

*Editors' Note: This issue contains a series of articles regarding the safe use of nondepolarizing neuromuscular blocking drugs. All anesthesia professionals should understand the importance of appropriately monitoring and reversing neuromuscular blockade. We believe that these articles will increase awareness, provide important educational information, and improve patient safety.*

## Monitoring of Neuromuscular Blockade: What Would You Expect If You Were the Patient?

by Robert K. Stoelting, MD

The Anesthesia Patient Safety Foundation (APSF) believes that residual neuromuscular blockade in the postoperative period is a patient safety hazard that could be addressed partially by better and consistent use of our qualitative standard train-of-four (TOF) nerve stimulator monitors, but will ultimately require quantitative (objective TOF) monitoring along with traditional subjective observations to eliminate this problem completely.<sup>1-2</sup> APSF and other anesthesia professionals believe that every patient receiving nondepolarizing neuromuscular blocking drugs (NMBDs) should have at least qualitative, and preferably quantitative monitoring of the intensity of neuromuscular blockade using a peripheral nerve stimulator during the intraoperative period and assessment of the pharmacologic antagonism of neuromuscular blockade and adequacy of neuromuscular function prior to tracheal extubation.<sup>1-10</sup>

**Table 1: Potential adverse effects of residual neuromuscular blockade in the immediate postoperative period**

Need for tracheal reintubation
Impaired oxygenation and ventilation (may be erroneously attributed to opioids)
Impaired pulmonary function (reduced forced vital capacity and peak expiratory flow rate)
Increased risk of aspiration and pneumonia
Pharyngeal dysfunction
Delayed discharge from the PACU

The peer review literature supports the conclusion that residual neuromuscular blockade in the immediate postoperative period is more common than appreciated. This weakness may contribute to adverse patient events (Table 1).<sup>3-9</sup> Based on quantitative TOF monitoring as many as 40% of patients arriving in the PACU have evidence of residual neuromuscular blockade.<sup>4,9</sup>

Despite the evidence in the peer review literature and a survey of anesthesia professionals in which 90% of respondents agreed that quantitative TOF monitoring should be used routinely for patients receiving nondepolarizing NMBDs prior to transfer to the PACU, quantitative measurements of drug-induced neuromuscular blockade and the

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## Large Anesthesia/Practice Management Groups: How Can APSF Help Everyone Be Safer?

by Robert K. Stoelting, MD

On September 10, 2015, APSF invited representatives of large anesthesia and practice management groups to meet with members of the APSF executive committee to discuss mutually relevant anesthesia patient safety issues. The goal was to help APSF identify and implement patient safety initiatives of particular interest and value to the conference participants.

Thirty-six attendees representing 23 large anesthesia/practice management groups participated in the half-day session (Table 1). These 23 groups represented a wide geographical cross-section of the United States and a variety of practice models

that included all categories of anesthesia professionals. The American Society of Anesthesiologists, which has a committee on Large Group Practice, was represented by Daniel J. Cole, MD, President Elect, and Paul Pomerantz, CEO.

As an introduction to the conference, Robert K. Stoelting, MD, APSF President, reviewed past, current, and possible future APSF patient initiatives and provided "his view" of the three options available for APSF recommendations to become "best practices."

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Dr. Robert Stoelting, moderating.

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NEWSLETTER

The Official Journal of the Anesthesia Patient Safety Foundation

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APSF Newsletter  
*guide for authors*



The APSF Newsletter is the official journal of the Anesthesia Patient Safety Foundation. It is published 3 times per year, in June, October, and February. The APSF Newsletter is not a peer-reviewed publication, and decisions regarding content and acceptance of submissions for publication are the responsibility of the editors. Individuals and/or entities interested in submitting material for publication should contact the editors directly at Morell@apsf.org and/or Lee@apsf.org. Full-length original manuscripts such as those that would normally be submitted to peer review journals such as *Anesthesiology* or *Anesthesia & Analgesia* are generally not appropriate for publication in the Newsletter due to space limitations and the need for a peer-review process. Letters to the editor and occasional brief case reports are welcome and should be limited to 1,500 words. Special invited articles, regarding patient safety issues and newsworthy articles, are often solicited by the editors. These articles should be limited to 2,000 words. Ideas for such contributions may also be directed

