

# Special 35th Anniversary Jade Edition

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## NEWSLETTER

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## "What Then?" and "What Now?" 35th Anniversary Edition of the APSF Newsletter

by John Eichhorn, MD; Robert Morell, MD; and Steven Greenberg, MD

The APSF Editorial Board reviewed 35 years of APSF Newsletter articles, prior to the COVID-19 pandemic, and voted to establish the "top 10" most impactful articles to be highlighted in this special issue with the overall theme of "What Then?" and "What Now?"

Ten years ago, the APSF Newsletter celebrated its 25th year "Silver" Anniversary (<https://www.apsf.org/wp-content/uploads/newsletters/2010/summer/pdf/APSF201010.pdf>). In that commemorative edition, John Eichhorn, MD recapped the creation of the APSF and discussed

its innovative accomplishments in patient safety. That issue also focused on the challenges ahead and APSF's commitment to creating and promoting safety initiatives for improving care, research, education, awareness, and national/international exchange of information.



1986 – Reviewing the first issue of the APSF Newsletter, L-R: Burton Dole, Treasurer; Jeffrey Cooper, PhD, Executive Committee (EC); John Eichhorn, MD, Editor; Jeep Pierce, MD President; J.S. Gravenstein, MD, EC; James Holzer, EC; Dekle Roundtree, Vice President.

## ASA 1986 Monitoring Standards Launched New Era of Care, Improved Patient Safety

by John H. Eichhorn, MD

See the original article online at: <https://www.apsf.org/article/asa-adopts-basic-monitoring-standards/>

Anesthesia professionals who trained after the late 1980s have never known a time without "routine ASA monitors," often represented on the anesthesia record by a check box indicating compliance with the American Society of Anesthesiologists Standards for Basic Anesthetic Monitoring, meaning the application and correct use of routine essential monitoring.



See "New Era of Care," Page 74

### The 35th Anniversary Issue Editorials Are Based on These Original Ten Articles

- #1 ASA Adopts Basic Monitoring Standards**  
John H. Eichhorn, MD. Spring 1987. <https://www.apsf.org/article/asa-adopts-basic-monitoring-standards/>
- #2 From the Literature: ECRI Review Explains, Warns of OR Fires**  
Chester H. Lake, Jr., MD. Winter 1991. <https://www.apsf.org/article/from-the-literature-ecri-review-explains-warns-of-fires/>
- #3 Induced Hypotension Tied to Possible Vision Impairments**  
Ann S. Lofsky, MD; Mark Gorney, MD. Summer 1998. <https://www.apsf.org/article/induced-hypotension-tied-to-possible-vision-impairments/>
- #4 Special Issue: Production Pressure – Does the Pressure to Do More, Faster, with Less, Endanger Patients? Potential Risks to Patient Safety Examined by APSF Panel**  
Robert C. Morell, MD; Richard C. Prielpf, MD. Spring 2001. <https://www.apsf.org/article/special-issue-production-pressure-does-the-pressure-to-do-more-faster-with-less-endanger-patients-potential-risks-to-patient-safety-examined-by-apsf-panel/>
- #5 Beach Chair Position May Decrease Cerebral Perfusion**  
David J. Cullen, MD; Robert R. Kirby, MD. Summer 2007. <https://www.apsf.org/article/beach-chair-position-may-decrease-cerebral-perfusion/>
- #6 Managing Cardiovascular Implantable Electronic Devices (CIEDs) During Perioperative Care**  
Jacques P. Neelankavil, MD; Annemarie Thompson, MD; Aman Mahajan, MD, PhD. Fall 2013. <https://www.apsf.org/article/managing-cardiovascular-implantable-electronic-devices-cieds-during-perioperative-care/>
- #7 Monitoring of Neuromuscular Blockade: What Would You Expect If You Were the Patient?**  
Robert K. Stoelting, MD. February 2016. <https://www.apsf.org/article/monitoring-of-neuromuscular-blockade-what-would-you-expect-if-you-were-the-patient/>
- #8 National Partnership for Maternal Safety – Maternal Safety Bundles**  
Jennifer M. Banayan, MD; Barbara M. Scavone, MD. October 2016. <https://www.apsf.org/article/national-partnership-for-maternal-safety-maternal-safety-bundles/>
- #9 The Effect of General Anesthesia on the Developing Brain: Appreciating Parent Concerns While Allaying Their Fears**  
Luke S. Janik, MD. October 2016. <https://www.apsf.org/article/the-effect-of-general-anesthesia-on-the-developing-brain-appreciating-parent-concerns-while-allaying-their-fears/>
- #10 Perioperative Brain Health—It's Not All Positive Attitude, Exercise, and Superfoods**  
Nirav Kamdar, MD, MPP; Lee A. Fleisher, MD; Daniel Cole, MD. February 2019. <https://www.apsf.org/article/perioperative-brain-health-its-not-all-positive-attitude-exercise-and-superfoods/>

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## Guide for Authors

The *APSF Newsletter* is the official journal of the Anesthesia Patient Safety Foundation. It is widely distributed to a variety of anesthesia professionals, perioperative providers, key industry representatives, and risk managers. Therefore, we strongly encourage publication of those articles that emphasize and include the multidisciplinary, multi-professional approach to patient safety. It is published three times a year (February, June, and October). **Deadlines for each issue are as follows: 1) February Issue: November 15th, 2) June Issue: March 15th, 3) October Issue: July 15th.** The content of the newsletter typically focuses on anesthesia-related perioperative patient safety. Decisions regarding content and acceptance of submissions for publication are the responsibility of the editors. Some submissions may go in future issues, even if the deadline is met. At the discretion of the editors, submissions may be considered for publication on our APSF website and social media pages. Articles submitted that are not in accordance with the following instructions may be returned to the author prior to being reviewed for publication.

1. Please include a title page which includes the submission's title, authors' full name, affiliations, conflicts of interest statement for each author, and 3–5 keywords suitable for indexing. Please include word count on the title page (not including references).
  2. Please include a summary of your submissions (3–5 sentences) which can be used on the APSF website as a way to publicize your work.
  3. All submissions should be written in Microsoft Word in Times New Roman font, double-spaced, size 12.
  4. Please include page numbers on the manuscript.
  5. References should adhere to the American Medical Association citation style.  
 Example: Prielipp R, Birnbach D. HCA-Infections: Can the anesthesia provider be at fault? *APSF Newsletter*. 2018; 32: 64–65. <https://www.apsf.org/article/hca-infections-can-the-anesthesia-provider-be-at-fault/> Accessed August 13, 2019.
  6. References should be included as superscript numbers within the manuscript text.
  7. Please include in your title page if Endnote or another software tool for references is used in your submission.
- Types of articles include (1) Invited review articles, Pro/Con Debates and Editorials, (2) Q and As, (3) Letters to the Editor, (4) RAPID Response, and (5) Conference reports.
1. Review articles, invited Pro/Con debates, and Editorials are original manuscripts. They should focus on patient safety issues

and have appropriate referencing (see <http://www.apsf.org/authorguide/>). The articles should be limited to 2,000 words with no more than 25 references. Figures and/or tables are strongly encouraged.

2. Q&A articles are submitted by readers regarding anesthesia patient safety questions to knowledgeable experts or designated consultants to provide a response. The articles should be limited to 750 words.
3. Letters to the editor are welcome and should be limited to 500 words. Please include references when appropriate.
4. RAPID Response (to questions from readers), formerly known as, "Dear SIRS," which was the "Safety Information Response System," is a column that allows for expeditious communication of technology-related safety concerns raised by our readers, with input and response from manufacturers and industry representatives. Dr. Jeffrey Feldman, current chair of the Committee on Technology, oversees the column and coordinates the readers' inquiries and the response from industry.
5. Invited conference reports summarize clinically relevant anesthesia patient safety topics based on the respective conference discussion. Please limit the word count to less than 1000.

Commercial products are not advertised or endorsed by the *APSF Newsletter*; however, upon exclusive consideration from the editors, articles about certain novel and important safety-related technological advances may be published. The authors should have no commercial ties to, or financial interest in, the technology or commercial product.

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#### Additional information:

1. Please use metric units whenever possible.
2. Please define all abbreviations.
3. Please use generic drug names.
4. Please be aware of HIPAA and avoid using patient names or personal identifiers.
5. Plagiarism is strictly prohibited.

**Individuals and/or entities interested in submitting material for publication should contact the Editor-in-Chief directly at [greenberg@apsf.org](mailto:greenberg@apsf.org). Please refer to the *APSF Newsletter* link: <http://www.apsf.org/authorguide/> that will provide detailed information regarding specific requirements for submissions.**

## The Official Journal of the Anesthesia Patient Safety Foundation

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## APSF Created as a Multidisciplinary, All-Inclusive Organization

### From “35th Anniversary,” Cover Page

Ten years later we are celebrating our 35th Anniversary with the “Jade Issue.” Jade is the modern symbol for a 35th anniversary and a stone that is prized throughout the world. This symbol also represents the APSF’s recent international expansion of the *Newsletter* and outreach, which will be highlighted. We hope that this special issue will inform our rapidly growing national and international readership about the importance of perioperative patient safety and APSF’s role in continuing to improve it for our patients.

The APSF Editorial Board reviewed 35 years of *APSF Newsletter* articles, prior to the COVID-19 pandemic, and voted to establish the “top 10” most impactful articles to be highlighted in this special issue with the overall theme of “What Then and What Now?” To place these articles in proper context, past and current editors provide their perspectives on the significance and role of the *APSF Newsletter* during their tenures.

### JOHN H. EICHHORN, MD: FOUNDING EDITOR 1985–2001

When the APSF was created in late 1985, the vision was that “*No patient shall be harmed by anesthesia.*” Central to pursuing this vision at that time in history was the creation and dissemination of a journal-quality publication that would be the centerpiece of all APSF activities, the integrated “final common pathway” for communication and coordination of research, education, initiatives, and debate. With this goal in mind, the *APSF Newsletter* was born.

As difficult as it may be for many to imagine today, in 1985, there was no internet/world wide web, public email, smartphones, or Google search engine. Printed newspapers, magazines, and, particularly for health professionals, journals were the principle sources of information flow and, importantly, influence on behavior. Accordingly, the *APSF Newsletter* was established as a quarterly printed “mini-journal,” mailed to all anesthesia practitioners and related professionals in the U.S. and to selected leaders in other countries. It was printed in black and white with bright green accents that were symbolic as they matched the color of American medical oxygen tanks, with the hope of triggering an identifying familiarity in the anesthesia community.

Detailed in the 2010 25th Anniversary *APSF Newsletter* (cited on the cover page) is the remarkably serendipitous sequence of coincidences that resulted in the establishment of the APSF, especially the passion of Ellison C. (“Jeep”) Pierce, Jr., MD. He became the inaugural APSF president and then approached me and asked if I could apply my past journalism and newspaper editing experience to creating the *APSF Newsletter*.



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

Note that the APSF was specifically created as a uniquely multidisciplinary and all-inclusive organization. Its initial leadership included two CEOs of major anesthesia machine manufacturers. Launching the *Newsletter* was facilitated in large part by the inaugural APSF Treasurer, Mr. Burton S. Dole, then CEO of Puritan-Bennett Corp. In addition to 33% of the seed money to establish the APSF, he generously offered the services of his company’s in-house print shop to typeset, proof, and print the *APSF Newsletter*.

The first issue of the *APSF Newsletter* was mailed out on schedule in March, 1986, to 45,000 recipients (ASA, AANA, risk managers, and corporate and international supporters). Beyond the lead story about the creation of APSF, there was a discussion of what was required for “minimal intraoperative monitoring,” and a report on the initiation of the ASA Closed Claims Study. Other stories covered the expansion of the Confidential Enquiry into Perioperative Death in England, statistics on cardiac arrest due to anesthesia at one teaching hospital, and the relative dangers of hypoxemia and hypercarbia. The first *Newsletter* was very well received, and it set the tone for all subsequent issues. Later the first year, there were presentations of an ECRI report on “Deaths during General Anesthesia,” verification of correct endotracheal tube placement, analysis of anesthesia deaths in Australia, and a report of decreasing anesthesia claims at one major insurance company. There was also an announcement of the first FDA anesthesia machine check-out protocol and reprinting of Jeep Pierce’s important article, “Risk Modification in Anesthesiology.” Standards figured prominently in early issues as there was extensive discussion of the 1986 ASA adoption of standards for intraoperative monitoring (see article on cover page) and also a variety of evolving anesthesia machine device and performance standards (fresh gas ratio protection, vaporizer exclusion, etc.) intended to enhance safety. Strong support for the universal use of intraoperative pulse oximetry, and then capnography, was a major early APSF theme.

One additional beneficial effect of the publication of the *Newsletter* was its value in helping the foundation’s fundraising efforts. Copies were sent to corporate officers of as many companies as could possibly be identified that provided products used in anesthesia practice. Results of these efforts were positive by the end of the 1980s. One company really helped the *Newsletter*. Hewlett-Packard, Inc., donated what was then new advanced technology: a desktop personal computer, a laser printer with lots of font cartridges, a scanner, and, most importantly, what was then a state-of-the-art word processing program. By 2020 standards, all this “technology” is archaic. But then it was revolutionary. Even though for some time the submissions still arrived on paper and had to be typed in, editing was much more efficient. Eventually, technology spread, and submissions could arrive on floppy disks sent via U.S. Mail. Galley proofs at the time were printed out and cut up with scissors and arranged like a puzzle to compose the pages of each issue on a template. In the late 1990s, Puritan-Bennett was acquired (for the third time) and was no longer available to print the *Newsletter*. Fortunately, that responsibility was taken up by another generous APSF corporate supporter, Mr. Bob Black, president of AstraZeneca, PLC. Production of the *Newsletter*, which was then over 60,000 copies, was moved to Wilmington, DE, where the production contractors were supported as a donation to APSF for many years. Several of those skilled and dedicated professionals continue to produce the *Newsletter* to this day.

### Key Themes

During my 16 years as editor, the quarterly *APSF Newsletter* chronicled the now widely known story of the dramatic improvement in anesthesia patient safety, along with an abundance of features, reports, opinion pieces, controversial issues, and breaking news.

Concerns about look-alike medication labels and medication errors first appeared in the *Newsletter* in 1987 and persist today. The ASA Closed Claims Project was covered episodically as new safety issues were identified. The FDA equipment checkout protocol and checklist were first introduced to the anesthesia community in the *Newsletter*. A multitude of safety-related presentations, exhibits, and technology displays that appeared at a wide variety of meetings all over the world were routinely featured. Debates on the safety implications of practitioner fatigue, work hours, aging, and impairment, as well as discussions of obsolete equipment and reuse of disposables, appeared periodically. Off-site and office-based anesthesia came into existence during this era, and the special patient safety consequences were presented and debated in detail.

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## APSF Newsletter Circulation Grows from 36,825 to over 122,000

From “35th Anniversary,” Preceding Page

Many fundamental concepts in anesthesia patient safety and their implications for clinical practice were introduced in the *Newsletter*, including human factors in anesthesia practice, smart alarms in anesthesia delivery and monitoring systems, production pressure in clinical practice (as early as 1992 and, of course, persisting today—as are virtually all the other topics), crisis management in the OR, patient postoperative cognitive dysfunction, the danger of obstructive sleep apnea, wrong-site surgery, opioid overdose from PCA pumps, and even the Y2K computer bug doomsday predictions.

There were many “breaking news” items credited to the *Newsletter* that alerted the anesthesia community to new dangers, e.g., carbon monoxide production by carbon dioxide absorbents in certain situations, risk of succinylcholine administration in children, cardiac arrest from sympathetic blockade during spinals, neurologic complications from intrathecal 5% lidocaine administration, lidocaine toxicity from tumescent liposuction, sulfites in generic propofol causing anaphylaxis, and bacterial contamination of open propofol glass ampules. Still more “hot topics” included a recall of sevoflurane due to contamination, post-anesthesia blindness from ischemic optic neuropathy, a wide variety of equipment/supply issues (such as gas pipeline errors causing OR deaths), and specific human factors discussions, such as reading in the OR (which is now distraction from cell phone and Internet use).

At the end of 2001, I was privileged to turn over the editor’s position to a most worthy successor. Robert Morell, MD, had spent many hours helping me on the Editorial Board and then with production, all while learning the craft. He carried on mightily, bringing energy and innovation that, over his tenure, made me very proud, both of him and the *APSF Newsletter*.



During the 2001 ASA Annual Meeting, at the APSF booth, John Eichhorn, MD (left), founding Newsletter Editor, turns over the page proofs and all good wishes to his successor Editor Robert Morell, MD.

### ROBERT C. MORELL, MD: EDITOR 2002–2009 (AND CO-EDITOR WITH LORRI A. LEE, MD, 2009–2016)

I initially became involved with the APSF and the *Newsletter* in 1993 when Rick Siker, MD, put me in touch with John Eichhorn, MD, who then encouraged me to attend and report on an FDA/Anesthetic and Life Support Advisory Committee meeting pertaining to safety regarding the use of succinylcholine in children and adolescents. John Eichhorn served as a mentor to me for that first safety reporting assignment, which resulted in a pro/con column published in the *APSF Newsletter* (<https://www.apsf.org/article/in-my-opinion-a-debate-is-succinylcholine-safe-for-children/>). He continued to be my mentor for many years as he encouraged my involvement with the *Newsletter* and appointed me to the Editorial Board. Eventually I became the associate editor and then succeeded John Eichhorn as editor-in-chief in 2001.

At that time the circulation of the *APSF Newsletter* was 36,825 and printed in black, white, and green. When I stepped down as editor in 2016, the circulation had grown to over 122,000, and it was printed in full color, with excerpts that were translated into Chinese due to the inspiration and efforts of Nikolaus Gravenstein, MD, and his Chinese colleagues.

As I reflect on the changes, progress, and impact of the *Newsletter* over those 15 years, it is strikingly evident that these successes were due to the incredible efforts of a number of wonderful and talented individuals. Michael Olympio, MD, was co-founder of the **Dear SIRS (Safety Information Response System, now known as Rapid Response)** column (see page 99 for further information). He was a powerhouse leader of the APSF Committee on Technology (COT), contributing many important articles ranging from safety ramifications of anesthesia machine technology to a comprehensive review of the types of carbon dioxide absorbents and the safety ramifications of each.

Memorable *Newsletter* issues for me include a special issue on nuclear, biological, and chemical terrorism as well as the (now once again timely and important) issue on Severe Acute Respiratory Syndrome (SARS), which addressed both patient and clinician safety. Key contributions to patient safety have included extensive discussions of postoperative visual loss and ischemic optic neuropathy as well as the risks of cerebral hypoperfusion related to surgery in the sitting or beach chair position. The educational value of articles and reports and the APSF video related to intraoperative fire safety were important and extremely popular with the readership.

The *Newsletter* would not have succeeded were it not for the contributions of John Eichhorn, MD, and Editorial Board members such as Jeffery Vender, MD, Glenn Murphy, MD, Jan

Ehrenwerth, MD, Joan Christie, MD, and Wilson Somerville, PhD. Also, Sorin Brull, MD, diligently read every word of every prepublication draft in addition to providing frequent and important content pertaining to issues of monitoring neuromuscular blockade along with annual comprehensive reports of all grant recipients. Richard Prielipp, MD, former chair of the APSF Education Committee has always been a role model and was the inspiration and facilitator for the initial and ongoing relationship between the *APSF Newsletter* and the journal, *Anesthesia and Analgesia* (A&A). A long-ago meeting in Chicago between Richard, myself, and then A&A Editor Steve Shafer, MD forged that incredibly important collaboration between the APSF and A&A, ably cultivated for many years by Sorin Brull and now Richard Prielipp.

Lorri Lee, MD, a world-renowned expert in neuroanesthesia and postoperative visual loss rose from Editorial Board member to associate editor and soon became co-editor. Lorri Lee, along with Bob Caplan, MD, and Karen Posner, MD, also provided ongoing guidance and content gleaned from their expertise in the ASA Closed Claims Database.

Steven Greenberg, MD, with tremendous expertise in critical care, cardiac anesthesia and neuromuscular blockade, contributed many important articles and provided amazing academic credibility and inspiration. Steve started as an Editorial Board member and soon rose to assistant and then to associate editor and finally became editor-in-chief upon my retirement. He has recently made the *Newsletter* even more influential as well as a truly international publication.

Over the 23 years of my involvement with the APSF, I was fortunate to participate in many important initiatives that have greatly improved patient safety. The *Newsletter* has always been, and continues to be, the face of the APSF, the means of communicating important and often critical information, and now, under the leadership of Steven Greenberg, serves as an international education tool. The *Newsletter* enjoys the largest circulation of any anesthesia publication in the world. None of this would have been possible without the support and guidance of former President Bob Stoelting MD, the Executive Committee, the Board of Directors, and most importantly, the Editorial Board. In memoriam, Rick Siker, MD, Jeep Pierce, MD, and J.S. Gravenstein, MD, were giants in patient safety and I was truly blessed to have known them and been inspired by them. I will always be grateful to all who have dedicated their selfless efforts and expertise and for the opportunity to have contributed to the *APSF Newsletter* and patient safety.

