°C saline mixed with gastrografin or iopamidol). Ninety-five percent of patients did not develop esophageal ulcers when cooling was initiated at ≥39°C. However, 4 patients in this cohort developed bronchitis from aspiration of the saline/contrast solution. All of these patients recovered within 1 week without long term sequelae. Further studies are warranted prior to routine adoption of this technique.

Atrial fibrillation is an extraordinarily common arrhythmia in clinical practice and therefore techniques such as catheter ablation are a relatively less invasive (than surgery) treatment modality employed throughout the world. However, like any other procedure, it has its own inherent risks. Catheter ablation induced esophageal ulcer is quite common, but fortunately most of these ulcers heal without reported long term sequelae. Still, many cardiologists believe that these same esophageal ulcers can be harbingers for the deadly atrioesophageal fistula complication. Several preventative modalities discussed have been proposed to reduce the incidence of esophageal injury. Further research is required in order to determine which one if not all of these techniques should be adopted by cardiologists worldwide.

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References

Are There Guidelines For Anesthesia Suction?

by A. William Paulsen, MMSC, PhD

Suction in the operating rooms where I work seems inadequate for full stomach or bleeding airways. Are there any guidelines for anesthesia suction for emergency airways?

Lana Wanstreet
West Frankfort, IL

Suction plays a critical role in the delivery of anesthesia. There is surprisingly little information about what constitutes adequate suction. The International organization for Standardization (ISO), through ISO 10079-3:2014, specifies safety and performance requirements for medical suction equipment powered from a vacuum. It applies to equipment connected to medical gas pipeline systems and other apparatus. This standard quotes a minimum air flow of 20 liters/minute. All of the

Figure 1. Suction system on several new anesthesia machines (General Electric [Aisys, Aespire, Aestiva] and from Dräger [Apollo, Fabius]) demonstrating demonstrating the step down in air flow from the wall to the tip of the Yankauer.

See “Q&A,” Next Page
Efficacy of Suction Dependent on Several Factors

“Q&A,” From Preceding Page

machines that were tested (n=5) had a mean flow at the Yankauer tip of 47.6 liters/minute.

Another standards body, the National Fire Protection Association (NFPA 99) states there must be 85 LPM flow of air at the wall with no tubing attached. In the operating rooms reported on here, the maximum flows obtained from the wall vacuum outlets were 114 liters/minute for Diamond fittings and 121 liters/minute for DISS fittings.

Figure 1 (previous page) illustrates that the suction system that was employed on the new machines from General Electric (Aisys, Aespire, Aestiva) and from Dräger (Apollo, Fabius). The figure illustrates the flow measured at the wall or column connector and the NFPA requirement for 85 liters/minute. The white color-coded hose from the Diamond fitting to the DISS fitting on the anesthesia machine, 14.5 feet long, further reduced the flow to 80.2 liters/minute where it was attached to the anesthesia machine. The regulator, trap, collection canister, and standard suction tubing with bulbous Yankauer suction brought the flow down to 47.6 liters/minute at the tip. Comparing the regulator in the full or max position (47.6 liters/minute) with the flow regulation on and set to maximum (43.9 liters/minute) the act of regulating the flow adds additional resistance to the circuit resulting in lower flows. Full suction is desired for induction and emergence of anesthesia. Regulated flow permits the anesthesia provider to set the amount of suction applied to a nasogastric tube, for example, to much lower levels to protect the lining of the stomach.

Unfortunately, the flow of air from the vacuum connector may not guarantee that there will be adequate negative pressure and flow to remove liquids through the comparatively high resistance of the Yankauer tip and the suction tubing.

Classically, in the anesthesia environment suction is assessed by permitting the clean suction tubing from the suction canister to attach to the palm or thumb of the hand. If the suction tubing remains attached to the palm or the thumb without assistance it is assumed to be adequate. Unfortunately, this assessment is really nothing more than a measure of the suction’s ability to support the weight of the suction tubing. Little suction pressure is required if there is a short unsupported length of tubing (tubing coiled on the surface of the anesthesia machine), but fairly high suction pressure is required to support the weight of the entire 6-foot length of tubing. The average weight of the Precision Medical (Northampton, PA) 6-foot suction tubing was 100.58 grams.

The pressure at which the tubing attached to the palm or thumb (Pletgo), and the pressure at which the tubing “let go” from the palm or thumb (Pattach), and the pressure at which the tubing is supported by the suction pressure when there is no flow. Remember that pressure is measured when the tubing is being supported by the suction pressure when there is no flow.

Figure 2 illustrates the flow of water obtained by different settings of the pressure regulator, and the flow of SAE 40 motor oil, which simulates very thick mucus secretions. Viscosity is the resistance to flow due to neighboring particles in a fluid, more commonly referred to as thickness, with water being the reference viscosity of 1 centipoise (cP) and blood of normal hematocrit being 3 to 6 times more viscous at 37° C (Table 1). The vertical line is drawn at the mean age pressure, the Yankauer tip could remove 2.88 liters/minute of water. If the suction tubing on a gloved hand just supported the weight of the tubing at our average pressure, the Yankauer tip could remove 2.88 liters/minute of water, or only 60 ml/minute of a

Table 1: Viscosity of various substances that may require suctioning during an anesthetic compared to the viscosity of SAE 40 motor oil.