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# We As Patients Would Expect Better

## “Blockade Monitoring,” From Cover

adequacy of pharmacologic reversal have not been widely utilized by anesthesia professionals (Fig. 1).<sup>1</sup> Achievement of the goal of routine qualitative or quantitative monitoring using a peripheral nerve stimulator is difficult when the daily experiences of anesthesia professionals do not predictably demonstrate the existence of a problem that may occur well after the anesthesia professional has turned over care to another health care professional.<sup>4</sup> Universal adoption of quantitative monitoring is further impeded by the limited availability of easy-to-use, reliable monitoring technology. Many anesthesia professionals continue to rely on clinical signs (head lift, hand grip, negative inspiratory force, tidal volume) that are insensitive indicators of residual skeletal muscle weakness and applicable only to awake patients. Likewise, reliance on visual/tactile assessment of the TOF (low sensitivity to detect fade) to titrate the effects and assess the pharmacologic reversal of nondepolarizing NMBD is an insensitive and unreliable monitoring technique. Though double-burst stimulation (DBS) and fade with 100 Hz tetanic stimulation significantly improve the ability to detect residual neuromuscular blockade over single twitch or TOF monitoring or clinical signs, these modalities of assessing neuromuscular blockade are inferior to methods of quantitative monitoring such as acceleromyography.<sup>10</sup>

A recommendation for routine qualitative or quantitative monitoring of neuromuscular blockade with peripheral nerve stimulators as part of the “Standards for Basic Anesthetic Monitoring” has not been promulgated by any of the North American professional anesthesia associations (American Society of Anesthesiologists, American Association of Nurse Anesthetists, American Academy of Anesthesiologist Assistants, Canadian Anesthesiologists’ Society). To date, these anesthesia professional associations are either silent regarding monitoring neuromuscular blockade or limit their statements to (1) “monitor neuromuscular response” [no specific quantitative monitor mentioned] or (2) a “peripheral nerve stimulator should be available when patients receive neuromuscular blockers.”

In contrast, the 2015 “Recommendations for standards of monitoring during anaesthesia and recovery” published by the Association of Anaesthetists of Great Britain and Ireland (AAGBI) mandates that “a peripheral nerve stimulator must be used whenever neuromuscular blocking drugs are given.”<sup>9</sup> These recommendations also list a peripheral nerve stimulator (if neuromuscular blocking drugs are used) as part of the “minimum monitoring for anaesthesia” along with pulse oximetry and capnography.<sup>9</sup> This AAGBI mandate reflects the increasing recognition of the role of NMBDs in adverse postoperative pulmonary events.

In my opinion, there is no compelling reason to ignore this evidence-based patient safety issue and the obvious change in practice (qualitative, or preferably quantitative/objective monitoring with peripheral nerve stimulators to guide pharmacologic drug reversal) that would likely reduce the risk of potential adverse physiologic effects of lin-

### Objective functional monitoring (“twitch measurement”) of the intensity of neuromuscular blockade should be utilized routinely intraoperatively and prior to transfer to PACU.

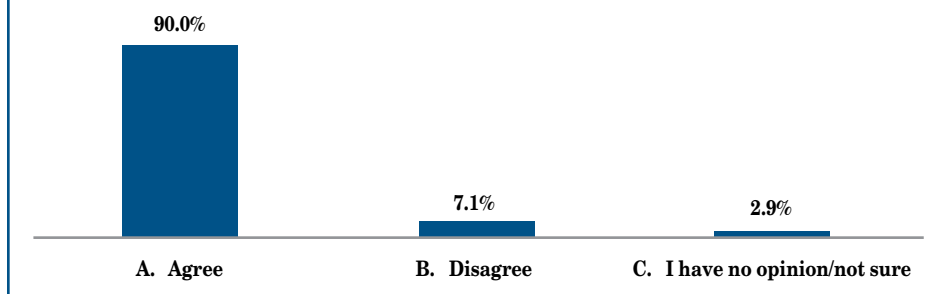


Figure 1: Stoelting RK. APSF survey results: Drug-induced muscle weakness in the postoperative period safety initiative. APSF Newsletter Winter 2013-14;28:69-71. <http://www.apsf.org/newsletters/pdf/winter2014.pdf>

gering drug-induced muscle weakness in the early postoperative period.