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# APSF Newsletter Now Available in Six Different Languages

From “35th Anniversary,” Preceding Page

**STEVEN B. GREENBERG, MD:**  
**(CO-EDITOR WITH LORRI A. LEE, MD, 2017)**  
**EDITOR-IN-CHIEF 2018–PRESENT**

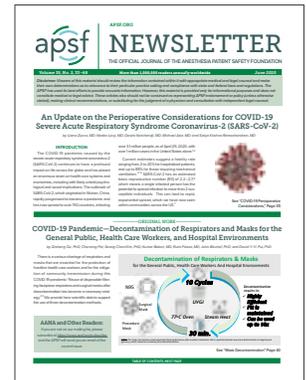
Mentorship is a relationship where a more experienced or knowledgeable person helps to guide a less experienced or knowledgeable person in a particular field or effort. It is the quintessential component to initiate and perpetuate successful patient safety endeavors. I have been fortunate enough to follow in the footsteps of “greatness.” From the moment one of my mentors, Jeffery Vender, MD, brought me to my first APSF Editorial Board meeting in 2007, I could see that room was filled with giants in the field of anesthesia patient safety. In particular, my predecessors, John Eichhorn, Robert Morell, and Lorri Lee clearly “walked the walk” when the time came to move the needle forward for safe perioperative patient care.

### Patient Safety Initiatives Abound in the APSF Newsletter

The mentorship of John Eichhorn, Robert Morell, and Lorri Lee guided my efforts to build on the already successful enterprise of the APSF Newsletter. With their tutelage and my desire to continue the great traditions of the educational aspect of the Newsletter, we have strengthened our educational endeavors to address the 12 APSF patient safety initiatives that were voted on by our multidisciplinary, multiprofessional APSF Board of Directors. These are: 1) Preventing, detecting, and mitigating clinical deterioration in the perioperative period; 2) Safety in non-operating room locations; 3) Culture of safety; 4) Medication safety; 5) Perioperative delirium, cognitive dysfunction, and brain health; 6) Hospital-acquired infections and environmental microbial contamination and transmission; 7) Patient-related communication issues, handoffs, and transitions of care; 8) Airway management difficulties, skills, and equipment; 9) Cost-effective protocols and monitoring that have a positive impact on safety; 10) Integration of safety into process implementation and continuous improvement; 11) Burnout; and 12) Distractions in procedural areas. In addition, we have highlighted other important topics such as safe management of COVID-19 patients, local anesthetic systemic toxicity, alarm fatigue, and opioid-induced ventilatory impairment.

### Diverse Editorial Expansion

The APSF has added to the Newsletter several excellent, talented editors, including Edward Bittner, MD, PhD, from Massachusetts General Hospital, Jennifer Banayan MD, from Northwestern Memorial Hospital, and Meghan Lane-Fall, MD, from the Perelman School of Medicine, University of Pennsylvania. These editors bring a vast amount of knowledge and expertise that continue to allow the APSF Newsletter to educate our readership on a broad scope of perioperative safety issues. In



The APSF Newsletter through the years, starting with the original design under John Eichhorn; changes to the logo and format under Bob Morell; and our latest edition with the new branding under Steven Greenberg.

addition, our Editorial Board has also expanded to include every specialty within anesthesia and a multiprofessional presence. Finally, the APSF Newsletter in its current updated form, wouldn't be what it is today without the incredible creativity and continued devotion of Bonnie Burkert and Jay Mahanna from MEBU Design & Marketing and the continued work of Celeste Pates, our project manager.

### Communications Greatly Expand Scope

With our investment in communications, the APSF has hired Mike Edens and Katie Megan from EdensWork, who have done an extraordinary job with helping the website grow and expand our global reach. The leadership and tireless work of both Arney Abcejo, MD, APSF website director, and Marjorie Stiegler, MD, APSF social media director have allowed the APSF Newsletter to occupy many different spaces in the complex digital world we know today. Edenswork has provided the APSF Newsletter with data analytics on unique visitors to each article that we publish both nationally and internationally. With this analytic information, we are now able to select topics which best target our constituency with especially relevant patient safety information.

### APSF Newsletter: An International Safety Educational Tool

In its original 1985 mission, one of the three axioms that the APSF wanted to promote was “national and international exchange of information and ideas (APSF Newsletter. 2010;25:21). Safe anesthesia care has no boundaries and, therefore, we have worked to establish an international translation program for the Newsletter. An article regarding the culture of Japanese anesthesia in 2016 by Katsuyuki Miyasaka, MD, sparked the creation of relationships with Hiroki Iida, MD, PhD, Tomohiro Sawa, MD, PhD, and many others to form the first-ever translated APSF Newsletter version in Japanese in 2017. This landmark issue provided a foundation for the development of countless other relationships with international safety professionals to develop and translate the APSF Newsletter to Chinese, Spanish, French, and Portuguese. Our

international family of reviewers have provided insightful feedback on their relationship with the APSF (please see page 77). With continued engagement from our international reviewers, our editor group has developed an international editorial board which has over 10 active members and continues to grow.

The addition of our international program has increased our overall presence and allowed further expansion of safety knowledge for anesthesia professionals worldwide. Since its inception in 2017, the number of online unique visitors to the international newsletter has grown 3000% to approximately 370,000. In addition, with our efforts during the COVID-19 pandemic to inform our readership of the most up-to-date practices, the number of Newsletter unique visitors has grown 120% to 676,402. We plan on translation of the Newsletter into additional languages, and we will continue to strive towards disseminating current safety knowledge and practices to anesthesia professionals throughout the world to help keep all our patients safe.

The future is bright for patient safety in anesthesia care. We hope to combine education, research, initiatives, and outreach to further promote our vision that “No patient shall be harmed by anesthesia care,” and to continue to strengthen APSF's reputation as an international hub for anesthesia patient safety information.

*John Eichhorn, MD, was the founding editor and publisher of the APSF Newsletter. Living in San Jose, CA, as a retired professor of Anesthesiology, he continues to serve on the APSF Editorial Board.*

*Robert Morell, MD, was past editor-in-chief of the APSF Newsletter. He is a private practice anesthesiologist in Niceville, FL.*

*Steven Greenberg, MD, is current editor-in-chief of the APSF Newsletter. He is vice chairperson, Education, in the Department of Anesthesiology, Critical Care and Pain Medicine at NorthShore University HealthSystem and clinical professor in the Department of Anesthesia and Critical Care at the University of Chicago.*

The authors have no conflicts of interest.

# Continuous Pulse Oximetry Becomes Official Standard of Care in 1989

## From “New Era of Care,” Cover Page

How those precedent-setting standards—the first ever detailed, explicit, minute-to-minute requirements for daily procedural practice in modern health care—came to be, and their implications for improved safety of all anesthetized patients, is a story that debuted in one of the very early issues of the *APSF Newsletter*.<sup>1</sup>

The ASA House of Delegates adopted the monitoring standards as official policy at the October, 1986 Annual Meeting. In spite of advance notice, discussion, and advocacy “politicking,” there was initially some concern by the organizers and sponsors of the resolution that there could be opposition to the proposed standards simply because people (and likely physicians in particular) often do not like being told what they must do. However, the proposed elements of conduct during all anesthetics for surgery (labor epidurals were excluded) were so logical as to be essentially obvious and were already being practiced in their own way by a majority of American anesthesia professionals. The resolution passed easily.

## THE ORIGINAL STANDARDS

Formulated and offered to the ASA membership by the brand-new Committee on Standards of Care, the original ASA monitoring standards were simple and straightforward. They opened with some caveats recognizing that there might be circumstances in which the standards could not be followed. There were even explicit definitions of the words “continuous” and “continual” in order to provide perfectly clear understanding of the requirements. The first standard mandated that qualified anesthesia personnel be present in the room throughout the conduct of all anesthetics. However obvious this may be to anesthesia professionals in 2020, the fact is that even into the 1980s, it was not unheard of for anesthesia practitioners to leave a patient on a ventilator in an OR in order to take a break or secure medication/equipment. Well-publicized sad (and expensive) patient-injury accidents resulting from that old habit motivated the ASA standards committee to make it explicitly clear that this practice would be absolutely forbidden.

A critical point that possibly was not emphasized enough to the broad anesthesia community at the time was the very important distinction between behavior and technology. The goal of the *behavior* that would come to be known as “safety monitoring” for the anesthetized patient was to provide the earliest possible warning of untoward dangerous developments during anesthesia that, unrecognized or left unattended, would injure the patient (the definition of a “critical incident”), providing time for diagnosis and treatment before injury could occur. While *technologic devices* were prescribed or encouraged as *methods* to affect the behaviors and, understandably, later became the focus of the implementation of the standards, the real underlying *objective* was

to create a required environment of continuous, every-moment attention to the key monitoring elements. Accordingly, with the monitoring standards, forever abandoned and laid to rest then was the stereotyped “old way” of about every five minutes scanning around the anesthetizing location to see if things looked okay, recording vital signs on the handwritten anesthesia record, and then, for some practitioners, returning attention to the crossword puzzle, stock market pages, or whatever (as sometimes satirized in cartoons or by surgeons).

The second of the two standards consisted of a section for each of the four elements of classic monitoring: oxygenation, ventilation, circulation, and temperature. For clarity, each section first stated the objective for the monitoring and then the *methods* specified to meet that objective.

Oxygenation monitoring first required an inspired gas oxygen analyzer. Tragic accidents had occurred from accidental discontinuation of O<sub>2</sub> flow, either from user error or supply failure. Then, blood oxygenation was the main focus of the desire for the earliest possible warning of developing hypoxemia. “Qualitative signs” (patient color) were mentioned, and pulse oximetry was only “encouraged” in the original 1986 version. This was somewhat controversial because some anesthesia professionals already recognized the unique value of pulse oximetry and thought it should be mandatory. The instruments were just coming into wider use in early 1986. Wanting to avoid mandating a technology not yet universally available and knowing it would soon become a required standard, the committee elected to wait for the inevitable first revision of the standards, which came in 1989, when continuous pulse oximetry during anesthesia care became the official standard of care across the profession.

Monitoring ventilation, the heart of anesthesia care, received the most attention in the original standards, which called for the continual qualitative evaluation of ventilation. Again, the technology of capnography was just becoming more widely available and its use for both verification of correct endotracheal tube placement and continuous ventilation monitoring was “encouraged,” but not yet officially mandated (which was done in subsequent years). Also, based on a significant number of anesthesia injury accident reports, use of a ventilator disconnect monitor with an audible alarm was mandated as the standard of care during mechanical ventilation. Finally, as a harbinger of things to come in later years, “the adequacy of ventilation shall be evaluated, at least, by continual observation of qualitative clinical signs” during regional anesthesia and monitored anesthesia care.

Monitoring of circulation included mandatory continuous ECG tracing display, measurement of blood pressure and heart rate at least every 5 minutes, and continual evaluation of circulatory function in any of various ways, but particu-

larly including mention of the plethysmograph of a pulse oximeter tracing.

Temperature monitoring, initially and then for many years, was the “fuzziest” of the standards. An immediately available means of temperature monitoring was required along with the well-known mandate: “When changes in body temperature are intended, anticipated or suspected, the temperature shall be measured.”

## GENESIS OF THE STANDARDS

Starting in the mid 1970s, there was a critical explosion of medical malpractice lawsuits in the U.S. (the “malpractice crisis”) resulting in extremely expensive and dramatic settlements and jury awards from anesthesia accidents, all of which received widespread publicity, particularly from a 1982 ABC Television special about anesthesia catastrophes: “The Deep Sleep: 6000 Will Die or Suffer Brain Damage.” 1984 ASA President, the late Ellison C. (“Jeep”) Pierce, Jr., MD, of Harvard (and later the inaugural President of the APSF) was profoundly concerned about this problem, particularly anesthesia fatalities caused by very late recognition of accidental incorrect placement of endotracheal tubes into the esophagus. He proposed and initiated the creation of the ASA standards committee, urging it to address these issues. Burton S. Epstein, MD, from George Washington, was chairman, and John H. Eichhorn, MD, of Harvard was the secretary, who brought the not-yet-published “Harvard monitoring standards”<sup>2</sup> to the committee as an example of an approach taken in an attempt to reduce preventable severe anesthesia accidents. In the early 1980s at Harvard’s 9 teaching hospitals, anesthesiologists constituted 3% of the faculty (common at the time), but accounted for over 12% of the malpractice insurance pay-outs, which approximated the national statistics.<sup>3</sup> This perceived excessive danger led a “Harvard risk management committee” chaired by John Eichhorn to create a 1985 set of anesthesia standards as a response, and these Harvard standards became a template for the ASA subsequent efforts, as comparing the two makes apparent. Both committees understood that it was critical to impress upon anesthesia professionals the necessity of changing behavior in order to help prevent injury accidents. Accordingly, first at Harvard, and then by the ASA, the proposed intra-operative monitoring efforts were not labelled “recommendations” or “guidelines,” but, rather, specifically “standards of care.” This fact had enormous medical-legal implications and was unprecedented in American health care. When the ASA published detailed, required “standards” for practice, any accident causing patient injury during willful deviation from these standards would be a guaranteed automatic loser in a malpractice lawsuit—an obvious incentive for all practitioners to implement the monitoring prescribed by the standards.

See “New Era of Care,” Next Page

## Literature Suggested Fivefold Reduction in Anesthesia-Related Catastrophic Events with Adoption of Standards

From “New Era of Care,” Preceding Page

As noted, many, if not most, anesthesia professionals had already adopted their own personal versions of several of the ideas. The published standards codified and clarified the required behaviors, prodded reluctant/resistant practitioners into compliance, and, importantly, introduced the concept of significantly enhancing the sensitivity and specificity of the human senses through application of the then-brand-new and genuinely innovative electronic monitoring technologies of pulse oximetry and capnography. The goal of this organized approach was to provide the earliest possible warning of any dangerous clinical developments, thus providing ample time for diagnosis and remedy before patient injury could occur. The fundamental idea of these standards constituted a “game-changer” for the anesthesia profession, as the late Paul G. Barash of Yale declared in 2015.<sup>4</sup>

### VALIDATION

In the late 1980s, it was quickly recognized that there would never be a prospective, controlled, randomized, “ $p < 0.05$ ” clinical trial to test the efficacy of “safety monitoring” as embodied in the monitoring standards. The cohorts would require truly massive numbers to hope for meaningful statistics regarding very low-frequency events, but, more importantly, the “no monitoring” control group would be both unethical and impossible to have patient-informed consent. However, a 1989 detailed retrospective analysis<sup>5</sup> of the catastrophic anesthesia accidents among 1,001,000 ASA Class I and II patients at the Harvard hospitals that prompted the original concerns there suggested that the large majority of the injury accidents (representing 88% of the malpractice insurance pay-out) prior to the implementation of the “safety monitoring” specified in the standards would have been prevented by those strategies. A subsequent review<sup>6</sup> covered additional patients and showed a more than fivefold reduction (to essentially zero) in catastrophic accidents after adoption/implementation of the

standards. Probably the most significant validation of the concepts of safety monitoring in the monitoring standards, however, was the dramatic reduction in malpractice insurance costs to anesthesiologists. This trend was seen throughout the country,<sup>7</sup> and, in 1990, the ASA leadership suggested: “Abiding by the ASA Standards for Basic Intra-Operative Monitoring and using pulse oximetry and capnography may result in significant savings for anesthesiologists now negotiating new policies.”<sup>7</sup> The impact was particularly noted at Harvard, where, in 1989, malpractice insurance cost was cut 33% in one year.<sup>3,8</sup> Overall, between 1986 and 1991, as personally experienced by this author, there was a 66% reduction in insurance premiums paid by anesthesia faculty. Because insurance company actuaries are inherently not charitable, this dramatic decrease resulted from the simple fact that there were far, far fewer and less severe anesthesia accidents, providing a form of “proof” (other than  $p < 0.05$ ) that the monitoring concepts in the standards improved anesthesia patient safety.

### SUBSEQUENT EVOLUTION

The ASA Standards for Basic Intra-Operative Monitoring have been expanded slightly and tweaked several times in the more than 30 years since their adoption, including a name change to “anesthetic” monitoring<sup>9</sup> to reflect their expanded scope, particularly the requirement for continuous capnography during all moderate or deep sedation (again reflecting the preeminence of ventilation in anesthesia care). However, all the original core elements, and their impact, persist. In part because of the enormity of the medical-legal implications, it is highly unlikely that the ASA will create any new detailed “standards of care” in the future. Furthermore, the ASA standards committee is now the “Committee on Standards and Practice Parameters.” The current approach to developing and implementing practice parameters (which, some can and do argue, are treated by plaintiffs’ malpractice attorneys as effectively standards of care) is staunchly evidence-based, involving

exhaustive literature searching by cybrarians, intense professional statistical review and meta-analysis, and painstaking review and debate by subcommittees and the Committee on Standards and Practice Parameters, and the



John H. Eichhorn, MD

ASA House of Delegates. It could be imagined that a future generation of brain/CNS monitoring technology would claim to promote smoother general anesthesia using less anesthetic medication and faster recovery with lower incidence of cognitive disruption. It might then evolve to a status of performance and confidence that would meet the rigorous criteria for endorsement in an ASA practice parameter (even possibly establishing a new *de facto* standard of care). If so, this definitely would be announced on the front page of the *APSF Newsletter*, just as were the original monitoring standards in 1987. Times have evolved, however, and there is no real parallel with the *ad hoc* process of the 1980s generated by the acute need to address a perceived crisis. That process worked well at that time. The ultimate results, still immediately relevant today, changed fundamental anesthesia practice forever and, consequently, improved patient safety.

*John Eichhorn, MD was the founding editor and publisher of the APSF Newsletter. He lives in San Jose, CA, as a retired professor of Anesthesiology, and continues to serve on the APSF Editorial Board.*

*The author has no conflicts of interest.*

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### ASA/APSF Ellison C. Pierce Jr., MD, Patient Safety Memorial Lecture



Anesthesia  
Patient Safety  
Foundation



### Is Safety Becoming the Poor Stepchild of Quality?

Annual Meeting of the American Society of Anesthesiologists

Presented by: Matthew B. Weinger, MD, MS

**Saturday, October 3, 2020**  
**10 am–11 am, CT**



Matthew B. Weinger,  
MD, MS



# Thank you APSF for 35 years of dedication

You have been a leading voice for anesthesia safety and have provided guidance, thoughtful counsel, and crucial resources to the anesthesia profession. Congratulations!

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# The International APSF Newsletter Community Continues to Grow

## JAPANESE TEAM: 2017—present

When the APSF was founded in 1985, safety issues in anesthesia in Japan were more of a personal nature involving ethics and discipline. The importance of keeping direct physical contact with the patient and the use of continuous monitoring with a monaural precordial stethoscope, especially in the field of pediatric anesthesia, where rapid changes in vital signs are the norm, was (and still is) of paramount concern. It was frightening to see the lack of physical contact or use of monitors in adult practice, except for the use of ECG. Pulse oximeters were not readily adopted and at some hospitals thought of as a nuisance, and not of value. Little effort was made to take advantage of their potential, until finally their usefulness was recognized. The present situation with capnometers is similar around the world, where their use with non-intubated and sedated patients has not become routine practice.

The “No Patient Shall Be Harmed By Opioid-Induced Respiratory Depression” campaign, an outstandingly proactive idea, led by the APSF in 2011 prompted me to champion the concept in Japan where a significant language barrier exists. Many of us understand English, but the knowledge has to be translated into our own language to make a lasting memory. Fortunately,



discussion about the possibility of an international newsletter occurred with Prof. Steven Greenberg, MD, in Tokyo at the IAMPOV meeting in October 2015, and at a subsequent discussion with Robert Stoelting, MD, past president of the APSF, in 2016 at ASA in Chicago. Prof. Greenberg moved very swiftly for us as did Mark Warner, MD, the current president of APSF, and Prof. E. Inada, ex-president of the Japanese Society of Anesthesiologists (JSA). Professor H. Iida, chairman of the anesthesia safety committee of the JSA was appointed as the person in charge of this project.

The first *Newsletter* in Japanese was released on November 2017, and notices of subsequent *Newsletters* were put in JSA's newsletters with 12,000 member-anesthesiologists taking advantage of reading selected articles in their own language. Many thanks are due to Prof. Greenberg, a man of action. We are so grateful to the APSF for their generous offer and support. With your support, we can continue to devote our attention to improving anesthesia patient safety.

We understand that the *APSF Newsletter* is now translated into four other languages. We respect the APSF as a true international pioneer and leader in anesthesia patient safety, actually

executing international leadership in the extremely difficult inward-looking political environment of so many countries. We admire the ability and energy that the APSF pours into its mission and the leadership of Prof. Warner, president of the APSF.

We look forward to the continued activity of the APSF in the international sphere and to expansion of its role in supporting scientific research and thought in medicine. This work is increasingly important given the pandemic and volatile political situation throughout the world. The importance of patient safety is a core value and we hope (y)our mission succeeds.



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**Tomohiro Sawa, MD, PhD**  
Professor in Anesthesia, Teikyo University School of Medicine, Tokyo, Japan

## CHINESE TEAM: 2018—present

From 2014, when we started off by translating select articles from *APSF Newsletters*, to now translating and publishing every edition on the Chinese Society of Anesthesiology websites and social media, APSF has grown to reach physicians all over China. Through our translations, we have been able to raise awareness on important perioperative safety measures and steps in quality patient care in China. These collective efforts have promoted anesthesia professionals to take ownership in implementing and



improving safe patient care. We would like to congratulate APSF on 35 years of advocacy for patient

safety, educating providers in America and all over the world.



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**Bin Zhu, MD, PhD**  
Professor and Vice Chairman, Department of Anesthesiology, Peking University International Hospital

## PORTUGUESE TEAM: 2018—present

The partnership between the São Paulo State Society of Anesthesiology (SAESP) and the *APSF Newsletter*, through well-planned content, has contributed a lot to enhance the discussion on patient safety.