<table>
<thead>
<tr>
<th>Viscosity in cP at room temperature</th>
<th>Reference</th>
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<tbody>
<tr>
<td>Viscosity of air</td>
<td>0.081 cP</td>
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<tr>
<td>Viscosity of water</td>
<td>1.0 cP</td>
</tr>
<tr>
<td>Viscosity of whole blood</td>
<td>3.6 to 6.0 cP</td>
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<tr>
<td>Viscosity of gastric mucus</td>
<td>75 to 230 cP</td>
</tr>
<tr>
<td>Viscosity of SAE 40 motor oil</td>
<td>650 to 900 cP</td>
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<tr>
<td>Viscosity of Sputum</td>
<td>148 cP to 15,000 cP</td>
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Figure 2. Flow of water compared to SAE 40 motor oil (simulating very thick mucous secretions) at different settings of the pressure regulator.
Viscosity is Significant Factor for Suction

“Q&A” From Preceding Page

...suction in an attempt to demonstrate the factors that contribute to having adequate suction for anesthesia. The real issues are 1) how fast the stomach contents or other substances such as blood are entering the pharynx versus how fast (flow rate) can the suction system remove them, and 2) the ability of suction to remove the substances from the glottis in adequate time so as not to significantly prolong intubation. It is important to have a suction system set to Full or Maximum that can provide removal of 2 1/2 to 4 liters/minute of water. One hopes there will be no particulate matter to clog the Yankauer tip, or fluid that is too viscous to remove quickly.

Dr. Paulsen is chair of the APSF committee on technology and director of the anesthesiologist assistant program at Quinnipiac University, Hamden, CT.

References

The APSF sometimes receives questions that are not suitable for the Dear SIRS column. This Q and A column allows the APSF to forward these questions to knowledgeable committee members or designated consultants. 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.

Rwanda Lessons Applicable to U.S. As Well

“Different Challenge” From Page 54

At the end of the course, the participants were asked to identify concrete changes they wanted to make in their practice, obstacles to those changes, and factors that would help them to make the changes. They were also provided with logbooks to record their progress. In addition, 90 Lifebox pulse oximeters were distributed to the participants as a start to country-wide distribution of 250 units. This includes training on use of the pulse oximeter, as well as an introduction to the WHO Surgical Safety Checklist.10

Going Forward

In order to assess impact, 6 months following the course, a purposeful (i.e., chosen to best enable the researchers to understand the subject being studied) sample of participants was visited and interviewed. These interviews and review of logbooks showed that real change had taken place: participants routinely performed preoperative assessment, prepared better for anesthesia, employed left lateral tilt, and managed emergencies more systematically. In addition, they felt more confident in speaking up for safety. However, resistance to change by colleagues who had not attended the course remained a problem, as were supply shortages.

To build on this momentum, a second course was held a year later for a smaller group, which (in response to feedback) also included surgeons, midwives, and nurses. Some of the TOT graduates taught

...
The Labor Epidural Time Out Checklist

by Joseph W. Myers, MD, and John Kwock, MD

The impact of The World Health Organization’s (WHO) 2008 Safe Surgery Saves Lives campaign has been significant. Further support for the initiative comes from the Joint Commission’s Universal Protocol requiring completion of a safety checklist before “all surgical and non-surgical invasive procedures.” Outside the operating room, pre-procedure checklists are used in GI Suites, Interventional Radiology units, and Vascular Labs. Labor & Delivery units should be no different. Parturients requesting a labor epidural deserve adherence to the Joint Commission’s safety standards also. Just as a surgical patient is “cleared for take-off” by completion of a checklist, a similar routine should be followed before the placement of a labor epidural. Our Labor Epidural Time Out (LETO) checklist (fig. 1), which was introduced in October 2011 and revised in May 2014, is used by all members of our Obstetric Anesthesia Team at MedStar Georgetown University Hospital.

Year after year, the Joint Commission reports errors in team communication as a significant cause of sentinel events. Various communications tools that require minimal monetary resources to implement and little time to perform on a daily basis include the “Huddle,” “Time Out,” or “Pause for Cause.” These tools enhance communication among all team members and have been shown in various settings to improve patient outcomes.

A recent meta-analysis of cohort studies utilizing safety checklists for surgery noted that “...checklists appear to be associated with” a reduction in the risk of major complications. Conducting a randomized controlled study to unequivocally prove this point would not be pragmatic since omission of the safety checklist for half of all subjects would be required.