What will it take for “North American” anesthesia professionals to accept the reality of this patient safety risk?

Why are “we” so “hesitant” to routinely use qualitative or quantitative assessments of neuromuscular function with peripheral nerve stimulators to guide both the administration and reversal of nondepolarizing NMBDs?

Would “we,” knowing what we know, or should know, regarding the facts relevant to residual weakness due to nondepolarizing NMBDs, expect, at a minimum, qualitative monitoring with peripheral nerve stimulators if we were the patient?

My guess is “we” would expect qualitative, and more likely, quantitative monitoring of neuromuscular blockade as part of our care!

It is time to “Do as I would expect, not as I do!”

Robert K. Stoelting, MD  
President, APSF

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## APSF-Sponsored Conference

Royal Palms Resort and Spa, Phoenix, AZ

### Distractions in the Anesthesia Work Environment: Impact on Patient Safety

Distractions in the anesthesia work environment manifest in many different ways and potentially impact patient safety by compromising the anesthesia professional's vigilance during direct patient care. APSF believes these distractions need to be identified and addressed by open discussion, education, research and appropriate policy statements for individual groups or practice management entities. This 1-day conference will include podium presentations, panel discussions, small group breakout sessions and attendee responses using an “audience response system.”



Save the Date  
Wednesday, September 7, 2016

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



# Expanding Our Influence: How the Perioperative Surgical Home Will Improve Patient Safety

*The 2015 Ellison C. Pierce, Jr., MD, ASA/APSF Patient Safety Memorial Lecture*



Mark A. Warner, MD, presented the 2015 Pierce ASA / APSF Patient Safety Memorial Lecture. He started by reviewing the anesthesia patient safety imperative that anesthesiology has embraced since the creation of the APSF in 1985: “no patient shall be harmed by anesthesia.”

The APSF used that visionary statement to create goals that still stand today. They specifically state that the foundation will:

1. Foster investigations that will provide a better understanding of preventable anesthetic injuries
2. Encourage programs that will reduce the number of anesthetic injuries
3. Promote national and international communication of information and ideas about the causes and prevention of anesthetic injuries

The following summarizes Dr. Warner’s comments from the lecture.

Improvement in anesthetic mortality and several major morbidities was dramatic during the first decade of the APSF...and anesthesia care has continued to become safer. The specialty provides outstanding, very safe patient care intraoperatively.

With all of that, the anesthesia community can and must continue to improve because patients are still harmed—every day—in the U.S. and elsewhere, during and by anesthesia care. There is still much to study, assess, and improve intraoperatively. Issues that have recently been discussed during workshops of the APSF are shown in Table 1.

Unfortunately, overall surgical and procedural safety lags. The incidences of a variety of major perioperative morbidities as well as death rates clearly

**Table 1. Recent APSF Workshop Topics**

Cerebral ischemia in head-elevated positions
Medication safety in the operating room
Opioid-induced postoperative respiratory depression
Perioperative vision loss
Pre-anesthetic induction checklists
Cognitive aids and checklists
Residual neuromuscular blockade
Training for advanced medical technologies

remain unacceptably high. Within anesthesiology, and working with health care colleagues outside of our specialty, we should, can, and must improve both intraoperative and perioperative patient safety. This is where the Perioperative Surgical Home concept comes into play.