Sharing experiences on a global level brings the lessons learned and the exchange of experiences as an important tool to build a positive safety culture in the engagement of the Society of Anesthesiology of the State of São Paulo with patient safety.



**Rita de Cássia Rodrigues, MD, PhD, MBA**  
SAESP President



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**Guilherme Henryque da Silva Moura, MD, MBA**  
SAESP Quality and Safety Coordinator

From "International," Preceding Page

**FRENCH TEAM: 2018—present**

**SFAR/APSF Collaboration: Another Step Towards The Common Goal of Patient Safety**

*Theissen A, Blanie A, Bordes J, Bordes-Demolis M, Bourgain JL, Fletcher D, Kurrek M, Lemarie J, Morau E, Pelligand L, Picard J, Piriou V, Soufir L, Trouiller P. From the Risk Analysis and Management Committee of the French Society of Anesthesia and Intensive Care Medicine*

A partnership was created in 2018 between the SFAR (French Society of Anesthesia and Intensive Care Medicine), under the auspices of the CAMR (Risk Analysis and Management Committee), and the Anesthesia Patient Safety Foundation (APSF). This new link that unites us was forged by the common desire to improve the safety of patients over the course of the perioperative period.



The CAMR is the task force of the SFAR that has been assigned the objective of analyzing the potential risks for patients and promoting strategies to overcome these risks.

Just like the APSF, in recent years the CAMR has worked on issues aimed at improving the quality and safety of anesthesia and intensive care: the creation and the dissemination of cognitive aids or crisis checklists, the formulation of recommendations for clinical practice (such as the prevention of medical errors, monitoring during patient transport to the postoperative anesthesia care unit and in the hospital, reducing distractions in the operating theatre, safeguarding of the

administration of opioids, and modalities for monitoring), partnering with insurance companies to provide information based on the analysis of the closed claims, fact sheets (e.g., transfers to the ICU, prevention of errors involving the wrong side, etc.)

The APSF and the SFAR hence have the same objectives of continued improvement of safety in anesthesia with zero tolerance for incidents. We are proud to join forces and we need everyone to participate in this endeavor. It is with this in mind that the CAMR helped to create a French version of the APSF Newsletter that is published by the APSF and distributed among its French constituency.



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**SPANISH TEAM: 2018—present**

Although a large number of Spanish speaking anesthesia providers can read scientific literature in English, translating the APSF Newsletter into their native tongue adds a new dimension. It assures that no one is left behind with the vital message and information the APSF brings. The effort on behalf of the organization and the editorial group to translate the Newsletter into several languages has been tremendous; and therefore, we are thankful for this. Carrying the flag of "safety" for such a long time is a testament to the role APSF plays.



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Consultant in the Department of Anesthesia and Critical Care, Hospital Universitario Fundación Alcorcón, Madrid, Spain



It is a great honor for Spain and SENSAR to be a part of such an amazing initiative in the history of the APSF to make its contents available in different languages, and in our case for the Spanish-speaking world. We consider availability of information a milestone to promote a culture of patient safety.

*Anesthesia Team at Hospital Universitario Alcorcón; standing from the left: Miriam del Vals (nursing assistant, Santiago Garcia del Valle (Chief of Staff), Rodrigo Molina (Anesthesiologist, Board Member of SENSAR, reviewer of the Spanish APSF Newsletter), Sara Garcia (Anesthesiologist), Antonion Bartolomé (Anesthesiologist, co-founder of SENSAR), Rocío Albarran (nurse). Below from the left: Lourdes Garro and Elena Garcia (nursing assistants), Maite Fernandez (nurse), Angel (patient recovered from Covid-19 in our unit)*

# Our Founders and Their Gift of Core Principles

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

Thirty-five years ago, leaders from the American Society of Anesthesiologists (ASA) and corporations that provided key technologies and pharmaceuticals for anesthesia practices joined forces through the establishment of the Anesthesia Patient Safety Foundation (APSF) to improve the safety of patients receiving anesthesia care. Their collaboration was novel and has led to a sustained and remarkably successful focus on anesthesia patient safety.

Measurement of improvement is challenging as many perioperative factors play important roles. However, by almost any measure it is clear that intraoperative safety of patients has increased dramatically during the 35-year span.

In retrospect, what key factors have contributed to this success?

## TRUST AND A SHARED VALUE

The ASA, through the APSF, was one of the first American medical professional organizations to integrate corporate leaders onto medical foundation boards. Whatever concerns there were about potential conflicts of interest were negated by the shared value of patient safety. The trust between and amongst the anesthesiology and corporate founding members of APSF proved crucial to the foundation's initial successful impact on anesthesia patient safety. These pioneering leaders were able to bring competing corporations and their knowledge and technologies together in the interest of improving patient safety, with the foundation's anesthesia professionals providing ideas and corporations developing the technologic



and pharmacologic advances. It is gratifying that this focused medical-corporate partnership, based on trust and a shared value of patient safety, continues today. The partnership has expanded and now includes input from the full scope of anesthesia professions, leaders from perioperative organizations such as the Association of PeriOperative Registered Nurses and the American Society of PeriAnesthetic Nurses, surgical organizations, risk management companies, and regulatory agencies.

## CREATION AND IMPLEMENTATION OF NEW PATIENT SAFETY KNOWLEDGE

APSF founders understood that anesthesia care at the time was being delivered with a paucity of knowledge related to patient safety and was subject to individual provider variations in skills and knowledge. The founders created an initial mission to foster investigations that provided a better understanding of preventable anesthetic injuries. The ASA, corporate supporters, and individuals donated the financial



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

support to develop the world's first dedicated anesthesia patient safety grant program. A very unique characteristic of this program was the availability of its support to non-anesthesia investigators (e.g., patient safety and organizational scientists, sociologists, and others). Today, this program continues and has awarded more than \$13.5 million to 145 principal investigators. The results of the studies by these investigators have played outsized roles in our understanding of anesthesia patient safety and led to dramatic improvements in patient outcomes.

See "Core Principles," Next Page

# APSF Newsletter Around the World, cont'd

From "International," Page 78



Steven Greenberg, editor-in-chief of the APSF Newsletter, with Gerardo Prieto, safety officer for The Mexican Federation of Anesthesiologists.



International Editorial Board meeting of the APSF Newsletter.



## ANNOUNCES THE PROCEDURE FOR SUBMITTING GRANT APPLICATIONS

FEBRUARY 18, 2021, IS THE DEADLINE

TO SUBMIT LETTERS OF INTENT (LOIs) FOR AN APSF GRANT TO BEGIN JANUARY 1, 2022

- LOIs will be accepted electronically beginning January 8, 2021, at: [apply.apsf.org](http://apply.apsf.org)
- The maximum award is \$150,000 for a study conducted over a maximum of two years to begin January 1, 2022.
- Based on the APSF's Scientific Evaluation Committee's review of these LOIs, a limited number of applicants will be invited to submit a full proposal.

Instructions for submitting a Letter of Intent can be found at:

[http://www.apsf.org/grants\\_application\\_instructions.php](http://www.apsf.org/grants_application_instructions.php)

## The APSF Core Principles Have Not Changed Over 35 Years to Keep Patients Safe

From "Core Principles," Preceding Page

### DISSEMINATION OF PATIENT SAFETY INFORMATION AND IDEAS

APSF was specifically tasked from the start to promote national and international communication of information and ideas about the causes and prevention of anesthetic injuries. The *APSF Newsletter* has been one of the most widely distributed and read anesthesia publications worldwide. In the past few years, its efforts to improve the international dissemination of anesthesia patient safety information have expanded. It is now published in six languages and has readers from every country in the world. More than 1.5 million pages of its content were viewed this past year. The *Newsletter* provides current information on the APSF's priority patient safety issues as well as other safety topics that are important to anesthesia professionals globally.

### LASER FOCUS ON PATIENT SAFETY

By design, APSF targets a single goal of improved anesthesia patient safety. The core principles of the APSF have changed little over its first 35 years. This is a remarkable strength of the foundation, resulting in a consistent as well as persistent focus on patient safety. As a small foundation, it can be nimble and flexible in addressing priority issues. If one approach does not work, others can be taken and their success rapidly assessed. In addition, the foundation is apolitical, allowing it to avoid distracting controversies.

Indeed, the first 35 years have brought great success, but much more is needed to ensure that patients who undergo anesthesia care are safe throughout the full extent of their perioperative care. For example, we need to direct efforts towards:

- The well-being of colleagues who provide perioperative care as it is increasingly clear

that impaired anesthesia and other health care professionals negatively impact patient safety. To that end, the APSF has modified its vision statement to be inclusive of all health care professionals as well as patients. It now reads, "that no one shall be harmed by anesthesia care."

- Research and implementation of effective clinical improvement programs that are directed towards patient safety during the entire span of perioperative care. The APSF is teaming with foundations and organizations within anesthesia such as the Foundation for Anesthesia Education and Research and the World Federation of Societies of Anaesthesiologists as well as those not typically considered within the anesthesia realm such as the Patient Safety Movement Foundation, American College of Surgeons, and the Institute for Safe Medication.
- Initiatives to disseminate patient safety information more broadly. The *APSF Newsletter* is expanding to include a new online component and additional translations are being considered. The *Newsletter* currently is available in English, Japanese, Chinese, Portuguese, Spanish, and French. APSF's social media initiatives are growing to allow the foundation to better reach the newest generation of our colleagues around the world. Facebook, Twitter, Instagram, and podcasts are now part of the APSF's social media family and are growing in popularity.

### THE FUTURE AND CORE PRINCIPLES

While it is not possible to project what the next five, and certainly 35 years will bring, APSF has long-standing core principles that will focus its patient safety efforts far into the future. While much in the foundation may change over time, it is these core principles that will sustain its



Mark A. Warner, MD      Robert K. Stoelting, MD  
Current APSF President      Past APSF President

positive contributions to anesthesia patient safety. These principals are

- Identifying safety initiatives and creating recommendations to implement directly and with partner organizations
- Being a leading voice for anesthesia patient safety worldwide
- Supporting and advancing anesthesia patient safety culture, knowledge, and learning.

We extend our sincere thanks to the APSF's founders and their initial vision "that no patient shall be harmed by anesthesia." Their contributions to the specialty of anesthesiology and all our patients deserve our highest praise, and we hope that we can emulate their achievements far into the future.

*Mark Warner, MD, is currently president of the APSF and the Annenberg Professor and former chair of Anesthesiology, Mayo Clinic, Rochester, MN.*

*Robert Stoelting, MD, is immediate past president of the APSF and emeritus professor and chair of Anesthesiology, Indiana University, Indianapolis, IN.*

*The authors have no conflicts of interest.*



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Nellcor™ pulse oximetry and Puritan Bennett™ ventilation — our trusted brands — were founding members of APSF in 1986. We are proud to be a legacy partner of APSF, working to help ensure that no one is harmed by anesthesia care. We continue to support the foundation in its promotion of safety awareness, and we've helped further anesthesia research by funding unrestricted grants for the last decade.

APSF's mission to improve patient safety during anesthesia care is as relevant today as it was 35 years ago. And we will continue to prioritize this shared commitment to protect patients.

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# Surgical Fire Prevention: A Review

by Charles Cowles MD, Chester Lake MD, and Jan Ehrenwerth, MD

See the original article online at: <https://www.apsf.org/article/from-the-literature-ecri-review-explains-warns-of-or-fires/>

The thought of a fire in the operating room sends chills down the spines of health care professionals that are trusted to ensure our patient's safety. This dreaded complication which often results in severe and disfiguring injuries can be eradicated at a minimal cost and should be a continued focus for the APSF and other organizations of stakeholders. Extrapolated study data from the Pennsylvania Patient Safety Authority to the country as a whole indicate a recent reduction in the number of surgical fires from 650 to 217 events each year in the United States.<sup>1,2</sup> While these data are encouraging, it magnifies the need to mandate reporting of surgical fires in all states, not just rely on a single state's data. The actual number of fires is probably higher than estimated since only half of the states require mandatory reporting of such occurrences. Our optimism for news that surgical fire cases have dropped is offset by the rate of anecdotal incidents and the solicitations for expert opinions in legal proceedings which have not changed since APSF's original efforts.

In the ASA closed claims database, surgical fires accounted for 1.9% (103/5297) of the liability claims.<sup>3</sup> Electrocautery induced fires increased from less than one percent of surgeries from 1985–1994 to 4.4% between 2000 and 2009.<sup>3</sup> Unfortunately, the circumstances surrounding these cases remain unchanged over time: it is usually the use of open delivery of oxygen via nasal cannula or face mask, coupled with the use of a monopolar electrical surgical device within the area of the head and neck. Most claims occur in outpatient settings, involving the upper body (85%), and utilize monitored anesthesia care (MAC) (81%).<sup>3</sup> The closed claims cases of OR fires with patients under general anesthesia, occur with otolaryngology procedures in which the  $FiO_2$  is greater than 0.30, ninety-seven percent of the time.<sup>3</sup> The data indicate that claims were paid in seventy-eight percent of the cases with the median settlement value, \$120,000.00.<sup>3</sup>

Many of the fires during MAC anesthesia occur when a clinician connects a nasal cannula or face mask to the auxiliary oxygen outlet. In most anesthesia workstations this outlet can only deliver 100% oxygen. However, some anesthesia workstations can now mix oxygen with air to provide a lower  $FiO_2$ . For instance, the GE Carestation 650 incorporates an  $O_2$ /air blender into the auxiliary gas outlet and analyzes the  $FiO_2$  of the gas mixture.<sup>4</sup>

High flow nasal oxygen is a newer technology that is being utilized in some MAC anesthesia cases. These devices can deliver 50–100 L/min of oxygen with an  $FiO_2$  of 1.0, unless an  $O_2$ /air blender is used. These very high flow rates of oxygen present a markedly increased fire risk,



unless great care is taken to ensure the oxygen is dissipated before the surgeon uses an electrosurgical unit (ESU) or laser.<sup>5</sup>

A particularly devastating type of OR fire can occur when a tracheal tube is ignited by a laser or ESU. In these cases, a “blowtorch” effect is created that can severely damage the airway and the lungs.<sup>4</sup> The anesthesia professional must always use a tracheal tube that is protective to the wavelength of laser being used by the surgeon. Tracheostomies are another airway procedure that can result in an airway fire. This often occurs when the surgeon uses an ESU to enter the trachea in the presence of high oxygen concentrations. The resulting fire often results in major morbidity for the patient.<sup>6</sup>

“The Patient Is On Fire” is an article published by the ECRI Institute (previously known as the “Emergency Care Research Institute”) in the January 1992 issue of *Health Devices*.<sup>7</sup> It describes the triad of fuels, oxidizers, and ignition sources that are still present in the modern operating room of 2020. Fuels include the alcohol-based surgical prep solutions, surgical drapes, towels, tracheal tubes, and laryngeal mask airways. Oxidizers include oxygen and nitrous oxide. Ignition sources include the ESU lasers, and fiberoptic lights.<sup>7</sup>

Alcohol-based surgical prep solutions can readily fuel an OR fire.<sup>8</sup> Not only is the alcohol itself highly flammable, but the alcohol vapors formed during evaporation are also combustible. The OR team must ensure that the prep has completely dried and any alcohol-soaked towels are removed from the area before the patient can be draped.

Surgical fires have been a key area for educational focus by the American Society of Anesthesiologists (ASA), the Anesthesia Patient Safety Foundation (APSF), the Association of periOperative Registered Nurses (AORN), and the National Fire Protection Association (NFPA).

The APSF has created and revised a safety algorithm, which is provided on the APSF website and which can serve as a cognitive aid for health care professionals to avoid high-risk situations for OR fires. The ASA has also revised their OR Fire Prevention algorithm since its original publication (Figure 1 on page 84).<sup>9</sup>

Educating physicians, nurses, technicians, and all surgical staff is vitally important. In 2013, the ASA published a practice advisory for health care providers in an effort to prevent surgical fires:<sup>9</sup>

1. Conduct a fire risk assessment at the start of every surgery. “A Fire Risk Assessment Tool” should be implemented before each surgery, in the “time out” or safety checklist. Assessment should be made to determine the presence of major risk factors such as: 1) Use of an open oxygen source; 2) The presence of an ignition source; 3) A procedure at or above the level of the xiphoid process; 4) Use of a flammable surgical prep solution.
2. Encourage communication among surgical staff.
3. Ensure the safe use and administration of oxidizers. Titrate the minimum concentration of oxygen necessary to meet the needs of the patient.
4. Safely use any devices that may serve as an ignition source. Support personnel should be aware of the use and maintenance of any instrument that may ignite a fuel source.
5. Safely use surgical suite items that may serve as a fuel source.
6. Practice ways to manage surgical fires. The ASA practice advisory has offered several steps for managing a surgical fire: 1) Eliminate the primary ignition source. 2) Extinguish the fire and remove all sources of fuel. 3) Discontinue the patient from the breathing circuit for airway fires and remove the tracheal tube.

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## Fire Prevention Requires Zero Additional Cost with Near 100% Effectiveness

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Move the patient to safety and re-establish the airway. 4) Review the fire scene and remove any potential sources of flammable materials.<sup>3</sup>

If a fire should occur, it is important that every member of the OR team knows the location and use of a fire extinguisher. The ECRI and the ASA practice advisory recommend the carbon dioxide (CO<sub>2</sub>) extinguisher as the most appropriate for use in the OR.

Preventive measures to avoid fires in operating rooms have a place in our daily preparation. Knowledge of the risks should encourage yearly programs to prepare personnel, minimize patient injury as well as limit damage to the operating room. The APSF’s surgical fire video is frequently viewed and downloaded, and the content remains useful and accurate.<sup>10</sup> The availability of treatment algorithms (Figure 1) for reference in each operating room and the performance of a fire risk assessment for each patient in the “time-out” certainly makes good clinical sense.

What is next regarding surgical fire prevention? The best answer is culture change. Integration of fire risk assessments and preventative actions in surgical safety checklists can mitigate this catastrophic and preventable event. We can also integrate surgical fire prevention into education simulation centers throughout the world. Engaging surgeons who perform high fire risk cases in prevention and education activities will ensure they are aware of the risks and can take mitigation steps when possible. We can also promote educational programs such as the “FUSE program” by SAGES (Fundamental Use of Surgical Energy by the Society of American Gastrointestinal and Endoscopic Surgeons) which is an excellent educational tool for surgeons and anesthesia professionals, as well as anyone working in the OR. As a specialty, we must remain engaged with professional organizations, standards groups, accreditors, and certification boards to ensure the topic of surgical fire prevention remains prominently positioned with emphasis on increasing knowledge and practice.

Anesthesia professionals are trained to be vigilant. Our patients trust us with their well being. Continual education and the knowledge of the risks as well as management in the event of an operating room fire continue to deserve our time and study. We emphasize that fire prevention requires zero additional cost and approaches 100% effectiveness. Therefore, we strongly believe that surgical fire prevention is a primary way in which to exemplify the APSF’s vision that “No one shall be harmed by anesthesia care.”

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*The authors have no conflicts of interest.*

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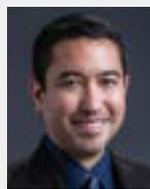
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## APSF and FAER Announce the 2021 Co-Sponsored Mentored Research Training Grant

The Anesthesia Patient Safety Foundation (APSF) and Foundation for Anesthesia Education and Research (FAER), related organizations of the American Society of Anesthesiologists (ASA), join to provide a third year of the co-sponsored APSF-FAER Mentored Research Training Grant (APSF-FAER MRTG). The APSF-FAER MRTG provides \$300,000 over a two-year period to fund patient safety research directly related to the perioperative care of patients, as well as chronic pain and critical care medicine. Patient safety is defined as the avoidance, prevention and improvement of adverse outcomes or injuries stemming from health care processes. In its first two years, the APSF and FAER awarded \$600,000 to the following researchers:

### Alexander Arriaga, MD, MPH, ScD, 2019 APSF-FAER MRTG Recipient



Brigham and Women’s Hospital (Boston, Massachusetts)

*Increasing the Frequency of Debriefing After Perioperative Crises: Altering Trajectories that Impact Provider Burnout and Wellness*

### Timothy Gaulton, MD, MSc, 2020 APSF-FAER MRTG Recipient



University of Pennsylvania (Philadelphia, Pennsylvania)

*Mapping the Epidemiology of Perioperative Driving Safety and Behavior*

Those interested in applying for the 2021 APSF-FAER MRTG will need to submit a Letter of Intent (LOI) prior to submitting a full application. The submission window for LOIs for this

grant will be open from December 1, 2020, through January 1, 2021. Information on the APSF-FAER MRTG can be found on FAER’s APSF-FAER Mentored Research Training Grant page at [www.asahq.org/faer/researchfunding/apsffaergrant](http://www.asahq.org/faer/researchfunding/apsffaergrant).

### ABOUT THE FAER

For over 30 years, FAER has been dedicated to developing the next generation of physician-scientists in anesthesiology. Charitable contributions and support to FAER help fuel the future of anesthesiology through scientific discovery. Funding priorities include Research, Education, and Training. FAER has awarded over \$45 million in research grants and programs since 1986. To learn more about FAER, visit our website at [FAER.org](http://FAER.org). To donate to FAER, visit [FAER.org/donate](http://FAER.org/donate).