The WHO’s original surgical safety checklist is an excellent template. With 19 items, it is both thorough and efficient. More focused on pre-surgical issues, the WHO’s recommendation to “modify and revise” is advantageous when constructing a LETO checklist. Modifications that are contextually responsive as well as revisions highlighting changing circumstances and near-miss situations maintain its high level of utility. We found that we could make better use of recently adopted electronic medical records (EMR) in our Labor & Delivery Unit after a near-miss situation—a patient received an anticoagulant before her epidural catheter had been removed. If the order for the placement of the epidural had been entered into the computer at the appropriate time, our nurses, obstetricians, and pharmacy would have been alerted to the situation by the EMR before the anticoagulant had been given. We now include, “Order for epidural in computer?” as an item on our LETO checklist; just one example of the benefit of regular checklist modifications.

With the abundance of information to be processed before placing an epidural and the speed at which the entire team moves in response to the patient in obvious pain, a sense of urgency and confusion can develop. The ability of the checklist, once completed, to reduce distraction and uncertainty, is a welcome effect, allowing for a more complete focus on the task at hand.

We are now considering the formulation of a second part of the LETO checklist analogous to the debriefing portion of the Time Out performed in the operating room. After placement of the labor epidural, we should confirm the frequency of blood pressure measurements and the blood pressure parameters to be maintained. An estimate for the time of onset of the epidural, notification of an inadvertent dural puncture, or encouragement for the patient to notify the team if the block becomes one-sided should be communicated to everyone. Finally, assuring that the nurse is aware of the anesthesia team’s contact numbers would also be practical.

Laboring women anxious for pain relief can be intolerant of delays. Some physicians also occasionally consider a safety checklist too “cumbersome” or “time consuming.” Because these attitudes are not uncommon, it is understandable that there is wide variability in the completion of the checklist. Lapses in care that would be noted by a properly conducted
**Bringing the Checklists for Safety to Labor Epidurals**

“Epidural Checklist,” From Preceding Page

safety checklist are unacceptable, but do occur. Since reading each item aloud, correcting any deficiency, and then checking the box is critical to its effectiveness, we have noted this on our LETO checklist form. Experts in human factors engineering recommend these structured communication processes along with continual revisions of the checklist content as most effective in assuring safety. They use the phrase “design trumps training” and believe that writing new policies or attempts at reeducating staff are weak responses to adverse events.

We believe that combined with improvements in the mechanics of checklist completion, development of positive attitudes can be a powerful prevention to the silence that concedes improper performance or complete disregard for a safety checklist. Ultimately, the key to success is a culture of safety that encourages and empowers all members to speak up for the safety of the patient.

Our 12-item LETO checklist has been well received by both nurses and anesthesiologists. While there is an ongoing desire to improve the checklist’s utility it should not blind us to the circumstances of our living labor patient. Labor can be anxiety-provoking, painful, and dangerous. Although safety is of utmost importance, the checklist can never be comprehensive. Careful consideration is required to balance the number of items on the checklist with the time needed for its completion. This, combined with regular revisions, will play an important role in the utility, acceptance, and support of this safety initiative.

Joseph W. Myers, MD, is an Associate Professor of Anesthesiology at MedStar Georgetown University Hospital in Washington, DC. John Kwock, MD, is a CA3 Anesthesiology Resident at MedStar Georgetown University Hospital in Washington, DC.

Disclosure: There are no financial gains associated with the writing or content of this article.

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**Highlighted Patient Safety Abstracts at the American Society of Anesthesiologists 2014 Annual Meeting**

Numerous abstracts were presented at the 2014 American Society of Anesthesiologists Annual Meeting in New Orleans, LA. Because of space limitations, we could only highlight a few of the numerous safety abstracts presented. We encourage readers to visit the ASA abstract website at http://www.asaabstracts.com/.

**Comparative Safety of Anesthetic Type for Hip Fracture Surgery in Adults (A3011)**

(Based on subsequently published retrospective cohort study with same title). BMJ. 2014;348:g302.

Patorno E, Neuman MD, Schneeveis S, Mogun H, Bateman BT.

Few interventions have been directly related to reducing mortality among patients with hip fracture. Patorno et al. conducted a retrospective cohort study to evaluate the risk for postoperative mortality comparing hip fracture patients treated with regional, general, and combined regional/general anesthesia using the Premier Perspective Comparative Database. Over 73,000 patients with hip fracture undergoing surgical repair over a 4-year period were included. After adjusting for over 60 covariates, the authors found no statistically significant difference in mortality risk associated with the use of either regional (risk ratio [RR] = 0.93, 95% confidence interval [CI] 0.78 to 1.11) or combined regional/general (RR 1.00, 95% CI 0.82 to 1.22) compared to general anesthesia. These findings suggest that the beneficial effect of regional anesthesia on short-term mortality is not nearly as robust as previously reported.

**Somatosensory Deficits from Steep Trendelenburg Position During Gynecologic Robotic Surgery (A5021)**


Our 12-item LETO checklist has been well received by both nurses and anesthesiologists. While there is an ongoing desire to improve the checklist’s utility it should not blind us to the circumstances of our living labor patient. Labor can be anxiety-provoking, painful, and dangerous. Although safety is of utmost importance, the checklist can never be comprehensive. Careful consideration is required to balance the number of items on the checklist with the time needed for its completion. This, combined with regular revisions, will play an important role in the utility, acceptance, and support of this safety initiative.

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