In general, we have not looked intensely into the long-term consequences of anesthesia care. That is changing—data are increasingly strong that there are prolonged physiologic and pathologic changes associated with intraoperative anesthesia care. Several key questions for 2015 are shown in Table 2. Anesthesiologists and members of the anesthesia care team are well positioned to design, assess, and improve perioperative care of patients who will be anesthetized for surgical, diagnostic and therapeutic procedures.

How can the anesthesia community expand its influence in the perioperative period and improve patient safety? Let’s look at several examples.

**Penicillin Allergy:** Nearly 90% of surgical patients in the U.S. who indicate that they have a penicillin allergy—do not have that allergy. Anesthesiologists and surgeons rarely check, instead ordering broad spectrum third and fourth generation antibiotics because it is expedient. Unfortunately, there is a cost to society and patient safety. Unfiltered, proliferate use of these high-end antibiotics is expensive and supports the evolution of resistant bacteria—and these resistant bacteria, of course, require more expensive antibiotics that have an increased proportion of adverse effects. Simple preoperative proto-

cols can result in skin tests that document the presence or absence of true penicillin allergies. Anesthesiologists, surgeons, and infectious disease specialists or internists, can readily work together to develop facility-specific clinical protocols to check for penicillin allergies preoperatively.

**Prehabilitation:** Anesthesiologists and the teams with whom they work can develop preoperative evaluation processes that extend beyond the typical pre-anesthetic assessment—beyond the ubiquitous “OK for anesthesia.” Issues that have yet undefined contributions to perioperative morbidity and mortality such as weight control, correction of general or specific nutrition deficits, cessation of smoking, and improvement of poor physical conditioning all merit additional study and, when appropriate, implementation of clinical protocols that may “prehabilitate” patients before they proceed through the perioperative process.

**Blood Product Transfusion:** Extensive use of algorithms and clinical protocols for transfusion of blood products can have a significantly positive impact on patient safety during the perioperative period. In a wide variety of clinical settings, the use of predetermined transfusion protocols and mechanisms to proactively intervene when physicians transfuse blood products outside of agreed algorithms have reduced blood product use 40–60%. Blood transfusion has distinct and measurable detrimental impact on immune responses and susceptibility to infection in surgical patients, especially those

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**Table 2: Key Questions Associated with the Long-Term Impact of Anesthesia**

• Do volatile anesthetic agents have a long-term effect on neurocognitive development in children?
• Does the administration of a blood product have long-term effects on immune and organ function?
• Do the various techniques we use to deliver care—the science of anesthesia care delivery—have long-term effects on patient safety and outcomes?
• Is there a negative impact of pharmacologically and surgically induced inflammation on the short- and long-term outcomes of our patients?

**Table 3: Quotes from Anesthesiology Leaders About Scope of the Specialty and Patient Safety**

• Dr. Jim Eckenhoff, former president of the ASA (1977): “anesthesiologists must be adequately prepared for assuming their roles in patient care services...to the ultimate best advantage of their patients.”
• Dr. Larry Saidman, former editor-in-chief of <i>Anesthesiology</i> (1995): “[I]...propose that the term anesthesiology should be changed to perioperative medicine and pain management.”
• Dr. Ellison (Jeep) Pierce, former president of the ASA and founder of the APSF: “Patient safety is not a fad. It is not a preoccupation of the past. It is not an objective that has been fulfilled or a reflection of a problem that has been solved. It must be sustained by research, training, and daily application in the workplace.”

# President's Report Highlights Accomplishments of 2015

by Robert K. Stoelting, MD

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

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

A highlight of the opening session of the annual meeting of the American Society of Anesthesiologists in San Diego, CA on October 24, 2015 was the ASA/APSF Ellison C. Pierce, Jr., MD, Patient Safety Memorial lecture delivered by Mark A. Warner, MD. Dr. Warner's topic was *Expanding Our Influence: How the Perioperative Surgical Home Will Improve Patient Safety*.

This named lectureship continues to be part of the annual ASA meeting thus providing sustained recognition for the vision and contributions to anesthesia patient safety made by Dr. Pierce as the founding president of APSF.