### ABOUT THE APSF

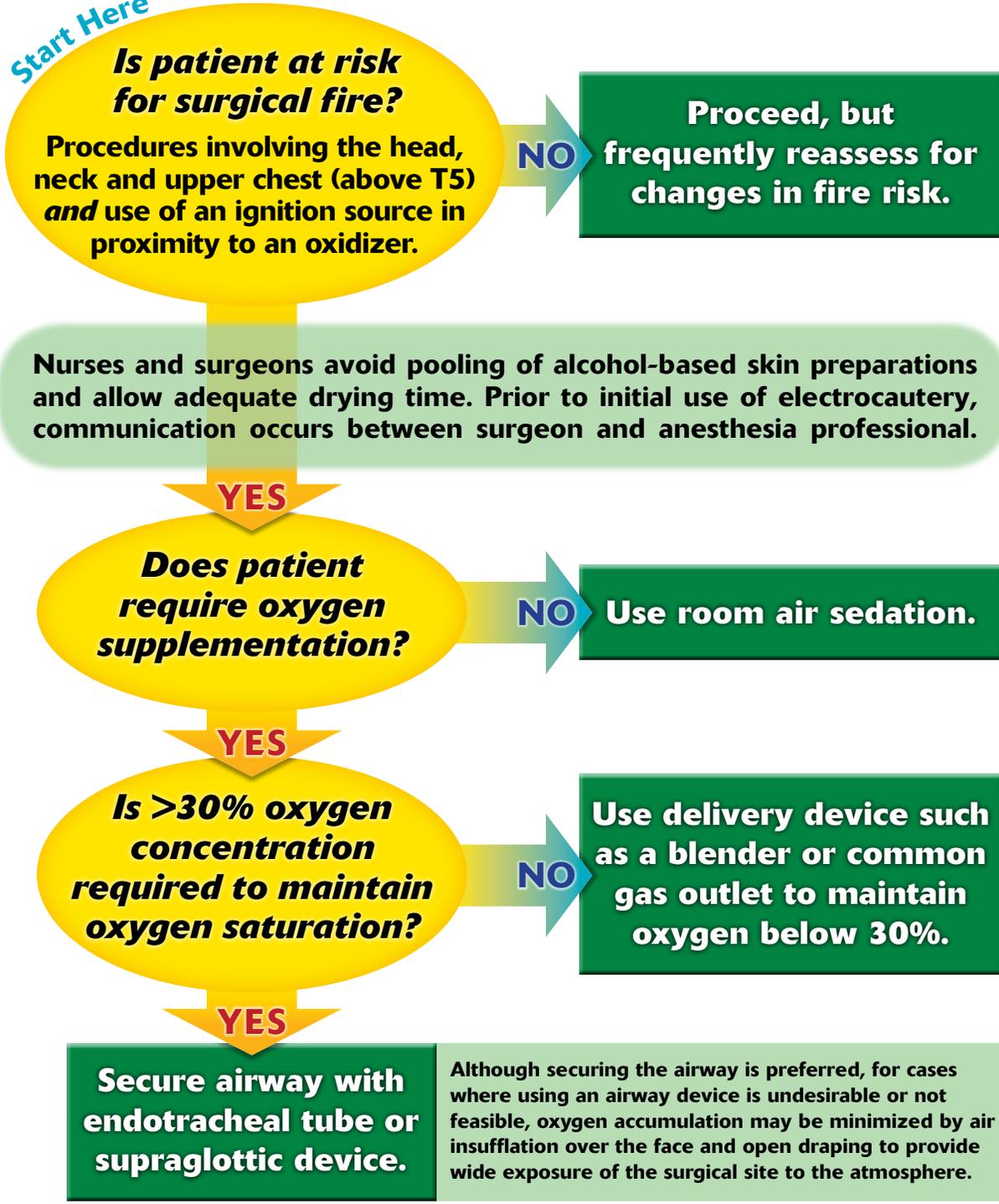
Founded in 1985, the Anesthesia Patient Safety Foundation (APSF) promotes research of perioperative patient safety issues, supports the development of careers in patient safety, provides patient safety educational materials and communications to all anesthesia professionals, and advocates for changes in clinical practices that improve patient safety. The APSF’s goal is that no one shall be harmed by anesthesia care.

The Anesthesia Patient Safety Foundation (APSF) is a related organization of the American Society of Anesthesiologists. APSF provides support for research and education in perioperative patient safety. Its past initiatives have resulted in significant contributions to the field of anesthesia patient safety. APSF has distributed over \$13.5 million in funding for anesthesia patient safety research projects over its 30+ year history. For more information on APSF or to donate, please visit [www.apsf.org](http://www.apsf.org).

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# OR Fire Prevention Algorithm

*Start Here*



Provided as an educational resource by the **Anesthesia Patient Safety Foundation**

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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

Figure 1: Fire Safety Algorithm (printable posters available at <https://www.apsf.org/videos/or-fire-safety-video/>)

# Postoperative Visual Loss (POVL)

by Lorri A. Lee, MD

See the original article online at: <https://www.apsf.org/article/induced-hypotension-tied-to-possible-vision-impairments/>

Perhaps the greatest strength of the APSF is its ability to gather multiple medical disciplines and their affiliated societies, organizations, and health care industries together to collaborate on patient safety issues. The APSF leveraged its role in this informal network by alerting health care providers in 1998 to an apparent increase in cases of the devastating complication of postoperative visual loss (POVL), particularly associated with spine surgery in the prone position.<sup>1</sup> These cases were occurring during a surge in instrumented spinal fusion procedures, which were associated with higher volumes of blood loss and longer operative times. Though POVL had long been acknowledged in the literature starting in the 1950s, most health care professionals thought it was related to either infarctions of the visual cortex (cortical blindness) or globe compression, an injury that causes central retinal artery occlusion (CRAO, Figure 1). In the early- to mid-1990s, an increasing number of POVL cases after spine surgery in the prone position were published associated with injury of the optic nerve, known as ischemic optic neuropathy (ION, Figure 1); however, general awareness of this complication was still low. Very few individuals in the anesthesia community were aware at this time that blindness could occur in these cases without cortical infarction or compression of the globe.<sup>2</sup> The lack of awareness was undoubtedly related to institutional variability in the incidence of ION associated with spinal fusion surgery. Although smaller multicenter studies identified an incidence as high as 0.1%,<sup>3</sup> national data revealed a much lower rate of 0.017% from 1996 to 2005.<sup>4</sup>

Ann Lofsky, an anesthesiologist and previous consultant to the APSF Executive Committee, and Mark Gorney, an internist, co-authored the *APSF Newsletter* article on POVL in 1998.<sup>1</sup> They were affiliated with The Doctors Company professional liability company, and as reviewers of professional liability claims, they had an opportunity to identify trends in perioperative complications that involved anesthesia care, long before these complications would be available for analysis in any national database. They published a brief description of 2 cases (which were composites of 12 similar claims) of POVL caused by ION occurring in association with spine surgery in the prone position. They suggested that the combination of deliberate hypotension, anemia, and prolonged duration in the prone position with elevated venous pressure were the most likely contributory factors to this problem. They noted one case that occurred with the head in Mayfield pins, a finding that elimi-

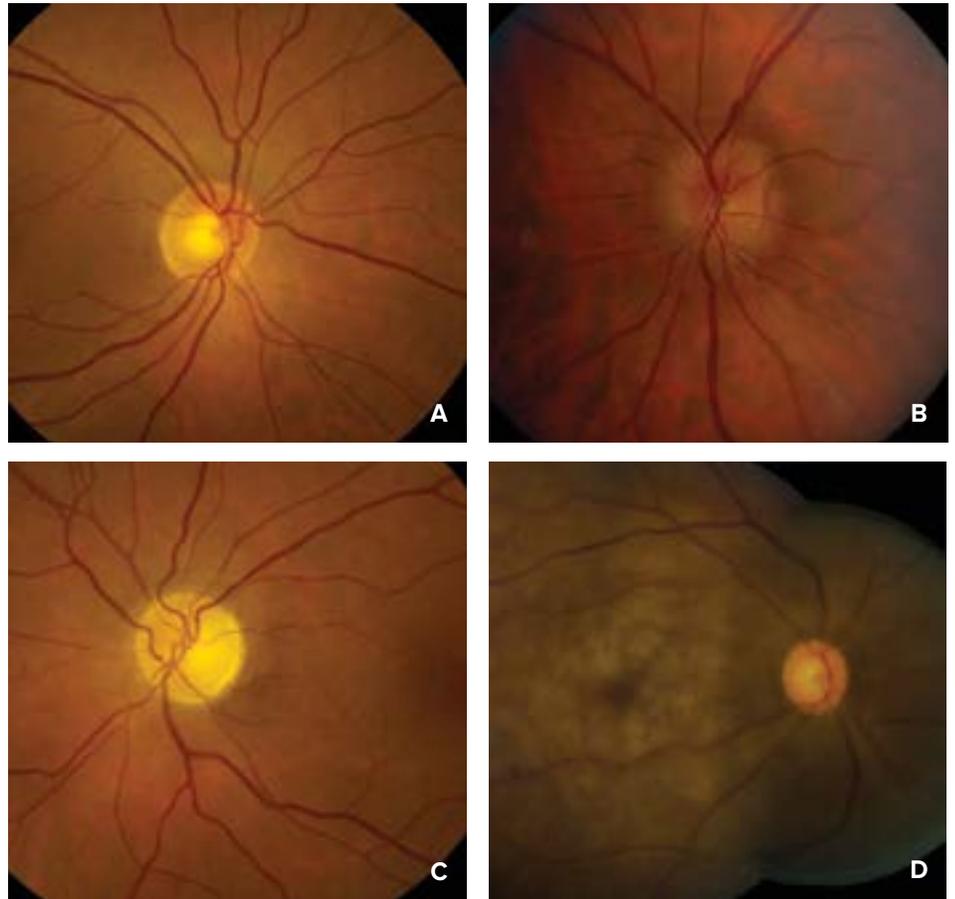


Figure 1: Photographs of the ocular fundus showing A) normal optic disc or early posterior ischemic optic neuropathy; B) mild disc swelling in early anterior ischemic optic neuropathy; C) optic nerve atrophy in late anterior or posterior ischemic optic neuropathy; and D) retinal whitening, cherry red spot (macula) and attenuated arteries in acute central retinal artery occlusion.

Photographs courtesy of Valerie Biousse, MD, and Nancy J. Newman, MD, Emory University School of Medicine, Atlanta, GA.

nated globe compression as a potential contributory cause for that particular case.

The American Society of Anesthesiology (ASA), via the ASA Closed Claims Project and the ASA Committee on Professional Liability, was simultaneously tackling this problem by the creation of the ASA POVL Registry. This registry was designed for voluntary submission of cases with anonymized data so that the most detailed data on these alarming POVL cases could be collected as expeditiously as possible. Subsequent articles published in the *APSF Newsletter* and the *ASA Newsletter* highlighted preliminary results from the ASA POVL Registry. These articles not only disseminated the latest information available on this complication, but they also encouraged health care providers to voluntarily submit any cases to the ASA POVL Registry. The success of the ASA POVL Registry was partially related to the impact that the *APSF News-*

*letter* and *ASA Newsletter* carried within the anesthesia community.

By 2006, the ASA POVL Registry had collected 93 POVL cases associated with spine surgery, 83 cases diagnosed with ION and 10 cases with CRAO.<sup>5</sup> The perioperative characteristics of patients diagnosed with CRAO and ION were markedly different. Of the CRAO cases, all had unilateral visual loss, 70% had periocular trauma, and none were placed in Mayfield pins. In contrast, 55% of ION cases had bilateral visual loss, almost one-fifth were in Mayfield pins, and only 1 of 83 had any periocular trauma. The estimated blood loss, subsequent volume administered, and duration of procedures were markedly and significantly greater in ION cases compared to CRAO cases. These findings were consistent with the theory at this time that ION was associated with systemic causes and not direct compression from

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## Ischemic Optic Neuropathy after Spine Surgery Has Declined Nearly Threefold from 1998–2012

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a headrest. Moreover, two-thirds of the ION patients were relatively healthy with an ASA physical status of 1–2, and patients were as young as 16 years old. It appeared that anyone was vulnerable to this catastrophic complication. Hypotension and anemia were not consistently identified in the ION cases, though these factors could not be ruled out as contributory causes.

The ASA Committee on Standards and Practice Parameters quickly utilized this information to develop the first practice advisory related to this complication, with subsequent updates in 2012 and 2019.<sup>6–8</sup> Expert neuro-ophthalmologists, anesthesiologists, neurosurgeons, and orthopedic spine surgeons were included on this task force to develop the practice advisory. Of note, one of the first recommendations was to consider consenting patients for this complication. It became a very controversial issue between spine surgeons and anesthesia professionals as surgeons were concerned that it would unnecessarily frighten patients about a complication that many had never encountered in their career. As awareness of this injury increased, collaboration between the ASA, APSF, and professional neurosurgical and orthopedic societies associated with spine surgery addressed the issue of consent in the practice advisories. The APSF subsequently held a special multidisciplinary conference on the topic of POVL in 2012 with a focus on preoperative consent of patients undergoing spine surgery for the risk of POVL. A consensus statement from the conference was published in 2013. Two educational videos were developed by the APSF in 2014 elucidating the rationale behind preoperative consent for this complication as well as simulations on how surgeons and anesthesia professionals can approach patients for consent for POVL.<sup>9,10</sup>

Another part of this collaborative, but informal group of health care organizations interested in determining the etiology and prevention of ION was the Society of Neurosurgical Anesthesia and Critical Care (SNACC, now the Society for Neuroscience in Anesthesiology and Critical Care). Members of SNACC from across the country had an intense interest in this complication and formed the POVL Study Group. This group performed a case-control study with the ASA Closed Claims Project utilizing POVL cases from the ASA POVL Registry and controls from SNACC members' respective academic institutions. Findings from this study were published in 2012 and identified six risk factors associated with ION after surgery in the prone position. These risk factors included male sex, obesity, Wilson frame use, longer

**Table 1: Risk Factors for Ischemic Optic Neuropathy Associated with Spinal Fusion Surgery<sup>9</sup>**

1.	Male Sex
2.	Obesity
3.	Wilson Surgical Frame
4.	Longer Anesthetic Duration
5.	Greater Estimated Blood Loss
6.	Lower percent of colloid in non-blood fluid administration

anesthetic duration (a surrogate value for operative duration), greater estimated blood loss, and a lower percent of colloid used in the non-blood fluid administration (Table 1).<sup>11</sup> This study remains the best data we have on this topic because of the large number of cases with one ophthalmologic diagnosis occurring after the same procedure and the detailed perioperative data that are absent from national databases. However, it has significant limitations because of its case-control methodology and voluntary submission of cases to the ASA POVL Registry. Results from this study were utilized to guide updates of the ASA practice advisory for this complication, with the latest update and recommendations published in 2019 (<https://anesthesiology.pubs.asahq.org/article.aspx?articleid=2718348>).<sup>8</sup>

Interest in this complication was significant and numerous case reports, retrospective multicenter case series, case-control studies, studies from national databases and literature reviews were published on the topic of POVL. These articles provided additional useful information on this complication for the ASA practice advisories and maintained a high degree of interest in determining the etiology, prevention, and treatment of POVL. The leading theory on the etiology of ION associated with spinal fusion surgery is that the elevated venous pressure in the prone position for a prolonged period of time is a major contributory factor.<sup>11,12</sup> Obesity with compression of the abdomen in the prone position and use of the Wilson frame which places the head in a more dependent position will both exacerbate venous congestion in the head in the prone position, and were identified as risk factors for this complication.<sup>11</sup> Further support for this unproven theory is the increased risk of ION in other procedures that have elevated venous pressure in the head such as bilateral radical neck dissection and robotic procedures with the head in a steep head-down position.

After these enormous efforts from numerous avenues, national data suggested that we had a success story. Data from the Nationwide Inpa-

tient Database demonstrated a 2.7-fold decline in ION cases associated with spinal fusion surgery from 1998 to 2012.<sup>13</sup> It is unclear if this improvement was related to the tremendous work of the ASA, the ASA Closed Claims Project, SNACC, APSF, the North American Neuro-Ophthalmology Society, the American Association of Neurologic Surgeons, the North American Spine Society, and numerous other health care professionals. Michael Todd, MD, suggested in his editorial that several changes may have occurred during this time to account for this success including decreased use of deliberate hypotension, decreased use of the Wilson frame by spine surgeons, and perhaps slightly shorter operative times.<sup>14</sup> Additionally, surgeons have increasingly adopted minimally invasive techniques that are associated with lower estimated blood loss.<sup>15</sup>

Further research into the etiology of this complication is critical; however, it is hindered by the low incidence of this complication, the ethical limitations of performing any interventional studies in humans and the lack of a suitable animal model. Is everyone vulnerable to this complication given similar perioperative surgical events and anesthetic management, or do certain unique anatomic, physiologic, and genetic factors contribute to this injury? These factors would not be identified in a case-control study or many other study designs. Research into potential treatment options for ION and other causes of POVL is equally as important, as POVL can occur after numerous other types of operations including cardiac surgery, vascular surgery, head and neck dissections, orthopedic surgery, general surgery, and robotic surgery (prostatectomy and hysterectomy) as well as in patients who have major gastrointestinal hemorrhage and other critical illnesses. No proven beneficial treatments for perioperative ION have been identified, although many neuro-ophthalmology consultants have recommended normalization of blood pressure, avoidance of significant anemia, and head-up positioning if significant facial edema is present. We should celebrate this partial success story, but there is clearly still much work to be done.

In closing, I would like to acknowledge the small “country” that participated in and drove these research and educational endeavors. The list of contributors to these efforts would easily exceed the length of this article, so space limitations will only allow a small portion to be named individually including Steven Roth, MD, Michael M. Todd, MD, Karen B. Domino, MD, MPH, Karen L. Posner, MD, Nancy J. Newman, MD, Nayak L. Polissar, PhD, Frederick W. Cheney, MD, Robert K. Stoelting, MD,

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# Production Pressure and Anesthesia Professionals

by Richard C. Prielipp, MD, MBA, FCCM

*"It's tough to make predictions, especially about the future"*

—Yogi Berra

See the original article online at: <https://www.apsf.org/article/special-issue-production-pressure-does-the-pressure-to-do-more-faster-with-less-endanger-patients-potential-risks-to-patient-safety-examined-by-apsf-panel/>

## INTRODUCTION [THEN]

Stimulated by increasing concerns expressed by anesthesia professionals and also the 1994 landmark systematic discussion of production pressure in anesthesia practice,<sup>1</sup> the APSF in 1998 first addressed this concept in the 27th videotape in the educational series produced and nationally distributed by the APSF during its early years. Recognition of the importance of and interest in this topic then led to the comprehensive Spring, 2001, *APSF Newsletter*—Special Issue: Production Pressure —Does the Pressure to Do More, Faster, with Less, Endanger Patients? Potential Risks to Patient Safety Examined by APSF Panel. Topics included multiple thoughtful discussions of patient safety and production pressure: a patient's perspective, academic practice, private practice, pre-op assessment, scheduling and staff, ICU, ICU nursing, industry, and administration. Despite these efforts, the problem has only intensified in the last two decades due to conflicting priorities and the involved complexities.

## [NOW]

Today's operating room (OR) culture applauds speed and multitasking as it simultaneously demands cost-cutting. Indeed, the classic mantra of NASA and business culture—"better, faster, cheaper"—has become the adopted stepchild of many OR managers and administrators. Given the universal downward pressures on hospital budgets across the world and the recognition that the operating theater remains a high-cost, high-salary, intensive consumer of resources, leaders believe they have few options but to prioritize increased efficiency (activity per unit time) within the OR. One consequence of these efforts applied to OR personnel is the ongoing evolution of production pressure—now a constant companion of most clinicians.<sup>1</sup> Indeed, ten years ago, during the 25th anniversary commemoration of the Anesthesia Patient Safety Foundation (APSF), John Eichhorn, MD,<sup>2</sup> reminded anesthesia professionals of two basic tenets: that basic preventable human errors will still occur, and that production pressure in anesthesia practice threatens past safety gains. His words portend the future... then and now.



*Production pressure was one of the underlying causes of the Challenger shuttle disaster in 1986. Similar pressures create patient safety challenges in anesthesia care.*

Production pressure may be defined as overt or subliminal pressure, metrics, and incentives experienced by anesthesia professionals to place production as their foremost priority: "do more with less." Clearly, virtually all anesthesia professionals experience the current OR cultural-economic climate in which more clinical services of higher quality are expected concurrent with fewer consumption of resources (both people and finances) to provide it. The consequences of such pressures are multidimensional, but we will highlight the impact of production pressure on three key areas of patient safety:

1. The normalization of deviance
2. Provider stress and burnout
3. Impact on education and training.

## NORMALIZATION OF DEVIANCE<sup>3</sup>

*"BETTER, FASTER, CHEAPER"*

—NASA

Why did NASA continue to fly the Challenger Shuttle while O-ring erosion problems were documented numerous times before that cold January launch in 1986? And why did NASA continue to fly the Columbia shuttle knowing foam insulation was regularly striking vulnerable areas of the vehicle years before Columbia's fatal accident? One explanation is that these mishaps had been "normalized" over many occurrences and many years until managers and engineers began to believe that these flaws were expected and therefore acceptable.<sup>3</sup> Diane Vaughan described this

behavior as the "Normalization of Deviance."<sup>4</sup> This incremental process is a gradual erosion of normal procedures that would never be tolerated if proposed in one single, abrupt leap. Instead, small incremental deviations are observed and tolerated. Lacking an accident, they become "normalized".<sup>4</sup>

Indeed, when the Shuttle was originally designed, no allowance was made for the possibility that the Challenger would launch in sub-freezing temperatures, knowing rocket booster O-rings would contract, weaken, and leak under these out-of-tolerance temperatures. When these events were first experienced, obvious safety implications were recognized. However, faulty analyses concluded that the vehicle could tolerate these abnormal events. Managers and engineers decided to either implement a temporary fix or simply accept the risk. This approach established a precedent for accepting safety violations as technical deviations that can be tolerated and managed. As the problems recurred and the Shuttle kept flying, the fallacy that the errors were acceptable was reinforced.