## APSF Board of Directors Workshop

The APSF Board of Directors Workshop occurred on Saturday, October 24, 2015. The topic for this 2-hour workshop was *"From APSF Educational Videos to your practice: How to make it happen."* During this workshop, the APSF educational videos, Prevention and Management of Operating Room Fires, Perioperative Visual Loss (POVL), and Simulated Informed Consent Scenarios for Patients at Risk for Perioperative Visual Loss were presented followed by small breakout sessions during which attendees met with members of the APSF Executive Committee and shared their opinions regarding strategies and impediments for implementing the recommendations in the videos. Drs. Jeffrey M. Feldman and Lorri A. Lee represented the APSF Board of Directors as co-moderators for the workshop.

## Implementing and Using Emergency Manuals and Checklists to Improve Patient Safety

APSF held a consensus conference on this topic on Wednesday, September 9, 2015 (Royal Palms Resort and Spa, Phoenix, AZ). APSF believes there is a need for anesthesia professionals and other members of the

perioperative care team to move towards the acceptance of cognitive aids (emergency manuals, checklists) and away from the traditional reliance on memory and the cultural perception of individual perfection. Cognitive aids include a variety of physical and electronic representations of knowledge "in the world" designed to assist those responsible for perioperative care in executing complex decision making in dynamic settings. This expert's conference concentrated on the practical aspects of systematically implementing Emergency Manuals/Cognitive Aids and Checklists in the perioperative setting.



Robert K. Stoelting, MD  
APSF President

## Developing the Relationship Between APSF and Large Anesthesia/Practice Management Groups

Following the September 9, 2015 conference on cognitive aids, APSF sponsored a half-day meeting on Thursday, September 10 with members of large anesthesia groups and representatives from practice management groups. The goal was for these representatives to meet with members of the APSF Executive Committee to discuss mutually relevant opportunities to address anesthesia patient safety issues and to incorporate potential solutions into best practices.

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

APSF believes that anesthesia professionals should demonstrate competence to use advanced medical technology before applying this technology to patient care. Anesthesia professionals have not generally been required to demonstrate their competence to use anesthesia technology to care for patients. Demonstrating competency to use medical devices is consistent with safe patient care.

The 2015 report from the Committee on Equipment and Facilities recognized the universal agreement that individuals need to be adequately trained in the complexities of advanced medical technology in order to provide optimum safe care for patients. The most practical way to disseminate this information and make it easily accessible is through an electronic format that can be accessed through the Internet. It is vital that the content for this educational program come from the manufacturer's engineers and technical specialists that developed the product to ensure that information is accurate. In that regard, it is being

proposed that a fully ACCME-compliant path be developed that can include manufacturers' participation. The most cost- and time-effective approach to establishing training of the many advanced technological devices used in anesthetic practice is to partner with manufacturers, providing appropriate and careful oversight of educational objectives and content to satisfy ACCME guidelines. As an initial project, it is proposed that ASA partner with manufacturers of anesthesia workstations to develop the educational tool for "teaching advanced medical technology" similar to previous ACCME-approved ASA workshops on the anesthesia workstation.

## Research

The APSF Committee on Scientific Evaluation chaired by Steven K. Howard, MD, received 44 letters of intent and invited eight investigators to submit completed applications for studies beginning January 1, 2016. In October 2015, the committee recommended funding two research awards totaling \$297,374 (see page 67).

In addition to the traditional research grant awards, APSF continues its support of the APSF Safety Scientist Career Development Award (SSCDA) (\$150,000 over 2 years). The current recipient is Meghan D. Lane-Fall, MD, MSHP, Department of Anesthesia, Perelman School of Medicine, University of Pennsylvania.

In July 2015, APSF and the Anesthesia Quality Institute (AQI) co-sponsored the APSF/AQI Patient Safety Career Development and Research Award with APSF and AQI sharing the cost of the grant award of \$120,000. The current recipient of this award is Joseph A. Hyder, MD, PhD, Department of Anesthesia, Mayo School of Medicine.