Most critically, the normalization of deviance process breaks the culture of safety and applies equally to clinical anesthesia practice.<sup>3,5</sup> Production pressure is frequently cited as a major driver to work even when fatigued, to create workarounds for safety systems, to stretch the boundaries of hospital or departmental guidelines, and to expedite patient care to the point of "cutting corners" in the interests of staying on schedule.<sup>6</sup>

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# Anesthesia Professionals Report Higher Than Average Rates of Burnout

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In the aggregate and over time, these practices generate a slippery slope of tolerating more and more “minor” errors and accepting more and more risk, always in the interest of efficiency and on-time schedules. This toxic thinking may progress to a mindset that demands evidence that these shortcuts would clearly harm a patient, instead of demanding proof that such deviations are safe and the patient is not at increased risk.

In reality, most medical organizations fail to recognize when they are drifting towards normalizing dangerous deviations. But brief reflection by most front-line clinicians will identify multiple such “normalizations” within their medical center practices and procedures—undoubtedly driven by ever-increasing expectations to stay on schedule, reduce turnover times, and eliminate delayed starts or even worse, case cancellations, all while consuming fewer resources and decreasing costs. Strategies to mitigate these aberrant practices begin with building a culture of open communication to identify and extinguish deviations before they become normalized. Failure mode and effects analysis (FMEA) is one proven, proactive method to evaluate policies and procedures that may be in need of change before patient harm occurs.<sup>7</sup>

## BURNOUT

*“It was the season of light, it was the season of darkness, it was the spring of hope, it was the winter of despair.”*

—Charles Dickens

Medical professionals exist in challenging times with change a constant companion to our daily practice (e.g., COVID-19!). Moreover, anesthesiology is experiencing a period of mergers, consolidation of practices, and a trend towards employee contracts that dramatically affect personal autonomy. Bundled payments, declining reimbursements, clumsy and quirky electronic health records (EHRs), and a host of regulatory demands (e.g., submission of clinical statistics) often consume daily life. Within this milieu, we are experiencing rising demand for anesthesia services while simultaneously facing a national shortage of specialized nurses and physicians. Furthermore, our practices are inundated with internal and external pressures to meet or exceed national benchmarks in hospital quality indicators and patient satisfaction/loyalty ratings to effectively compete with local competitors.<sup>8</sup> Thus, it is no surprise that over the

**Table 1: Elements that can contribute to burnout of anesthesia professionals**

• Production pressure
• Exaggerated and continually escalating job demands
• Erosion of autonomy
• Lack of recognition and respect at work
• Loss of professional respect from patients
• Breakdown of work-life balance
• Conflict between professional/personal values and organizational values
• Bureaucratic overload and dysfunctional electronic records
• Government regulations
• Employment insecurity

last decade, health care has also seen a significant rise in provider burnout, and anesthesia professionals are a vivid example of this growing epidemic.<sup>9</sup>

What is burnout and what contributes to it? Burnout is related to but different than depression. Burnout is a pattern of symptoms, with providers reporting physical and emotional exhaustion, cynicism arising out of depersonalization, and decreased work effort or even absenteeism.<sup>7,8</sup> This leads to significant personal and professional consequences. For example, studies have shown burned-out physicians are more likely to have broken relationships, increased incidence of alcohol and drug abuse, and a higher risk of depression and even suicide.<sup>10</sup>

Numerous studies have identified a handful of dimensions that contribute to burnout, such as excess workload, work-life imbalance, and a loss of professional respect, autonomy, and community (Table 1). Anesthesia professionals report higher than average rates of burnout compared to some other specialties. In fact, 50% of anesthesiologists reported feeling burned out in 2017, a marked increase from 2011, and a rate twice as high as the general working adult population.<sup>10</sup>

Over the past few years, our workplaces have seen a significant increase in number of cases, hours, and work effort per provider. The Medical Group Management Association (MGMA) data support this as a consistent trend throughout our specialty. Anesthesia professionals are working longer hours, spread over more locations, spending more time in front of electronic health records, and have less control over their schedules. Adding to this challenge is

the fact that work/life balance is a top priority for millennials, which is also the fastest growing segment of our anesthesia workforce. Professionals with burnout are less productive, have a higher likelihood of turnover, and are more likely to reduce their work effort in the coming years. Not surprisingly, all this can have a significant negative impact on patient safety. Providers experiencing burnout may deliver lower quality care with associated lower patient satisfaction scores and are more likely to make medical errors.<sup>7,8</sup> Therefore, health care professionals’ distress is a quality indicator that is worth measuring in medical centers.<sup>10</sup>

## IMPACT ON EDUCATION

*“Education is not the filling of a pail, but the lighting of a fire.”*

—W. B. Yeats

Conventional wisdom holds that economic (i.e., production) pressure on teaching faculty in the operating room adversely impacts anesthesia resident education and bedside case-oriented teaching. Currently, only a modicum of data exists to directly support this proposition. A German national survey on anesthesia education confirms that 96% of respondents identified “daily workload,” “time pressure,” and “lack of time” as primary obstacles to teaching.<sup>11</sup> A more recent cross-sectional survey at four U.S. academic centers found over one-third of the faculty identified “insufficient time,” “covering multiple rooms,” and “an emphasis on efficiency” as key factors that preclude optimal anesthesia resident teaching.<sup>12</sup> Regardless, it is reassuring that the majority of faculty return rou-

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## Threat of Production Pressure Continues to be a Focus of the APSF

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tinely to the operating room during the maintenance phase of anesthesia specifically to teach, and exhibit a high degree of engagement with their role as an anesthesia educator.

### SUMMARY

Anesthesia professionals must navigate the colliding tectonic plates of patient safety and OR efficiency. But we are not unique in facing this industrial challenge. Indeed, Erik Hollnagel describes the engineering efficiency–thoroughness trade-off (ETTO) principle<sup>13</sup> that acknowledges the inviolate swap between efficiency on one hand and thoroughness on the other—analogous to medical professionals debating OR efficiency vs. patient safety. In any industry, if forces become misaligned, an accident with defects or harm becomes more likely. Thus, we must continue our vigilance as we endeavor to avoid normalizing deviations, to maintain the balance of efficiency and thoroughness, and to avoid the potential erosion of our educational heritage and responsibility. The

thorny and, so far, unyielding threat of production pressure has been a focus of the APSF for over 20 years and likely will continue well into the future.

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*The author has no conflicts of interest.*

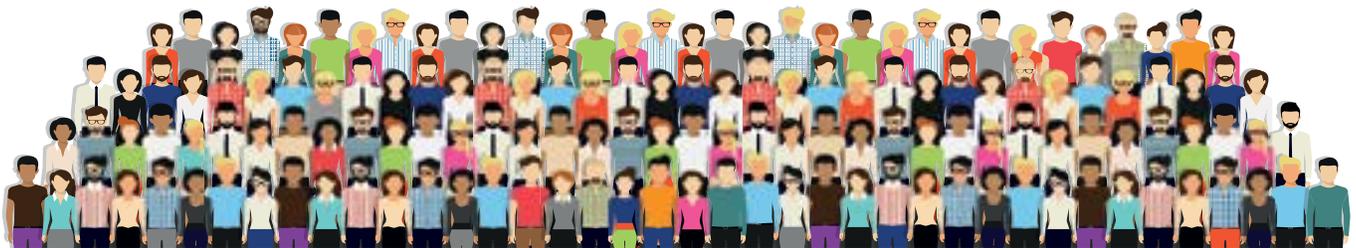
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*“no one shall be harmed by anesthesia care.”*

# Why Worry About Blood Pressure During Surgery in the Beach Chair Position?

by David J. Cullen MD, MS

See the original article online at: <https://www.apsf.org/article/beach-chair-position-may-decrease-cerebral-perfusion/>

Many factors have decreased the incidence of anesthetic-related complications. Development of a cultural awareness and special emphasis on patient safety began with the acceptance of monitoring standards of care<sup>1</sup> and has evolved since 1985 in many ways. The anesthesia-related mortality rate prior to 1985 was about 1:10,000 cases. Following publication of standards in JAMA, which we emphasized were applicable only to the Harvard Affiliated hospitals, public pressure led the American Society of Anesthesiologists (ASA) to adopt these standards verbatim within a few months.

The introduction of new technology, starting with pulse oximetry, followed by capnography, continued improvements in anesthesia machines and monitoring equipment, and safer drugs, etc., dramatically reduced anesthesia malpractice premiums and anesthetic-related mortality rates to one in several hundred thousand healthy ASA I and II patients.<sup>2-4</sup>

However, as exemplified by our original article,<sup>5</sup> new problems will always arise, such as brain damage in healthy patients undergoing shoulder surgery in the beach chair position (BCP). Four cases came to my attention around 2000.<sup>5</sup> Not one physician directly involved in the care of these four patients understood why the “stroke” occurred because, by their own admissions, the anesthesia professionals, surgeons, and subsequent neurology, cardiology and radiology consultants were unaware of the gravitational effects and hydraulic mechanism of the upright or BCP on cerebral perfusion. In short, cerebral perfusion pressure (CPP) fell to borderline or below threshold levels that ensured adequate cerebral perfusion.

For many well-known reasons, blood pressure (BP) almost always decreases during the early stages of general anesthesia in the BCP and is usually and safely reversed with fluid boluses and/or vasopressor infusion. When regional anesthesia to the shoulder is established prior to the operation, the surgical stimulus will be muted or absent, thus eliminating a potent way to counter the decreasing BP during surgery. Finally, many surgeons request/prefer that a mild degree of hypotension or even deliberate hypotension be maintained to reduce tissue swelling, limit bleeding and improve visualization in their surgical field.<sup>6,7</sup> This leads to mean arterial pressures (MAP) that can be insufficient to sustain adequate cerebral blood flow (CBF) because, depending on the angle of the BCP and the height of the patient, the BP at the brainstem level will be approximately 20–40 mmHg lower than the BP as actually measured by cuff on the arm which is at the level of the heart.

As first described by Enderby et al. in 1954 regarding sitting craniotomies, for every inch in vertical height from the BP cuff placement on the arm to the brainstem, using the external auditory meatus (EAM), a surrogate for the brainstem level, one must subtract 2 mmHg of BP (or 1 mmHg per 1.25 cm.) to approximate the cerebral perfusion pressure (CPP).<sup>8</sup> In 3 of the 4 cases I reported, and more I have reviewed, cuff systolic and diastolic BPs were usually in the 80s–90s/50s–60s measured at the arm/heart level and often lower. Therefore, MAPs at the brainstem would be about 20–40 mmHg lower, and at the level of the cerebral cortex, another 6–9 mmHg below that. Thus, MAPs in the brain would almost always be at or below the earlier established acceptable Lower Limit of Autoregulation (LLA), a MAP of about 50 mmHg.<sup>9</sup>



In the 1990s, studies by Drummond<sup>9</sup> and others<sup>10</sup> (Table 1) revised the LLA upward to account for the variable but incomplete vasculature in the Circle of Willis (found in 40–45% of cases), unpredictable collateral blood flow, and variations in the regional distribution of blood flow and cerebral oxygenation. Since the late 1990s, the range of the LLA has been revised upward and varies from 70–93 mmHg, with a mean value of 80 ± 8 mmHg.<sup>9,10</sup> Recently, Brady et al. reported that the MAP with the most robust autoregulation during cardiopulmonary bypass in adults, obviously in the supine position, was 78 ± 11 mm Hg while the average LLA was 65 ± 12 mm Hg.<sup>11</sup>

The physical and hydraulic principles involved in the gravitational difference in MAP when using the upright or sitting position were well understood for decades. When sitting craniotomies were in vogue, it was standard practice, if monitoring intra-arterial BP, to zero the transducer at the height of the EAM. If only a BP cuff was used to monitor BP, correction for the vertical height from the cuff to the EAM was applied. When sitting craniotomies ceased being performed, this principle appears to have been forgotten or not taught to new anesthesia professionals.

In 2009, the APSF Symposium on Cerebral Perfusion in the Management of BCP Surgeries organized by Robert Stoelting, MD, resulted in most attendees agreeing that the mechanism of global ischemia (and I would add regional ischemia as well) had not been proven, but because the LLA has been revised upwards over the years, we should err on the side of caution when using deliberate hypotension or allowing patients to become hypotensive until we have better information.<sup>6</sup> Obviously, this recommendation should be corrected to rule out the use of deliberate hypotension.

Anesthesia professionals cannot know the adequacy of circulation inside the brain because no routine clinical monitor exists which

**Table 1: Lower limit of autoregulation in human studies<sup>10</sup>**

Investigators	LLA mean (mm Hg)
Strandgaard S. <i>Br Med J.</i> 1973;1:507–510.	70
Strandgaard S. <i>Circulation.</i> 1976;53:720–727.	73
Ohsumi H, et al. <i>Resuscitation.</i> 1985;13:41–45.	81
Waldemar G, et al. <i>J Hypertens.</i> 1989;7:229–235.	93
Schmidt JFG, et al. <i>J Cardiovasc Pharmacol.</i> 1990;15:983–988.	85
Larsen FS, et al. <i>Stroke.</i> 1994;25:1985–1988.	79
Olsen KS, et al. <i>Br J Anaesth.</i> 1995;75:51–54.	88
Olsen KS, et al. <i>J Neurosurg Anesth.</i> 1996;8:280–285.	73
<b>Mean LLA for eight studies 1973 through 1996</b>	<b>80 ± 8</b>

LLA = lower limit of autoregulation

## Clinicians Must Remain Aware of Cerebral Hypoperfusion in the BCP

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can monitor CBF, cerebral perfusion pressure (CPP) or cerebral tissue oxygenation during anesthesia in the BCP. By contrast for example, imagine an awake person sitting upright in a chair. For whatever reason, due to fear or fright, a sudden event, etc., their BP falls. Their first complaint would be lightheadedness, perhaps some nausea, or feeling faint. The first response would be to lay the person down, supine. This ensures, at least, that the CPP is the same as the BP at the heart and usually suffices to alleviate the distress. Unfortunately, the anesthetized patient cannot complain of these early symptoms as hypotension develops and affects the brain, so the anesthetic appears to proceed uneventfully. It is the responsibility of the anesthesia professional, to ensure as best they can, using indirect methods, that CPP and brain oxygenation are sufficient. During anesthesia, to ensure oxygenation, we first rely on knowing that the inspired oxygen concentration and oxygen supply from the anesthesia machine is sufficient. Next, to ensure the blood is well oxygenated, we rely on the pulse oximeter to monitor oxygen saturation and therefore know the blood going to the brain is well saturated. Then, by monitoring end-tidal CO<sub>2</sub>, we can maintain normal levels of CO<sub>2</sub> to ensure that hypocarbia is not occurring, which would cause cerebral vasoconstriction. Finally, we use the BP measured at the arm to infer the CPP is high enough to move the well oxygenated blood through the brain. If the patient is supine, this assumption is reliable.

In the 2009 Symposium's proceedings, published in the *APSF Newsletter*,<sup>6</sup> current best practices recommendations for BP management in the BCP included the following: 1) Adjust BP in the BCP to account for the hydrostatic gradient; 2) Deliberate hypotension should be avoided in the BCP; 3) Maximum reduction from baseline BP should be no more than 30% with adjustment for any hydrostatic gradient in the BCP. In the opinion of myself and others, this recommendation should be changed. Instead, cuff BP should be maintained at or very near to the baseline awake BP when surgery is done in the BCP in order to protect the LLA.<sup>12,13</sup> If necessary, BP should be restored to baseline by titrating fluids and vasopressors as needed.<sup>10</sup>

Scientific research was called for, and by now, many studies have been presented looking at ways to monitor cerebral oxygenation, regional cerebral blood flow, and jugular venous bulb oxygenation in relation to changes in BP. In a 2013 APSF article, Shear and Murphy reviewed the available studies on the impact of the BCP on cerebral perfusion.<sup>12</sup> They wrote that until we know more about oxygenation and regional perfusion inside the brain, clinicians should remain aware of the danger of cerebral hypoperfusion in this patient population. In 2019, the same team extensively reviewed these and many newer studies.<sup>13</sup> Twenty-two studies used various research tools to measure regional

brain oxygen saturation, cerebral blood flow, and jugular venous oxygenation, and 68 studies looked at intraoperative management and outcomes. The authors summarized that there was often an imbalance of oxygen or CBF supply and demand during BCP surgery. However, an association between these variables of cerebral oxygenation and regional cerebral blood flow was not clearly shown. They concluded that in the absence of data generated within the patient's brain, the safest approach toward perioperative BP management is to maintain MAPs close to baseline values throughout the procedure; wise advice. However, even if these studies of cerebral oxygenation and regional CBF had demonstrated a true cause and effect relationship between low BP and cerebral hypoperfusion or regional cerebral hypoxia, such research tools are not yet available for routine clinical monitoring. Perhaps in the future we'll see the development of cost-effective, noninvasive monitors of CPP, CBF, and oxygenation using equipment derived from cerebral oximetry, near infrared spectroscopy, monitors of CBF, processed EEGs, or other new technologies. Until then, CPP must be maintained at extra safe levels, given what we currently know about the LLA versus how little we know about the adequacy of cerebral perfusion in each person's brain during anesthesia.

Two very large studies of intra-operative hypotension (IOH) in patients undergoing a broad range of operations place the potential risk of the BCP to reduce cerebral perfusion into perspective. Monk et al. showed that about 5 minutes of BPs below the threshold limits for systolic BP of 70 mmHg, for MAP of 55 mmHg and for diastolic BP of 35 mmHg, with appropriate risk adjustment, was strongly associated with increased postoperative 30-day mortality from all causes.<sup>14</sup> Similarly, Staplefeldt et al. extended this observation to find that when MAPs decreased progressively from 75 mmHg to 45 mmHg coupled with time of exposure to the IOH, the increase in all-cause 30-day postoperative mortality was also highly significant.<sup>15</sup> A third study by Ahuja et al.<sup>16</sup> examined myocardial and acute kidney injury in 23,140 patients undergoing noncardiac surgery, all of whom had intra-arterial BP measurements recorded at 1-minute intervals. When systolic BP fell below 90 mmHg, and mean BP fell below 65 mmHg, sustained for 5 minutes, significant and clinically meaningful associations were shown for myocardial and kidney injury. These three studies reinforce the concern that the risk of brain damage could also be increased when operating on patients in the BCP while not maintaining baseline BPs at the level of the brain. Why? Because the MAP at the brainstem (30–50 mmHg) and the cortex (20–40 mmHg) is lower, and the time of exposure to these very low BPs during surgery in the BCP is usually far longer than what was reported in these 3 studies.<sup>14-16</sup> Thus, if a few minutes of decreasing MAPs towards 45 mmHg can

increase postoperative 30-day mortality, and 5 minutes of decreasing MAPs below 65 mmHg can increase myocardial and kidney injury, it is reasonable to worry about the risk of brain damage when CPP decreases below 30–50 mmHg along with a one- or two-hour duration of cerebral hypotension as is common during shoulder surgery. Meanwhile, the anesthesia record will show a smooth and stable anesthetic since recorded cuff BPs at the arm/heart level seem relatively normal, having not been adjusted for the upright, BCP position.

Granted the outcome of brain damage is rare, as are many other catastrophic outcomes resulting from anesthetic complications. For example, malignant hyperthermia, or hypoxic encephalopathy, or death following failed intubation are rare outcomes, but enormous attention and resources justifiably have been and continue to be devoted to these topics and others. As Drummond et al. stated, “We cannot take assurance from the notion that at any given time “some” of the brain is not ischemic. It would be slim consolation to the devastated patients or their families to know that blood flow continued to some portions of the nervous system while disabling damage was evolving in others.”<sup>17</sup>

Knowing how autoregulation affects cerebral blood flow is critical in clinical practice because it leads us to gently react to mild decreases in BP in order to preserve cerebral perfusion. But, by knowing when the LLA (70–80 mmHg) is approached, thereby increasing the risk of cerebral ischemia as CBF falls in parallel with worsening hypotension, one must take into account the hydrostatic gradients and aggressively restore the patient's BP to baseline at the arm/heart level. To paraphrase Lanier's cautionary warning, this is consistent with our historic role as the vulnerable patient's last homeostatic defense for avoiding brain damage during anesthesia and surgery.<sup>18</sup>

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*The author has no conflict of interest.*

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# Change of Pace: An Update on the Perioperative Management of Cardiovascular Implantable Electronic Devices (CIEDs)

by Jacques P Neelankavil, MD; Annemarie Thompson, MD; Aman Mahajan, MD, PhD, MBA

**Editors' Note:** This editorial addresses the APSF article that has been the most viewed article by our readers throughout the world based on our analytics in the pre-COVID-19 era.

See the original article online at: <https://www.apsf.org/article/managing-cardiovascular-implantable-electronic-devices-cieds-during-perioperative-care/>

## SUMMARY

Cardiovascular implantable electronic device (CIED) is a general term for pacemakers, implantable cardioverter defibrillators (ICDs), and cardiac resynchronization therapy (CRT) devices. The goal of the APSF article from 2013 "Managing CIEDs during Perioperative Care" was to provide anesthesia professionals a general framework for managing patients with CIEDs in the perioperative period.<sup>1</sup> The 2011 Heart Rhythm Society (HRS)/American Society of Anesthesiologists (ASA) consensus statement<sup>2</sup> on which the APSF article was based, was a pivotal manuscript that demystified many confusing aspects of perioperative care of CIEDs. These issues are summarized below:

From a preoperative standpoint, many patients with CIEDs do not need a new evaluation prior to surgery. Patients with pacemakers necessitate yearly evaluations, and patients with ICDs or CRT devices require interrogations every 6 months.<sup>2</sup> The preoperative assessment of CIEDs is primarily focused on communication between the anesthesia professional, the surgeon, and the CIED team (cardiologist, nurse practitioners, and/or manufacturer representative). It is important for all members of the team to understand the patient and surgical factors that are necessary so as to create an individualized approach for each patient. Critical information for the anes-

thesia professional includes date of last interrogation, device type, indication for device placement, battery longevity, current programming, pacemaker dependence, and magnet response (see Table 1 from original article—<https://www.apsf.org/article/managing-cardiovascular-implantable-electronic-devices-cieds-during-perioperative-care/>).<sup>1</sup>

The CIED plan must include an assessment of electromagnetic interference (EMI). While there are several causes of EMI, the most common cause in the operating room is monopolar electrocautery.<sup>1</sup> If the EMI is within 6 inches of the pulse generator, it can inhibit pacing and/or cause inappropriate tachycardia therapy depending on the type of CIED. Damage to the pulse generator is rare, though possible. While CIEDs have algorithms for minimizing inappropriate sensing and pacing, EMI can still cause oversensing. Pacemaker oversensing will cause a pacemaker to interpret EMI as intrinsic cardiac activity, preventing delivery of pacing stimuli in a pacemaker-dependent patient. ICD oversensing will cause EMI to be interpreted as a tachyarrhythmia, and it may lead to inappropriate defibrillation. For surgery below the umbilicus, the HRS/ASA consensus document recommends that there is minimal need to reprogram a CIED or place a magnet because the risk of oversensing is small as long as the grounding pad is appropriately positioned. To minimize the risk of electromagnetic interference, the dispersive electrode (grounding pad) should be positioned so the current pathway does not pass through or

near the cardiac implantable electronic device generator or leads.

Magnets are commonly used by many practitioners in the intraoperative environment due to ease of application; however, the CIED response to a magnet is varied depending on the type of the device, the age of the battery, and the way the device was programmed. In addition, placing a magnet may place the patient into an asynchronous mode, but the rate may not meet the physiologic demands of the patient. An important caveat is that while magnet application to an ICD will turn off the tachyarrhythmia functions, it will not have any effect on the pacemaker. It is important for the anesthesia team members to confirm the magnet effect on each patient's CIED.

The 2013 APSF article by Neelankavil et al. outlined an algorithm for the perioperative management of patients with CIEDs undergoing elective and emergent surgeries.<sup>1</sup> The algorithm for elective surgery focused on risk of EMI to the device, made the distinction between pacemakers and ICD, and suggested a different management approach based on pacemaker dependence (see Figure 1 from original article—<https://www.apsf.org/article/managing-cardiovascular-implantable-electronic-devices-cieds-during-perioperative-care/>).

## WHAT'S NEW IN 2020?

CIED technology has evolved since the original article, but many of the previously suggested perioperative approaches remain relevant today. The management of CIEDs continues to be a common clinical scenario for anesthesia professionals, especially since the prevalence of these devices in the population has increased. One study examining pacemaker implantation in the United States from 1993–2009 demonstrated an increase in utilization by 55%.<sup>3</sup> National ICD registries have identified over 1.7 million devices placed in the United States alone.<sup>4</sup>

Are we too concerned about CIED management in the perioperative settings? Has technology improved so much since the last APSF article that anesthesia professionals should not worry about perioperative CIED care? A clinically relevant study by Schulman et al. concluded that EMI still poses a significant risk to patients with CIEDs undergoing surgery with EMI. Their prospective study placed ICDs in a "monitor mode" for patients undergoing a variety of surgeries.

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## Electromagnetic Interference and Oversensing of CIEDs remains a Perioperative Patient Safety Concern

### From “CIEDs,” Previous Page

Monopolar electrocautery resulted in clinically important EMI (EMI that would have caused inappropriate antitachycardia pacing or defibrillation by an ICD had the device not been reprogrammed) in 20% of patients during noncardiac surgery above the umbilicus, in 29% of patients during cardiac surgery, and in 0% of patients if surgery was below the umbilicus. The study used protocolized electrosurgery dispersive electrode positioning as recommended by the ASA and HRS.<sup>5</sup> The strength of the study identifies the importance of an individualized care plan for CIED patients based on the type of cardiac device as well as CIED position and location of surgery because the risk of clinically significant EMI is real even with improved contemporary CIED technology.

Since the 2013 article,<sup>1</sup> newer types of pacemakers and ICDs have been FDA-approved and are being used clinically. These devices have specific CIED perioperative considerations for anesthesia professionals. The Medtronic Micra™ is a leadless pacemaker approved for use in the United States. The Micra is a self-contained generator and electrode single chamber device placed in the right ventricle via the femoral vein. Its modes include VVIR (ventricular pacing, ventricular sensing, pacing inhibition in response to sensed event, rate modulation), VVI, VOO (asynchronous ventricular pacing), and OVO (ventricular sensing only), and there is no defibrillation capacity. The advantage of leadless pacemakers is the elimination of major and at times devastating complications associated with transvenous leads: pocket infections/hematomas, intravascular lead infections, vascular thrombosis, lead dislodgment, and lead fracture. These devices do not have a magnet sensor and thus will not respond to a magnet as they are of very small size. It is recommended that these devices be reprogrammed to VOO mode to reduce oversensing when EMI is anticipated.<sup>6</sup>

The subcutaneous ICD (S-ICD) manufactured by Boston Scientific is another newer type of ICD encountered in clinical practice. It is used for patients at risk for ventricular arrhythmias who do not need bradycardia or antitachycardia pacing.<sup>7</sup> Although this device is not able to provide long-term pacing, it is capable of pacing at 50 pulses per minute for 30 seconds after a defibrillator shock, should the patient become profoundly bradycardic post-treatment.<sup>8</sup> The S-ICD consists of a pulse generator and a single subcutaneous lead. Both the pulse generator and the lead are implanted in the subcutaneous tissue and are extra thoracic.<sup>9</sup> The pulse generator is usually implanted between the anterior and mid-axillary lines at the level of the 6th intercostal space. The lead is then tunneled medially from the pulse generator pocket to the xiphoid process and then superiorly along the left paraster-



nal border. Like the Micra, an advantage of the S-ICD is lack of transvenous leads. The S-ICD has the same response to a magnet as a traditional ICD. Magnet application over the pulse generator will turn off the antiarrhythmic features of the device and removing the magnet will revert the device to its prior programmed state. A feature the S-ICD has that ensures the magnet is properly positioned is a “beeping” sound which indicates that arrhythmia detection and shock therapy have been suspended. If the beep is not heard with magnet application, it is recommended that the magnet be repositioned over the device until a beep is elicited. It may be difficult to keep the magnet over the generator; reprogramming the device may be more practical depending on the type of surgery and patient position.

The ASA recently published an updated practice advisory for the perioperative management of CIEDs in 2020.<sup>10</sup> The document emphasizes similar tenets of the 2011 ASA/HRS consensus statement including the importance of the preoperative evaluation and the importance of determining the risk from EMI. There are several new suggestions contained in the practice advisory that offer clarity in specific clinical situations. The document addresses what to do if emergency cardioversion or defibrillation are needed in a patient with a CIED. In this situation the advisory recommends termination of all EMI, removal of a magnet (if applied), and observation of the patient for appropriate antitachycardia therapy from the CIED. If the CIED was programmed to turn off antitachycardia therapy, determine the need to reprogram the device. If removing the magnet does not restore the CIED antitachycardia therapy or if the device cannot be programmed quickly, proceed with emergency external cardioversion or defibrillation. The new practice advisory also addresses the increasing use of MRI conditional CIEDs and the perioperative management of these devices. The advisory specifically discourages the “indiscriminate” application of magnets to CIEDs, which is consistent with the 2011 HRS/ASA statement recommending that magnet response be known for a patient’s CIED prior to applying a magnet.

Technology has changed since the original 2013 APSF article; however, the basic principles outlined by this important article are still

relevant today. EMI and oversensing of CIEDs in certain patients continues to be a clinical problem for anesthesia professionals. With the advent of new pacemakers and ICDs, anesthesia professionals will continue to see a myriad of devices, and we have the ability to create thoughtful individualized plans for all patients with CIEDs.

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# Residual Neuromuscular Blockade: A Continuing Patient Safety Issue

by Glenn Murphy, MD

See the original article online at: <https://www.apsf.org/article/monitoring-of-neuromuscular-blockade-what-would-you-expect-if-you-were-the-patient/>

Careful intraoperative management of neuromuscular blockade may optimize patient recovery and improve postoperative outcomes. Four important articles in the February 2016 *APSF Newsletter* described why postoperative residual neuromuscular blockade (PRNB) was an important patient safety issue, and how appropriate dosing, monitoring, and reversal of neuromuscular blocking agents could reduce the incidence of this complication following anesthesia and surgery.

In the first article, Robert Stoelting, MD, summarized the opinions of the APSF relating to the use of qualitative monitoring (peripheral nerve stimulator) and quantitative monitoring (devices which objectively measure muscular function and display the results) in the perioperative period (Figure 1).<sup>1</sup> The APSF recommended that every patient receiving a muscle relaxant should have at least qualitative, and preferably quantitative monitoring, to assess requirements for reversal agents and adequacy of neuromuscular function prior to tracheal extubation. Literature was reviewed documenting that PRNB was a significantly underappreciated problem that occurred in up to 40% of patients. Subjects with train-of-four (TOF) ratios < 0.9 (the threshold for adequate neuromuscular recovery) were at risk for a number of adverse outcomes including hypoxemia, airway obstruction, impaired pharyngeal function and an increased risk for aspiration, delayed PACU discharge, postoperative pulmonary complications, and need for reintubation. Although evidence clearly documented that quantitative monitoring could significantly reduce the risk of PRNB, these devices were infrequently applied in clinical practice. Possible reasons why clinicians were slow to adopt quantitative monitoring included the erroneous belief that PRNB was an uncommon problem, the unavailability of simple, easy-to-use devices, and the over-reliance on insensitive indicators of neuromuscular recovery (5-second head-lift and no fade observed TOF stimulation). Robert Stoelting concluded by stating that North American professional anesthesia associations should provide recommendations that neuromuscular monitoring (qualitative, and ideally quantitative)



Figure 1: Depicts a quantitative neuromuscular blockade monitor being applied to the subject's ulnar nerve.

should be used whenever muscle relaxants are administered.

In the second article, investigators from The Massachusetts General Hospital, Boston, MA, reported on an evidence-based initiative instituted at their hospital to decrease the incidence of PRNB.<sup>2</sup> This initiative consisted of four components: implementation of an education program; distribution of a cognitive aid; provision of feedback regarding departmental progress; and the adoption of a TOF documentation requirement for the department's quarterly QI incentive bonus. Department-wide presentations provided information regarding the incidence of PRNB and associated clinical outcomes. The cognitive aid, which was a TOF-based neostigmine dosing guide, was distributed to all members of the department. Finally, quarterly QI bonuses were tied to the rate of documentation of the number of twitches (TOF count) within the 15 minutes of neostigmine administration. This initiative was an example of an integrated interdisciplinary approach to promote sustained adoption of best practices related to neuromuscular management, instituted with the aim of reducing PRNB and improving patient safety.

A third article reviewed the development and regulatory history of sugammadex in the United States.<sup>3</sup> Anton Bom, MD, at the Neuromuscular Research Group at Organon Newhouse Scotland, determined that modified cyclodextrins would bind steroidal muscle relaxants. The first human study with this new agent was performed and published in 2005, and sugammadex received regulatory approval in the European Union in 2008. At this same time in the United States, the FDA issued a Not-Approvable Letter over concerns relating to possible anaphylactic reactions, as well as the potential effects of the drug on coagulation and on the QT interval of the EKG. After conducting additional studies and further submissions to the FDA, sugammadex received FDA approval on December 16, 2015.

In the fourth article, Karl Hammermeister, MD, and colleagues briefly reviewed the literature examining the impact of neuromuscular management strategies on postoperative outcomes.<sup>4</sup> An early large-scale investigation by Beecher and Todd (1954) reported that postoperative mortality was six times higher in patients administered muscle relaxants, compared to a cohort managed without these agents.<sup>5</sup> Hammermeister et al. noted that there were only a few studies published comparing outcomes in patients given reversal agents versus those administered none. In a large clinical trial by Debaene et al., the risk of PRNB was examined in patients given a single intubating dose of a

muscle relaxant with no reversal agent. The investigators reported that in those patients in whom two or more hours had passed since muscle relaxant administration, 37% of these subjects had TOF ratios < 0.9.<sup>6</sup> The review concluded by stating that there was a consensus in the literature that PRNB was common and was associated with an increased risk of adverse outcomes, particularly respiratory. In addition, neuromuscular monitoring and appropriate reversal with neostigmine was highly variable amongst anesthesia professionals, and these practices likely accounted for the high incidence of PRNB.

## WHAT DO WE NOW KNOW ABOUT NEUROMUSCULAR MANAGEMENT AND POSTOPERATIVE OUTCOMES?

Since the publication of the February 2016 *APSF Newsletter*, a large number of clinical studies have been published, which have examined the incidence of PRNB in clinical practices, complications associated with PRNB, the impact reversal strategies have on outcomes after surgery, and the development of new quantitative monitors.

### Incidence of PRNB

Investigations have continued to document a high incidence of PRNB in anesthesia practices around the world. The RECITE-US study measured TOF ratios in 255 patients undergoing abdominal surgery in the United States.<sup>7</sup> The investigators observed that the majority of patients (64.7%) had TOF ratios < 0.9 at the time of tracheal extubation, despite reversal of rocuronium with neostigmine and the use of qualitative peripheral nerve stimulation. Similar findings were observed in RECITE trials performed in Canada<sup>8</sup> and China.<sup>9</sup> These findings suggest that PRNB continues to be a common anesthetic complication when quantitative monitoring and sugammadex are not used.

### Complications associated with PRNB

Patients with TOF ratios < 0.9 in the PACU are at increased risk for adverse respiratory outcomes. A large multicenter study from Spain reported that the patients with TOF ratios < 0.9 in the PACU were at an increased risk for postoperative adverse respiratory events (odds ratio [OR] 2.57) and had a higher incidence of reintubation.<sup>10</sup> Another investigation determined that the single most important independent predictor for adverse respiratory events during early recovery from anesthesia and surgery was PRNB (OR 6.4).<sup>11</sup> A retrospective cohort study, which assessed the impact of PRNB on ICU admissions rates, hospital costs, and hospital length of stay, reported that patients with TOF ratios < 0.9 had a three-times higher risk of ICU admission than those with TOF ratios ≥ 0.9.<sup>12</sup>

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# Recent Data Suggest Reduction in Adverse Events with Neuromuscular Blockade Reversal

## From “PRNB,” Preceding Page Effect of reversal strategies on postoperative outcomes

Failure to reverse neuromuscular blockade may increase the risk of postoperative pulmonary complications. In a large databased investigation, Bulka et al. observed that patients who were not administered a reversal agent had a 2.3-times higher risk of postoperative pneumonia compared to those given neostigmine.<sup>13</sup> In a similar large investigation of 11,355 surgical patients, the incidence of postoperative respiratory complications (defined as failure to wean, pneumonia, or reintubation) was significantly higher in patients who were not reversed versus those who were given neostigmine.<sup>14</sup> A third databased investigation determined that patients who were not reversed (versus neostigmine reversal) had higher incidences of major complications (6.05% vs. 1.7%), need for reintubation (4.6% vs. 0.8%), and unplanned ICU admissions (3.2% vs. 0.8%).<sup>15</sup>

Recent studies have documented that sugammadex may significantly reduce the risk of PRNB and beneficially impact outcomes related to PRNB. Oh et al. retrospectively collected data on 1,479 patients undergoing abdominal surgery whose neuromuscular blockade was reversed with either neostigmine or sugammadex.<sup>16</sup> Patients in the sugammadex group had a 34% lower 30-day unplanned readmission rate, a 20% shorter hospital stay, and a 24% reduction in hospital charges. A prospective observational study (558 patients) reported that major respiratory complications (pneumonia or atelectasis) occurred in 1.1% of patients reversed with sugammadex, versus 7.2% to 9.7% of all patients not reversed or reversed with neostigmine.<sup>17</sup> Neuromuscular monitoring was used in only approximately 30% of patients in each group, which may have explained the lack of benefit observed with neostigmine reversal (neostigmine is ineffective if administered at a deeper level of blockade). A large multicenter observational matched-cohort study examined the effect of choice of reversal agent (neostigmine or sugammadex) on major postoperative pulmonary complications (pneumonia, respiratory failure, or other pulmonary complications).<sup>18</sup> In the study, 22,856 patients receiving sugammadex were matched with 22,856 patients given neostigmine. The investigators observed that sugammadex administration was associated with a 30% reduced risk of pulmonary complications, a 47% decreased risk of pneumonia, and a 55% reduced risk of respiratory failure. In contrast to these studies, a large multicenter observational study (POPULAR) did not find that the administration of reversal agents was associated with a reduced risk of postoperative pulmonary complications.<sup>19</sup> Additionally, better pulmonary outcomes were not observed in patients given sugammadex versus those administered neo-

stigmine. However, a number of Letters to the Editor were subsequently published outlining concerns relating to the study, which included limitations inherent in many observational studies such as lack of standardization of anesthetic, ventilatory, or fluid management; improper management of monitoring and reversal of neuromuscular blockade; and an inability to oversee potential protocol violations or other factors resulting in bias.

## NEW QUANTITATIVE MONITORS

A recent Consensus Statement on the Use of Perioperative Monitoring recommended that quantitative monitors should be used whenever a nondepolarizing muscle relaxant has been administered.<sup>20</sup> However, in order for objective monitors to be widely accepted into clinical practices, improvements in the design of the devices are required so that function is not affected by patient hand position, monitors are self-calibrating and provide reliable and repeatable results, and monitor setup times are minimal.<sup>16</sup> Unlike first-generation technology, recently developed quantitative monitors appear to fulfill most of these criteria. Three-dimensional acceleromyographic (AMG) technology has been recently incorporated into quantitative monitors developed for routine intraoperative use. Good agreement between the TOF-Watch SX with calibration and preload application (clinical “gold standard”) and an uncalibrated three-dimensional acceleromyography monitor has been observed throughout all stages of neuromuscular recovery.<sup>21</sup> Portable electromyographic (EMG) devices have also been recently developed and approved for routine clinical care. Train-of-four ratio data can be rapidly obtained after placing an electrode strip on the hand and connecting the strip to a cable. EMG monitors provide accurate quantitative data without the need for immobilization of the studied muscle, preload application, or free movement of the thumb (arms can be tucked at the sides).<sup>20</sup> However, further studies are needed to assess the accuracy and reliability of these new quantitative monitors in clinical practices.

## CONCLUSIONS

Despite advances in pharmacology and technology that have occurred over time, PRNB continues to occur frequently in clinical practices, with a rate that has remained essentially unchanged for four decades. These important articles published in the February 2016 *APSF Newsletter* helped to raise awareness of this important patient safety issue and helped pave the way for further research and improvements in clinical care. With the increasing use of both sugammadex (dosed appropriately based upon neuromuscular monitoring) and quantitative monitoring by anesthesia care teams, it is likely that the risk of patients suffering complications from PRNB will be reduced in the coming decade.

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# National Partnership for Maternal Safety— Maternal Safety Bundles

by Jennifer M. Banayan, MD, and Barbara M. Scavone, MD

See the original article online at: <https://www.apsf.org/article/national-partnership-for-maternal-safety-maternal-safety-bundles/>

The United States is one of only eight countries worldwide and the only high-resource nation where maternal mortality has increased since 1990.<sup>1</sup> Parturients in this country are three times more likely to die from pregnancy-related complications than women in Britain, Germany, or Japan.<sup>1</sup> These findings are shocking, especially considering that prior to 1982, United States maternal mortality had improved dramatically over the prior century,<sup>2</sup> with the progress attributed to advances in medical care, more hospital deliveries by those trained in obstetrical care, and better aseptic technique.<sup>3</sup>

Traditionally, the most common causes of maternal death were hemorrhage, hypertensive disorders, thromboembolic events, and infections.<sup>4,5</sup> The proportion of deaths due to conventional causes—including anesthesia-related causes—is now declining. The increase in maternal death was attributed to cardiovascular conditions and other co-existing medical diseases.<sup>5,6</sup> Given these increases in maternal mortality and morbidity, urgent action is needed to identify and evaluate the causes of these deaths and to identify preventable factors. This need resulted in the formation of the National Partnership for Maternal Safety (NPMS), housed within the Council on Patient Safety in Women's Healthcare. Its stated mission was to “continually improve patient safety in women's health care through multidisciplinary collaboration that drives cultural change,” and it aimed to reduce United States maternal morbidity and mortality by 50%. To accomplish their objective, NPMS created patient safety bundles—evidence-based interventions designed to be implemented together to improve outcomes.<sup>7</sup> NPMS began by creating materials on three topics: hemorrhage, hypertension in pregnancy, and thromboembolic disease, and published their recommendations on the website: <https://www.safehealthcareforeverywoman.org>.