In April 2015, the APSF Committee on Education and Training chaired by Richard C. Prielipp, MD and with assistance of committee members, Brian J. Cammarata, MD, Sandeep Markan, MD, and Lianne Stephenson, MD, announced the *APSF Resident Quality Improvement (QI) Recognition Program*. Program submissions will consist of a brief written narrative and video submission describing the resident's QI project. The two winners were announced at the Annual Meeting of the APSF Board of Directors meeting in October 2015 during the annual ASA meeting in San Diego, CA. The first and second place winners received financial awards of \$1,000 and \$500, respectively and the winning entries will also be showcased on the APSF website.

APSF is the largest private funding source for anesthesia patient safety research in the world. Since the inception of the APSF grant program, 779 grant applications have been received by APSF. When the first grants were funded in 1987, funding for anesthesia patient safety was virtually unknown. Since 1987, APSF has awarded 105 grants for a total of more than \$9,744,227. The impact of these research grants is more far-reaching than the absolute number of grants and total dollars, as APSF-sponsored research has led

See "President's Report," Next Page

# APSF Seeks Candidates for Next APSF President

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

to other investigations and the development of a cadre of anesthesia patient safety investigators.

### APSF Newsletter

The *APSF Newsletter* continues its role as a vehicle for rapid dissemination of anesthesia patient safety information with Robert C. Morell, MD, and Lorri A. Lee, MD, acting as co-editors. Steven B. Greenberg, MD, has recently been appointed as Assistant Editor.

The *APSF Newsletter* is provided as a member benefit by the ASA, American Association of Nurse Anesthetists (AANA), American Association of Anesthesiologists Assistants (AAAA), American Society of Anesthesia Technologists and Technicians (ASATT), American Society of PeriAnesthesia Nurses (ASPAN), American Society of Dentist Anesthesiologists (ASDA), American Dental Society of Anesthesia (ASDA) and the American Association of Oral Maxillofacial Surgeons (AAOMS) with a resulting circulation of 122,210. In addition to the electronic version of the *APSF Newsletter*, a hardcopy is mailed to all members of the ASA, AANA, AAAA, ASPAN, and ASDA.

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

### Communication

The APSF website design and appearance ([www.apsf.org](http://www.apsf.org)) continues under the direction of APSF Executive Vice President George A. Schapiro. Online donations to APSF are possible via the website.

The APSF website includes a monthly poll question related to anesthesia patient safety issues. The poll question is coordinated by Timothy N. Harwood, MD, a member of the APSF Committee on Education and Training chaired by Richard C. Prielipp, MD.

Sorin J. Brull, MD, continues as the Patient Safety Section Editor for *Anesthesia and Analgesia*. Dr. Brull will complete his tenure on January 1, 2016. APSF and the journal, *Anesthesia and Analgesia* thank Dr. Brull for his outstanding leadership as the "first anesthesia patient safety section editor" for our specialty.

### APSF-IARS Safety Panel

APSF sponsored a panel entitled *Three Myths of Anesthesia Patient Safety* at the March 2015 annual congress of the International Anesthesia Research Society. The panel was moderated by Richard C. Prielipp, MD, Chair, APSF Committee on Education and Training.

### APSF-NYPGA Safety Panel

Robert K. Stoelting, MD, moderated a panel entitled *APSF Safety Initiative: Implementing and Using Cognitive Aids (Emergency Manuals and Checklists) to Improve Patient Safety* on Sunday, December 13 during the 2015 annual meeting of the NYPGA.

### APSF-AANA Annual Meeting

APSF sponsored a 1-hour session at the 2015 AANA annual meeting. The topic was fire safety with Charles Cowles, MD, and Maria van Pelt, PhD, CRNA, presenting.