## EDITORIAL-WHAT'S NEXT?

It has been four years since the *APSF Newsletter* published our article on maternal safety with a specific focus on the NPMS maternal safety bundles, and unfortunately our dismal maternal mortality and morbidity rates have not changed as much as we had hoped. In our original article, we referred to the 2007 United States maternal mortality rate (MMR), which was 12.7 per 100,000. With high hopes for an improvement in our numbers, we eagerly



waited a decade for the National Vital Statistics Report from the National Center for Health Statistics (NCHS) with the updated MMR from 2018 which was released in January 2020. Unfortunately, our MMR increased to 17.4, making us worst among developed countries, again.<sup>8</sup> The newest NCHS data are similar to the old. Women over age 40 carry a higher risk of dying, with a rate of 81.9 per 100,000 births, almost 8 times the risk for a 25-year-old woman. African American women are at particularly high risk. Their MMR is 37.1 deaths per 100,000 live births, a rate 2.5 times that of non-Hispanic white (14.7), and 3 times that of Hispanic (11.8) women.<sup>8</sup> Advanced age and Black race together confer a particularly high lethality risk: a Black woman over the age of 40 has a 1 in 700 chance of dying during her delivery hospitalization.<sup>4</sup>

What happened? Why are our mortality numbers not improving? Those are the questions epidemiologists, clinicians, and researchers are asking. At the time of our original article's publication, the Bundle on Obstetric Hemorrhage,<sup>9</sup> published in 2015, was in the midst of being incorporated into birthing centers across the country. Using the bundle as a starting point, clinicians changed the way they managed a maternal hemorrhage by creating hemorrhage kits and carts, forming response teams, designing updated checklists and time outs for handling a hemorrhage, and establishing huddles and debriefings focused on system issues. Is three years enough time to see a change in our mortality numbers? Perhaps not. First, many delivery centers failed to implement recommended protocols or adhere strictly to changes in practice. Second, three years may not be enough time to see a real difference in out-

comes even after the bundles are widely adopted. In spite of the lack of change in national numbers, we have good evidence that instituting maternal hemorrhage protocols can have a real impact on maternal morbidity and mortality.<sup>10-12</sup> California mandated the incorporation of the hemorrhage bundle in all birthing centers several years ago and was able to demonstrate differences in severity of hemorrhage, transfusions required, and possibly even in emergency hysterectomies performed.<sup>13</sup>

When we take a closer look at the Center for Disease Control and Prevention's (CDC) Pregnancy Mortality Surveillance System, we are able to identify a striking pattern in mortality, similar to those of the NCHS: many minority groups, specifically Non-Hispanic Black and non-Hispanic American Indian/Alaska Native women, experiencing higher MMRs (40.8 and 29.7, respectively) than all other racial/ethnic groups.<sup>14</sup> Many blame this disparity on poverty, lack of education, limited access to prenatal care, and general poor physical and mental health. But even when investigators control for education and socioeconomic status, Black women remain at higher risk for mortality. In fact, African American women with relative social and economic advantages, such as a college degree, have considerably higher risks of adverse outcomes in pregnancy than white women without such advantages.<sup>15</sup> Researchers and clinicians have struggled to explain the striking disparity for Black women. One theory is that chronic stress from unrelenting systemic racism experienced by Black women in this country creates a physiological strain which leads to hypertension and/or pre-eclampsia,

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## Minority Groups Have Higher Rates of Adverse Outcome During Pregnancy

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which we know leads directly to higher rates of maternal death.<sup>16</sup> In other words, the everyday stressors experienced simply by being a Black woman in America increase the likelihood of experiencing illness and dying from it, and this extends to the pregnancy and postpartum periods. Racism is also experienced as a result of implicit bias, causing health care workers to ignore legitimate concerns and symptoms in Black patients.<sup>17</sup> Sometimes the pain is vague or the symptoms are unclear, but they may be the critical warning signs clinicians need to appreciate and act upon in order to prevent the next maternal mortality.

In addition to concerns over racial disparities, new attention has focused on opioid-use disorders and mental health and suicide-related deaths. Unfortunately, the CDC does not include deaths due to overdose or self-harm when reporting maternal mortality, considering these deaths pregnancy-associated, rather than pregnancy-related. Therefore, most of our knowledge on these topics is limited to information collected from the death certificate, and it is difficult to ascertain whether injury deaths such as drug overdoses, suicides, and homicides occurring during pregnancy or within one year postpartum should be considered pregnancy-related. The opioid overdose epidemic has been identified as a major cause of mortality in both men and women in this country, and pregnant woman may be at particular risk. Between 2007 and 2016, pregnancy associated mortality resulting from overdose of medication more than doubled.<sup>18</sup>

Last year, a retrospective, population-based cohort study following over a million women who delivered a live-born infant in California hospitals demonstrated deaths caused by drugs was the second leading cause of death (3.68 per 100,000 person-years) and suicide was the seventh leading cause (1.42 per 100,000 person-years) in the postpartum period. In this instance, the United States is not alone. The United Kingdom has reported suicide as their primary cause of postpartum pregnancy-associated death,<sup>19</sup> and Japan has struggled with mental health and suicide for many years.<sup>20</sup>

As opioid dependency increases, we, as anesthesia professionals will be managing patients who abuse opioids and consequently develop opioid tolerance and hyperalgesia. Women with opioid dependency often report higher pain scores postpartum than those in the general obstetric population; it is essential that clinicians are aware that despite the higher dose requirements, opioid-dependent women

**Figure 1: Council on Patient Safety in Women's Health Care Maternal Safety Bundles**

Obstetric Hemorrhage
Severe Hypertension in Pregnancy
Maternal Venous Thromboembolism
Obstetric Care for Women with Opioid Use Disorder
Reduction of Peripartum Racial/Ethnic Disparities
Prevention of Surgical Site Infection
Maternal Mental Health: Depression and Anxiety
Safe Reduction of Primary Cesarean Birth

<https://safehealthcareforeverywoman.org/>

are not immune to the sedative effects of opioids. The anesthesia professional faces a challenging balance between adequate analgesia and sedation and respiratory depressant effects. Women with substance abuse are at increased risk of needing a cesarean delivery, requiring a blood transfusion, and death.<sup>21</sup> Conversely, women who are opioid-naïve have a small risk of becoming dependent on opioids if their clinician prescribes postpartum opioids after discharge. Vulnerable patients include those with a history of psychiatric illness, use of other illicit substances, and chronic pain disorders such as headache or chronic back pain. Caregivers must become aware of attributes that place patients at risk and emphasize multimodal pain management to limit opioid administration.<sup>22</sup>

These new findings underscore that first, we must support the CDC and other maternal mortality committees to look beyond traditional causes of maternal death and include pregnancy-associated deaths in their data. If we do not count those deaths, it is impossible to prevent them. Second, more must be done to address mental health and substance abuse as it relates to maternal health overall.

We have a lot of work to do. It is going to take considerable effort for all clinicians to incorporate the bundles as they're published. In an effort to combat our rising morbidity and mortality, the NPMS has continued its important work. In our original article, we discussed the publication of the Bundle on Obstetric Hemorrhage in 2015<sup>9</sup> and the Bundle on Venous Thromboembolism in 2016.<sup>23</sup> Since then, the NPMS has published the Bundle on Racial and Ethnic Disparities<sup>15</sup> and the Bundle on Obstetric Care for Women with Opioid Use Disorder.<sup>24</sup> All who participate in the care of pregnant women should employ these bundles. Numerous other bundles have been released: in January 2017, the Bundle on Preven-

tion of Surgical Site Infections<sup>25</sup> followed closely by the Bundle on Maternal Mental Health.<sup>26</sup> In August 2017, the Bundle on Severe Hypertension during Pregnancy was issued,<sup>27</sup> and in 2018, the Bundle on Safe Reduction of Primary Cesarean Births (Figure 1).<sup>28</sup>

Despite widespread awareness that the United States MMR is the highest among high-resource countries, and concerted efforts are underway on a national scale to make real changes, the latest NCHS and CDC numbers reveal a continued worsening in our MMR.<sup>8</sup> Perhaps our mothers are older and sicker than others across the world, or perhaps our statistics are lagging and we will see an improvement in our numbers over the next decade. Either way, we cannot become complacent and stop with a hemorrhage bundle. As anesthesia professionals, we should continue to take an active role in implementing all maternal bundles. Now, more than ever, we must act as peripartum clinicians and participate with other caregivers to optimize maternal safety.

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*The authors have no conflicts of interest. Jennifer Banayan is associate editor of the APSF Newsletter.*

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## NPMS Has Released Several More Bundles For Obstetric Care Since Original Campaign

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## PostOp Visual Loss, cont'd

From “PostOp Visual Loss,” Page 86

Mark A. Warner, MD, Ann Lofsky, MD, Richard T. Connis, MD, Robert A. Caplan MD, and the SNACC members from The POVL Study Group.

Lorri A. Lee, MD, is a practicing anesthesiologist in Richland, WA, former Director of the ASA POVL Registry and member of the ASA Task Force on Perioperative Visual Loss.

The author has no conflicts of interest.

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## Anesthesia Patient Safety Foundation Panel

### The APSF: Ten Patient Safety Issues We've Learned from the COVID Pandemic

**Saturday, October 3, 2020**

1:00 pm–2:00 pm CT

Moderator: Mark A. Warner, MD



**Mark A. Warner, MD**

# RAPID Response

to questions from readers

# RAPID Response and the APSF Mission

by Jeffrey Feldman, MD, MSE

In the spring of 2004, the *APSF Newsletter* published a groundbreaking article entitled “Misplaced Valve Poses Potential Hazard” as the inaugural contribution to the **Dear SIRS** (now **RAPID Response**) column. In that article, James Berry, MD, and Steve Blanks, CRNA, reported the unexpected occurrence of high airway pressure, up to 40 cm H<sub>2</sub>O of PEEP, when the exhaust line from the scavenging system became occluded. It turned out that the active scavenging systems they used had been assembled with a relief valve intended for the passive scavenging system product. Datex-Ohmeda was the manufacturer at that time and in response, Michael Mitton, CRNA, Director of Clinical Affairs, wrote: “Datex-Ohmeda has identified the cause of the incorrect assembly and has instituted changes in the assembly process to avoid a repeat of this error.” Collaboration identified a problem that could be fixed by the manufacturer, the cause was identified and the problem publicized in a publication circulated to large numbers of anesthesia professionals.

This collaboration between users and manufacturers to identify and solve problems highlights the unique role that APSF plays in engaging all stakeholders to address patient safety concerns.

The concept for the RAPID Response column was developed by Michael Olympio, MD, and Robert Morell, MD, then chairman of the APSF Committee on Technology and editor of the *APSF Newsletter*, respectively. The initial name for the column was **Dear SIRS**, an acronym for **Safety Information Response System**. Michael Olympio and Robert Morell recognized that users were uniquely qualified to identify patient safety concerns related to medical devices, but that collaboration with industry to address these concerns was lacking. The APSF has always been highly effective at convening stakeholders in patient safety and the APSF Committee on Technology (COT), by design, includes both users and manufacturers. The seeds were there for a collaborative forum between industry and users.

**Figure 1: Top 25 RAPID Response Articles by Page Views, May 1, 2018–June 2, 2020**  
Data analytics initiated in 2018.

<a href="#">How Do Flow Sensors Work?</a>	6,325
<a href="#">Humidity Levels in ORs</a>	3,905
<a href="#">Potential Burn Hazard from General Electric MRIs</a>	3,765
<a href="#">Reusable Anesthesia Breathing Circuits Considered</a>	3,499
<a href="#">Not All Manifolds are the Same: Lessons in Intravenous Drug Administration</a>	2,021
<a href="#">Dräger Fabius Leak Test Questioned</a>	1,662
<a href="#">Safety Issues With Gas Scavenging System in GE Avance and GE Aespire Anesthesia Machines</a>	1,645
<a href="#">Measurement of Expiratory Limb Circuit Pressure: A Potential Anesthesia Machine Safety Issue</a>	1,581
<a href="#">Why Do the Gauss Lines Matter?</a>	1,441
<a href="#">Line Isolation Still Important</a>	1,256
<a href="#">Volatile Anesthetic Unintentionally Not Delivered</a>	1,140
<a href="#">PEA Arrest During Transport of a Ventilated Patient Due to a Clogged Respiratory Filter on Ambu® Bag</a>	860
<a href="#">Reader Questions Why Some Anesthesia Machines Allow O<sub>2</sub> Flow Below Basal Metabolic Needs</a>	843
<a href="#">LTA Tip Breaks in Patient’s Airway</a>	765
<a href="#">Airway Topicalization Atomizer Parts Break Off in Patient’s Airway</a>	720
<a href="#">An Incident of GlideScope® Stat Cover Failure</a>	713
<a href="#">Nitrogen Contamination of Operating Room Oxygen Pipeline</a>	676
<a href="#">"No Read" Errors Related to Prefilled Syringes</a>	672
<a href="#">Perils and Pitfalls With the Rapid Infusion Catheter (RIC)</a>	672
<a href="#">O<sub>2</sub> Blender Causes Concern</a>	649
<a href="#">Descending Bellows Drives Question</a>	645
<a href="#">Defective Pediatric Endotracheal Tubes (ETTs)</a>	543
<a href="#">Burette Malpositioned Shut Off Valve Could Lead to Venous Air Embolism</a>	522
<a href="#">Defective Central Venous Catheter Introducer Needle</a>	440
<a href="#">Monitoring Gaps</a>	393

Since its inception, the **RAPID Response** column has become an integral part of the *APSF Newsletter*, a highly accessed part of the website and a major activity for the members of the APSF COT. One or more letters to this column appear in almost every issue of the *APSF Newsletter*. Other letters are addressed by facilitating a connection between the reporting individual and the related manufacturer but are not necessarily published. In the last two

years, the **RAPID Response** articles generated more than 45,000 pageviews to the APSF website. Figure 1 highlights topics from the top 25 accessed articles during that time.

Managing the communication between users of devices and manufacturers can be delicate at times. Users can be emotional and confrontational in reporting perceived safety

See “Rapid Response,” Next Page

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

**RAPID Response**  
to questions from readers

## RAPID Response, cont'd

### From "Rapid Response," Preceding Page

concerns. Manufacturers are appropriately concerned about the market perception of their products, especially when the problem is a use error and not inherent to the device. APSF attempts to broker a constructive conversation that fosters education on the proper use of devices and product improvement, without endorsing or criticizing a particular device or design.

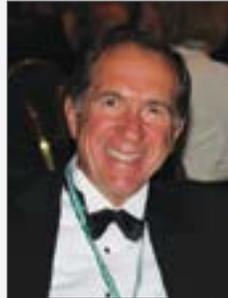
While the large majority of people reading this column are almost certainly clinicians, the value of the **RAPID Response** column is appreciated by our colleagues in industry.

*Congratulations to the Anesthesia Patient Safety Foundation (APSF) on the impact of the **Dear SIRS** column now named **RAPID Response**! While providing clinicians an environment to alert their peers of unique findings is important, what's made **Dear SIRS** so special is the process. The careful evaluation of each submission. Determining the opportunity to educate versus the need for a possible design change. Providing industry the opportunity to explain their technology as part of the publication. The process is unique. It's pure and unbiased. It's true to the APSF's mission to improve the safety of patients during anesthesia care.*

*As someone who is called upon to co-author a response from time to time in order to provide an industry perspective, I'm proud for the opportunity to play a small part in the **RAPID Response** column. And I'm thankful for the vision the APSF had to create a forum where clinicians and industry around the world can learn and advance the delivery of anesthesia together.*

David Karchner  
Senior Director of Marketing  
Draeger Medical

*The APSF focuses on the noble cause of patient safety during anesthesia care. In pursuing that cause, APSF provides an environment for rare collaborations. As an engineer, my training was to solve the root cause of problems so that they do not reoccur. **RAPID Response** has contributed directly to making anesthesia safer by providing a forum for selfless clinicians to share their observations and safety concerns. The process of evaluating these reports, a collaborative process between expert clinicians and experts in*



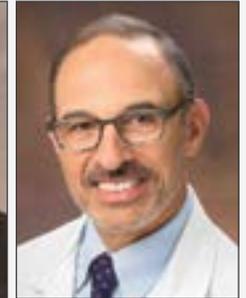
Michael Olympio, MD



Robert Morell, MD



A. William Paulsen, PhD



Jeffrey Feldman, MD

*industry, leads to better devices and safer anesthesia care. **RAPID Response** has led to education and device improvements to eliminate root causes of harm—and that leads toward improved safety! I've been honored to be a part of this process for a number of years, both working in industry R&D and at ECRI while serving in APSF. Kudos to everyone involved with making the Rapid Response happen!*

David T. Jamison PMP  
Executive Director, Selection and Evaluation  
ECRI

Some contributors to this column have raised the question about publishing in the *APSF Newsletter* rather than sending a letter to the editor of a major anesthesia journal. In general, journals do not necessarily have the editorial priority or connections to insure a collaborative response with industry. More importantly, the *APSF Newsletter* has much greater visibility in the anesthesia community. At the time of this writing, the *APSF Newsletter* circulates to more than 100,000 anesthesia professionals in North America and is translated into five different languages for international distribution. Recently, APSF created the ability to publish newsletter content on the APSF website in advance of print publication. No journal provides that degree of accessibility for time-critical patient safety information.

While the **RAPID Response** column appears in print every four months, letters received by APSF are acted upon as they are received. If appropriate, a connection with the manufacturer or related industry is sought. Depending upon the complexity of the report, it can sometimes take time to make the appropriate connection with industry which can delay the response. As soon as the response is available, it is sent to the original letter writer in advance

of the printed response. Recently, APSF has developed the capability to post the **RAPID Response** reports with industry response to the APSF website and announce them through social media in an effort to communicate information to the anesthesia community as rapidly as possible.

Michael Olympio, MD, and Robert Morell, MD, are to be congratulated for their vision in creating the **RAPID Response** process. The chair of the APSF COT and editor-in-chief of the *Newsletter* manage this activity and I want to recognize the contributions over the years of A. William (Bill) Paulsen, PhD, former COT chair, and Steven Greenberg, MD, current editor-in-chief of the *APSF Newsletter* who succeeded Robert Morell. Medical devices and technology are integral to the patient care process. For all parties involved, clinicians and manufacturers, patient safety is a paramount concern and there are always opportunities for improvement, whether it be in user training, product design, or manufacturing. The collaboration between users and manufacturers is essential to rapid identification of patient safety issues. **RAPID Response** is just one of many programs in support of the APSF mission that "No one shall be harmed by anesthesia care."

*Jeffrey Feldman, MD, MSE is professor of Clinical Anesthesiology, Children's Hospital of Philadelphia, Perelman School of Medicine, University of Pennsylvania, and chair of the APSF Committee on Technology*

*Dr. Feldman has received consulting compensation from Micropore, Inc., and Draeger Medical.*

*Thanks to Michael Olympio, MD, A. William Paulsen, PhD, and Robert Morell, MD, for contributing to the content of this article.*

# Anesthesia Patient Safety Foundation

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# The Effect of General Anesthesia on the Developing Brain: Is it Time to Temper the Concern?

by Luke S. Janik, MD

See the original article online at: <https://www.apsf.org/article/the-effect-of-general-anesthesia-on-the-developing-brain-appreciating-parent-concerns-while-allaying-their-fears/>

The effect of general anesthesia on the developing brain is arguably the most widely discussed, highly publicized, and controversial patient safety issue that the pediatric anesthesia community has faced in the past two decades. The potential for adverse neurodevelopmental outcomes after anesthesia exposure has called into question the intrinsic safety of our primary anesthetic agents, leading to understandable concern for both parents and anesthesia professionals. In October 2016, the *Anesthesia Patient Safety Foundation (APSF) Newsletter* addressed these concerns in an article titled “The Effect of General Anesthesia on the Developing Brain: Appreciating Parent Concerns While Allaying Their Fears.”<sup>1</sup> In today’s issue, we revisit the topic of anesthesia neurotoxicity, with a focus on three recent studies and their implications for the daily clinical practice of anesthesia professionals.

In 2016, the U.S. Food & Drug Administration (FDA) issued a Drug Safety Communication warning that “repeated or lengthy use of general anesthetic and sedation drugs during surgeries or procedures in children younger than 3 years or in pregnant women during their third trimester may affect the development of children’s brains.”<sup>2</sup> The new warning label was applied to nearly every anesthetic agent used in modern practice, including sevoflurane, isoflurane, desflurane, propofol, midazolam, and ketamine. When the FDA issued this warning, there was no definitive clinical evidence that showed anesthetic agents caused adverse neurodevelopmental outcomes. Rather, the warning was primarily driven by overwhelming data from animal studies across various species that demonstrated an association between anesthetic exposure and neurologic injury, such as widespread neuronal cell loss, oligodendrocyte loss, and impaired synaptogenesis during a period of rapid brain development.<sup>3–5</sup> Animal studies also demonstrated a link between early exposure to anesthetics and impaired cognition, behavior, and learning.<sup>4,5</sup>

While concerning, the animal data cannot be easily translated to humans. The dose and duration of anesthetic exposure in animal models is considerably higher than what an infant or child is typically exposed to in the operating room. The animal models lack the precise physiologic monitoring, controlled ventilation, and resuscitative efforts routinely utilized in clinical practice. Additionally, each animal model has a different “window of vulnerability” during brain develop-

ment, which is difficult to correlate with human brain development.