### Prevention and Management of Operating Room Fires

To date, more than 8,000 individual requests for a complimentary copy of the *Prevention and Management of Operating Room Fires* DVD ([http://www.apsf.org/resources\\_video.php](http://www.apsf.org/resources_video.php)) have been received. APSF has also created a Fire Prevention Algorithm Poster and an OR Fire Prevention Flyer that are available for download from the APSF website ([http://www.apsf.org/resources\\_safety.php](http://www.apsf.org/resources_safety.php))

### Medication Safety in the Operating Room

To date, more than 3000 individual requests for a complimentary copy of the 18-minute educational DVD entitled *Medication Safety in the Operating Room: Time for a New Paradigm* ([http://www.apsf.org/resources\\_video2.php](http://www.apsf.org/resources_video2.php)) have been received.

### Financial Support

Financial support to the APSF from individuals, specialty and components societies, and corporate partners in 2015 has been most gratifying. This sustained level of financial support makes possible the undertaking of new safety initiatives, the continuation of existing safety initiatives, and funding for anesthesia patient safety research. The level of

research support is particularly dependent on the level of financial support received.

### Online Donations

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

### Seeking Candidates for the Next APSF President

I informed the 2015 Annual Meeting of the APSF Board of Directors (October 24, 2015) that I will not be a candidate for President in October 2016. A Search Committee chaired by Robert A. Caplan, MD, has been charged with identifying candidates for the next APSF President with a term to begin October 22, 2016. The search process and deadline to receive applications (January 8, 2016) have been widely announced including in the *APSF Newsletter* and on the APSF website. On October 22, 2016, at the Annual Meeting of the APSF Board of Directors, the Search Committee will recommend a candidate for the position of APSF President.

### Concluding Thoughts

APSF thanks retiring Board Directors Robert A. Virag and John M. O'Donnell, CRNA, DrPH, and welcomes new directors, Jenney E. Freeman, MD, and Wanda O. Wilson, PhD, CRNA.

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

*Best wishes for a prosperous and rewarding 2016.*  
Robert K. Stoelting, MD  
President



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# Multi-Faceted Initiative Designed to Improve Safety of Neuromuscular Blockade

by Maria van Pelt, PhD, CRNA; Hovig V. Chitilian, MD; and Matthias Eikerman, MD, PhD

The hidden universality of residual neuromuscular blockade was initially brought to the attention of anesthesiologists in 1979 by Jorgen Viby-Mogensen, who reported a 42% incidence of unidentified residual neuromuscular blockade in the recovery room (defined as a recovery of the train-of-four (TOF) ratio to 0.7).<sup>1,2</sup> Current literature supports the idea that quantitative monitoring of the effects of neuromuscular blocking drugs reduces the likelihood of unrecognized, clinically significant residual muscle weakness in the postoperative period, which should improve patient safety.<sup>3</sup> National anesthesia societies have taken varied stances in support of this patient safety topic. The American Association of Nurse Anesthetists focused on the neuromuscular monitoring standard as early as 1989.<sup>4</sup> However, in 1992 when this standard was revised to ensure that monitoring of “the neuromuscular response to assess depth of blockade and degree of recovery” was included in the basic monitoring standard, the use of quantitative monitoring was not specified.<sup>5</sup> While the American Society of Anesthesiologists (ASA) recognizes the importance of the intraoperative monitoring of neuromuscular blockade, it has not made this a component of the ASA monitoring standard. The Anesthesia Patient Safety Foundation has concluded, based on an extensive review of the literature, that residual neuromuscular blockade is a common, under-appreciated condition that contributes to adverse events in the postoperative period.<sup>6</sup> Yet, despite the cumulative expert contributions made in this field over the past 35 years, published studies continue to report

similar occurrence rates of residual neuromuscular blockade as those reported in 1979.<sup>2,7-10</sup>