At the time of the FDA’s warning, the clinical data largely consisted of retrospective observational studies, comparing neurodevelopmental outcomes (e.g., cognition, behavior, learning disabilities) in individuals exposed to anesthesia at a young age to a matched, unexposed cohort. The results were variable and conflicting. Some studies showed no association between early anesthesia exposure and neurodevelopmental outcomes, suggesting that a single, brief exposure to anesthesia at a young age does not have negative effects on brain development.<sup>6–8</sup> Other studies, however, suggested exposure to anesthesia may result in neurocognitive deficits, particularly in children exposed to multiple anesthetics at an early age.<sup>9–11</sup> As the FDA acknowledged in their Drug Safety Communication, observational studies have many limitations and cannot prove causation.<sup>2</sup> Controlling for confounders including birth weight, gestational age, parental age/education, socioeconomic status, income, and ethnicity proved to be very difficult in these studies.

In the last five years, three well-designed, landmark studies made efforts to minimize these limitations, and their collective findings suggest that a single, brief exposure to general anesthesia in children is likely safe:

- 1) The Pediatric Anesthesia Neurodevelopment Assessment (PANDA) Study was a multicenter, retrospective, observational study comparing global cognitive function (IQ) of otherwise healthy children who were exposed to a single general anesthetic before age three to their unexposed sibling.<sup>12</sup> By utilizing sibling-matching, the PANDA study minimized the effects of confounding variables such as genetic background, socioeconomic status, parental age/education, and family income. A total of 105 sibling pairs were included in the study, and IQ testing took place between 8–15 years of age. There was no significant difference in IQ scores between the groups. Additionally, there were no significant differences in secondary outcomes of neurocognitive function including memory/learning, motor/processing speed, visuospatial function, attention, executive function, language, and behavior.<sup>12</sup>
- 2) The Mayo Anesthesia Safety in Kids (MASK) Study was a retrospective, observational study comparing general intelligence and neurodevelopmental outcomes in three groups of children—those never exposed to anesthesia, those exposed once before age three, and those exposed multiple times



before age three.<sup>13</sup> The authors utilized rigorous propensity-based matching of cohorts to minimize confounding variables, and administered a comprehensive battery of neuropsychological assessments. They found that anesthesia exposure—both single and multiple times—before age three was not associated with any deficits in general intelligence.<sup>13</sup> Single exposures were not associated with deficits in other neuropsychological domains.<sup>13</sup> However, multiple exposures were associated with a modest decrease in fine motor abilities and processing speeds, and parents of these children reported more difficulties with reading and behavior.<sup>13</sup>

- 3) The general anaesthesia or awake-regional anaesthesia in infancy (GAS) study is the only randomized controlled trial on this topic to date. In this international, multicentered trial, otherwise healthy infants less than 60 weeks postmenstrual age (born at greater than 26 weeks’ gestation) undergoing inguinal hernia repair were randomized to receive either sevoflurane-based general anaesthesia or awake-regional anaesthesia.<sup>14</sup> The primary outcome was intelligence quotient (Wechsler Preschool and Primary Scale of Intelligence Third Edition) at age five, and the secondary outcome was composite cognitive score (Bayley Scales of Infant and Toddler Development III) at age two.<sup>14</sup> In 2016, the secondary outcome showed no evidence that sevoflurane anaesthesia exposure of under one hour in infancy increased the risk of adverse neurodevelopmental outcome at age two compared to awake-regional anaesthesia.<sup>15</sup> In 2019, the primary outcome showed no difference in the intelligence quotient of children exposed to general anaesthesia compared to awake-regional anaesthesia.<sup>14</sup> The FDA’s warning—and timing—was controversial, and took many anaesthesia professionals by surprise.

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# General Anesthesia and the Developing Brain

## From “Developing Brain,” Preceding Page

The FDA met with an expert panel in 2007, 2011, and 2014 to advise them on the issue of anesthesia-induced neurotoxicity. Then, more than two years after the last expert advisory panel convened, the FDA issued the Drug Safety Communication warning about the potential risk of anesthesia neurotoxicity. Curiously, their warning came on the heels of reassuring results from the PANDA study<sup>12</sup> and GAS secondary outcome.<sup>15</sup> Usually FDA Drug Safety Communications are based on substantial clinical data,<sup>16</sup> but in this case there was no definitive clinical evidence of neurotoxicity in humans. The FDA warning was based on a potential risk, rather than a known risk.

The intention of the FDA was to “better inform the public about this potential risk”,<sup>2</sup> but their warning had downstream consequences. The FDA acknowledged that necessary surgery in children should proceed, but cautioned that “consideration should be given to delaying potentially elective surgery in young children where medically appropriate”.<sup>2</sup> Many pediatric, surgical, and anesthesia professionals found this recommendation to be oversimplified and lacking in evidence-based guidance. Some medical experts even cautioned that the FDA warning could expose medical professionals to increased malpractice risk regardless of their decision to either proceed with anesthesia or delay the procedure.<sup>17</sup> (Should myringotomy tubes be delayed knowing that hearing deficiencies secondary to recurrent otitis can lead to learning deficits? Should tonsillectomy for moderate sleep apnea be delayed, when sleep apnea itself can affect neurocognitive outcomes? If the child develops a learning disability later in life, will I be held liable for proceeding ahead? Will I be held liable for delaying?) After all, the risk-benefit discussion becomes more challenging when physicians are asked to consider an unsubstantiated risk. Just as attorneys would feel uneasy defending their clients under a presumption of “guilty until proven innocent,” anesthesia professionals were put in the challenging position of defending the appropriate use of anesthetic agents that were heavily stigmatized as neurotoxic after the FDA’s warning.

Discussions with parents regarding anesthesia-induced neurotoxicity are common. A survey of over 200 parents found that 60% report some degree of concern that general anesthesia will affect their child’s neurodevelopment.<sup>18</sup> How are anesthesia professionals approaching these conversations? A study of pediatric teaching institutions in the US provided insight into the attitudes of anesthesia professionals and the process of informed consent nationwide.<sup>19</sup> Of those surveyed, 91% discussed the topic “only if asked,” while 6% discussed it routinely, with the majority of those

discussions occurring moments before surgery. In addition to direct conversation with the anesthesia professional, one third of respondents referred parents to the SmartTots Consensus Statement,<sup>20</sup> and one third had specific departmental talking points. The majority of respondents did not discuss delaying “elective” surgery with parents, and chose not to offer a “safe age cutoff” to parents. Only 20% of respondents documented their discussion in the medical record, and few institutions specifically discussed the risk in the written consent.

Based on the available data, a single, brief exposure to general anesthesia in children under age three does not cause adverse neurodevelopmental outcomes. Anesthesia professionals and parents alike should be reassured by the findings of the PANDA, MASK, and GAS studies. Questions do remain, however, with regard to infants and children requiring multiple or prolonged anesthetics. In this vulnerable population, modest neurodevelopmental impairments may occur after anesthesia exposure,<sup>10,11,13</sup> and additional research is necessary to better understand what clinical implications, if any, this may have on perioperative care. Researchers are also studying the dose-response curve of anesthetic agents on neurodevelopmental outcomes. The TREX trial is an ongoing randomized control trial comparing neurodevelopmental outcomes of standard-dose sevoflurane versus low-dose sevoflurane, with an expected completion date in 2022. Additionally, we may see the focus of research shift towards the conduct of an anesthetic, rather than the type and route of anesthetic. The role of intraoperative hypotension, transient hypoxia, metabolic derangements, glucose control, and temperature maintenance on neurodevelopmental outcomes are important questions that remain unanswered.

Anesthesia professionals who care for children should be prepared to address parental concerns, and should be familiar with the reassuring results of the PANDA, MASK, and GAS studies. Concerned parents should be directed to credible resources, such as the SmartTots website (<https://www.smarttots.org>), a partnership between the International Anesthesia Research Society and the FDA with informational material for parents and medical professionals.<sup>20</sup> Caring for infants and children is a privilege, and anesthesia professionals should acknowledge the concerns of parents while allaying their fears related to the effects of general anesthesia on the developing brain.

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*The author has no conflicts of interest.*

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# Brain Safety: The Next Frontier for Our Specialty?

by Nirav Kamdar, MD, MPP, MBA; Phillip E. Vlisides, MD; and Daniel J. Cole, MD

See the original article online at: <https://www.apsf.org/article/perioperative-brain-health-its-not-all-positive-attitude-exercise-and-superfoods/>

## INTRODUCTION

Thirty-five years after the creation of the Anesthesia Patient Safety Foundation (APSF), we recall Macintosh’s adage that no patient should be harmed by anesthesia.<sup>1</sup> Articulated over 60 years ago, this concept set the cornerstone of the APSF, which codified our calling to safety, vigilance, and the endless pursuit of safe outcomes. At that time, the goal was clear—to address measurable events such as cardiac arrest, hypoxia, and human error. While the above are critically important, the future of patient safety is much more expansive. Let’s begin with a definition of patient safety that we have modified from Gaba and Weinger:<sup>\*</sup>

*Safety is how we deliver care in a way that prevents harm from the processes of care, and the behavior of the humans embedded in the system of care. Safety is an emergent property of the system that occurs when we actively try to achieve it.\**

David Gaba, MD, and Jeffrey Cooper, PhD, articulate that the foundation of our past suc-

<sup>\*</sup>David Gaba and Matthew Weinger presented at the APSF Board Meeting; permission granted for adaptation and citation by personal communication.

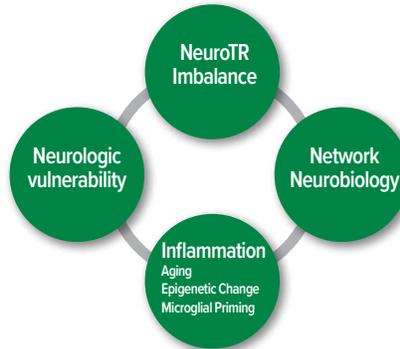


Figure 1: Pathophysiological hypotheses of PostOperative Delirium. NeuroTR: Neurotransmitter.

cess emerged from our trust in standards and guidelines, technological solutions, human factors, and the institutionalism of safety.<sup>2,3</sup> We assert that our specialty is at the frontier of patient care, addressing what matters most to our patients: their “healthspan.” We work as teams throughout the episode of perioperative care and beyond to return patients home with improved functional, psychological, and cognitive health.

The pursuit to combat postoperative delirium (POD)—a most surreptitious villain—is elusive and less defined, yet a formidable foe of our specialty’s safety initiatives. Admittedly, we

have gaps to fill regarding a comprehensive understanding of the pathophysiology of POD, diagnosis and identification, and tools to advance monitoring and treatment. We require resources for research and an implementation strategy to improve neurocognitive outcomes after surgery.

As perioperative physicians, we cannot ignore the magnitude of POD. The aging demographic of the United States population predicts that more than one-third of our patients will be older than 65. In these patients, POD has an estimated incidence ranging from 5–50% contributing to the \$150 billion of delirium-associated health care expenditures in the United States.<sup>4</sup> Finally, many of these cases are thought to be preventable through care pathways and best practice.<sup>4</sup>

## STANDARDS & GUIDELINES AND TECHNOLOGY

As Gaba and Cooper note, the history of anesthesiology’s success in attaining a six-sigma safety level in ASA<sup>1</sup> patients is in large part attributable to our specialty’s adherence to guidelines and standard operating procedures.<sup>3</sup> Two recent consensus statements guide our current understanding of POD. The

See “Brain Safety,” Next Page

### Mini-Cog<sup>®</sup>

### Instructions for Administration & Scoring

ID: \_\_\_\_\_ Date: \_\_\_\_\_

### Clock Drawing

ID: \_\_\_\_\_ Date: \_\_\_\_\_

#### Step 1: Three-Word Registration

Look directly at person and say, “Please listen carefully. I am going to say three words that I want you to repeat back to me now and try to remember. The words are [select a list of words from the versions below]. Please say them for me now.” If the person is unable to repeat the words after three attempts, move on to Step 2 (clock drawing).

The following and other word lists have been used in one or more clinical studies.<sup>1,3</sup> For repeated administrations, use of an alternative word list is recommended.

Version 1	Version 2	Version 3	Version 4	Version 5	Version 6
Banana	Leader	Village	River	Captain	Daughter
Sunrise	Season	Kitchen	Nation	Garden	Heaven
Chair	Table	Baby	Finger	Picture	Mountain

#### Step 2: Clock Drawing

Say: “Next, I want you to draw a clock for me. First, Put in all of the numbers where they go.” When that is completed, say, “Now set the hands to 10 past 11.”

Use preprinted circle (see next page) for this exercise. Repeat instructions as needed as this is not a memory test. Move to Step 3 if the clock is not complete within three minutes.

#### Step 3: Three Word Recall

Ask the person to recall the three words you stated in Step 1. Say, “What were the three words I asked you to remember?” Record the word list version number and the person’s answers below.

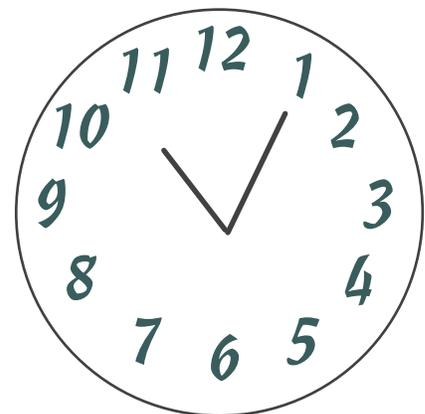


Figure 2: The Mini-Cog test. There are two Mini-Cog<sup>®</sup> components that include a score for accuracy of “clock drawing” and “three-word recall,” resulting in a cumulative score that can increase the detection of cognitive impairment. There are a total of five possible points for the test with three possible points for the three-word recall and two points for a normal clock. A total score of three or greater indicates a lower likelihood of cognitive impairment. Mini-Cog<sup>®</sup> copyright, Dr. Soo Borson (used with permission). See mini-cog.com for more detail.

# Anesthesia Professionals Should Take Leadership Role in Optimizing Perioperative Brain Health

## From “Brain Safety,” Preceding Page

2018 Perioperative Brain Health Initiative Summit Report<sup>5</sup> identified our current understanding for predisposing risk factors including baseline cognitive decline or dementia, poor vision, poor hearing, severe illness and underlying infection. Although the pathophysiology of POD is not well defined and no definite biomarker currently exists, interrelated mechanisms including neurotransmitter imbalance, inflammation, stress response, cellular metabolism, pre-existing neurologic vulnerability and changes in network neurobiology (Figure 1) may explain why the surgical episode of care contributes to its incidence and severity of results.<sup>6</sup>

Both the American Society of Anesthesiologists Perioperative Brain Health Initiative and the 2015 American Geriatrics Society Guidelines<sup>7</sup> recommend cognitive screening as a pre-surgical measure and metric of risk prior to and after surgery. Preoperatively, many experts advocate for use of the Mental Status Exam or a shortened version of this assessment tool (MMSE or mini-cognition questionnaire seen in Figure 2). A variety of tools for POD diagnosis are available, each with tradeoffs of receiver operator characteristics, including the Confusion Assessment Method (CAM), the CAM-ICU, Nursing Delirium Screening Scale, or Delirium

Symptom Interview.<sup>8</sup> Yet, abbreviated training often results in imprecise diagnostic rates for a condition that is known to wax and wane in severity within one surgical admission. While convergence on use of a single tool does not exist, both groups recommend additional training and experience in POD diagnostic tools for frontline staff.

Current strategies for prevention of POD include minimal use of high-risk drugs including benzodiazepines, anticholinergic medications, higher dose corticosteroids, meperidine, and polypharmacy in general. Current literature advocates for non-pharmacologic treatment measures as a first step but urges restraint for antipsychotic medications unless the patient poses potential for self-harm or harm to others.

Anesthesiology has achieved many safety goals using engineering and human factors in the design of instrumentation and monitoring. With this history in mind, we have continued to explore technological solutions towards reducing POD. Our specialty has developed specialized monitoring for cerebral blood flow and EEG-based monitoring to try to reduce the depth of general anesthetics. While early data suggested that excessive anesthetic depth may predispose to POD,<sup>9</sup> findings from the recent

ENGAGES trial<sup>10</sup> do not support this hypothesis and weigh against recent guidelines.<sup>7</sup>

## THE GAPS IN OUR RESEARCH—THE ROLE OF THE APSF

The brain is the target end-organ for general anesthesia. Neurocognitive recovery after surgery is not always a straightforward process, nor is it well understood. Nonetheless, the demand for surgical services will continue, and our engagement in best perioperative practices for neurocognitive health is critical. As such, we should take a leadership role for optimizing brain health for surgical patients.

Fortunately, our field is scientifically and clinically well positioned to address brain health knowledge gaps. We have the ability to track neuroinflammatory signatures for delirium in human participants using basic science models.<sup>11</sup> Network neuroscience approaches allow study of brain-state transitions relating to levels—and contents—of consciousness. When translated to clinical settings, preliminary analyses have identified neurophysiologic signatures associated with delirium.<sup>12</sup> Thus, opportunities to advance neuroscience related to pathologic brain states across the clinical spectrum, which may also contribute to the fundamental understanding of cognitive dysfunction, extend value beyond the perioperative setting. Lastly, as perioperative neuroscience matures, the time is ripe to probe implementation barriers for interventions that aim to optimize perioperative brain health.<sup>13</sup>

## WHAT DO WE DO TODAY? A ROLE FOR IMPLEMENTATION SCIENCE AND QUALITY IMPROVEMENT

Christian Guay, MD, and Michael Avidan, MD, recently argued brain health and POD should not be considered a single syndrome nor treated as such.<sup>14</sup> Rather, it is likely a collection of disparate disorders that share some common features. The most compelling, reproducible interventions target multiple modifiable risk factors. These interventions, similar to the Hospital Elder Life Program, mitigate cognitive and functional decline in older hospitalized patients using cognitive orientation, social support, sleep protocols, mobilization, and education for health care staff (Table 1). Until scientific research compels more precise interventions, we need to apply traditional methods of quality improvement, implementation science, and quality control from engineering science and weave modifiable risk factor prevention into our clinical workflows.

**Table 1: Proposed Interventions To Mitigate Cognitive & Functional Decline**

Intervention	Description
<b>Core Intervention</b>	
Daily visitor/orientation	Orientation board with names of care team members and schedule
Therapeutic activities	Cognitive stimulation three times daily
Early mobilization	Ambulation or active range-of-motion exercises three times daily
Vision protocol	Visual aids and adaptive equipment
Hearing protocol	Portable amplifying devices and special communication techniques
Oral volume repletion	Feeding and drinking assistance and encouragement
Sleep enhancement	Nonpharmacologic sleep protocols
<b>Program Interventions</b>	
Geriatric nursing assessment	Nursing assessment and intervention for cognitive and functional impairment
Interdisciplinary rounds	Twice-weekly rounds to discuss patients and set goals
Provider education	Formal didactic sessions, one-on-one interactions
Community linkages	Referrals and communication with community agencies to optimize transition to home
Geriatrician consultation	Targeted consultation referred by program staff
Interdisciplinary consultation	As needed consultation upon referral by staff

Adapted with permission from Inouye SK, Bogardus Jr ST, Baker, DI, et al. The Hospital Elder Life Program: a model of care to prevent cognitive and functional decline in older hospitalized patients. *J Am Geriatr Soc.* 2000;48:1697-1706.

## Frontline Clinicians Should Assess Patients for Delirium

### From “Brain Safety,” Preceding Page

First, frontline perioperative clinicians should commit to measuring cognitive function prior to surgery. Simple cognitive tools such as the Mini-Cog test (Figure 2) can be applied across primary care, anesthesiology, and geriatric clinics prior to elective surgery. These tools not only provide process data to establish a baseline measurement for the individual patient, but may also serve as population data for longitudinal studies. In her discussion at the Perioperative Brain Health lecture for the APSF in 2018, Deborah Culley, MD, showed the audience how quickly the Mini-Cog can be deployed without clinic workflow changes.

Second, while the precision of existing assessment tools for PODs are lacking, we should instill delirium assessment into the regular practice of frontline clinicians especially for geriatric patients and others at increased POD risk. Recurring, scheduled education should be the norm to maintain clinician familiarity with these tools and prevent protocol adherence drift. By codifying the act of search and diagnosis, we can eventually replace first generation tools with more robust clinical assessment tools.

Third, perioperatively, we can affect human factors changes, such as medication simplification, identification of vision and hearing deficits in the early postoperative course, and minimization of sedation. None of these proposed changes involve substantial capital expenditures nor complex practice redesign, and these interventions can be bundled into our daily work routines to achieve patient-centered goals for the elderly.

Finally, rather than focusing upon highly specific outcome measures required of research science, POD interventions should employ

implementation science measurements. We may benefit by utilizing performance improvement tools such as control charts and process measurements to measure diagnostic, monitoring, and therapeutic change, rather than relying on outcome measures until a reliable and valid diagnostic biomarker for POD or more specific therapeutics are developed.

### CONCLUSION

Thirty-five years ago, the APSF articulated its mission that “no patient should be harmed by anesthesia.” Over time, major advances toward prevention of cardiovascular collapse, hypoxemia, drug error, and human error emerged from the organization that made industry-changing improvements to anesthesia safety. These efforts are now engaged at a new frontier of perioperative brain health in order to prevent POD and return patients to their baseline cognitive function or better. In an era of a neuroscience revolution, the APSF has the high-stakes task to address the public health problem of POD. The costs are high; the science around pathophysiology, prevention and treatment has large gaps to traverse; and the workflows need standardization. We look forward to our specialty supporting the discovery of new knowledge that will be the foundation for the implementation science to codify our actions and conquer this next frontier.

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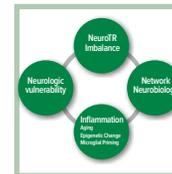
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