Strategies to prevent residual blockade include the judicious use of neuromuscular blocking agents (NMBD), the use of quantitative neuromuscular monitoring, and the titration of reversal agents to effect.<sup>11</sup> How then, can we explain the persistent incidence of postoperative residual neuromuscular blockade? The answer may in part be due to the over-reliance of anesthesia professionals on clinical signs, which are incapable of accurately identifying residual neuromuscular blockade. Clinical tests such as sustained head lift<sup>12-14</sup> or grip strength<sup>15</sup> are easy to perform, but their sensitivity to residual blockade that affects upper airway function without affecting diaphragmatic function is poor (11-14%).<sup>16</sup> Clinicians often administer a fixed dose of reversal agent intraoperatively and are predisposed to over-interpret the clinical exam as full recovery immediately after anesthesia, when patients are barely able to participate properly. Although these clinical tests require the generation of maximum volitional muscle strength, in the presence of a fixed dose of reversal agent and a qualitative TOF twitch return, the patient’s limited test response is often attributed to anesthetic recovery rather than residual neuromuscular blockade. The suboptimal clinical test results are thus erroneously interpreted as signs of sufficient neuromuscular recovery.

A TOF ratio greater than or equal to 0.9 indicates adequate recovery of neuromuscular transmission.<sup>17</sup> The use of quantitative TOF monitoring in the operating room has been shown to decrease the incidence of postoperative weakness.<sup>11</sup> The

inconsistent use of objective neuromuscular transmission monitoring as well as the inappropriate dosing of neostigmine may explain the observed persistence of residual neuromuscular blockade.<sup>2,7-10</sup> What should we do to complete Dr. Viby-Mogensen’s mission to eliminate residual neuromuscular blockade? Important next steps include interdisciplinary efforts to develop and adopt TOF-based guidelines for the intraoperative management of neuromuscular blockade and to implement these best practices consistently into clinical practice.<sup>18</sup>

Data from the Massachusetts General Hospital (MGH) revealed a significant incidence of residual neuromuscular blockade on admission to the post-anesthesia care unit (PACU).<sup>19</sup> Furthermore, an association between inappropriate neostigmine dosing and postoperative respiratory complications was found.<sup>12</sup> These outcomes revealed an opportunity to improve the quality of care provided with respect to intraoperative NMBD management. Under the guidance of a committee consisting of anesthesia professionals (attending anesthesiologists, CRNAs, anesthesia residents), PACU nurses, nurse practitioners, and departmental Quality Assurance (QA)/Quality Improvement (QI) leadership and personnel, a multifaceted initiative was designed to change departmental practice with respect to the intraoperative management of neuromuscular blockade. This initiative consisted of four components: implementation of an education program; distribution of a cognitive aid; provision of feedback

See “Neuromuscular Blockade,” Next Page

## NEOSTIGMINE REVERSAL GUIDE

Type of Monitoring		Neostigmine Dose (administer with anticholinergic)	
Qualitative	Quantitative	Ideal Body Weight (5 mg maximum)	70 kg patient
No twitch	No twitch	WAIT	WAIT
1 twitch	1 twitch	WAIT	WAIT
2-3 twitches	2-3 twitches	~50 mcg/kg	3 to 4 mg
4 twitches with fade	TOF ratio (<0.4)	~40 mcg/kg	2 to 3 mg
4 twitches without fade	TOF ratio (<0.4-0.9)	15 to 25 mcg/kg	1 to 2 mg
	TOF ratio (>0.9)	NONE	NONE

### Risk Factors for Residual Postoperative Paralysis

High total dose of neuromuscular blockade (>1.5 mg/kg rocuronium; >0.4 mg/kg cisatracurium)

High dose neostigmine reversal (>60 mcg/kg)

**Always dose neuromuscular blockers and reversal/anticholinergic according to monitoring and clinical condition.**

# Residual NMB Remains Common Problem

## “Neuromuscular Blockade,” From Preceding Page

regarding departmental progress; and the adoption of a TOF documentation requirement for our department's quarterly QI incentive bonus. Over the course of two months, two department-wide presentations (including a case conference) were devoted to a presentation of the data regarding the incidence and effects of residual paralysis. Attending anesthesiologists, CRNAs, and anesthesia resident champions were identified and designated as informational resources for questions and concerns. Furthermore, an online repository was created with links to the relevant literature in the field. The cognitive aid, a TOF-based neostigmine-dosing guide, was developed by one of our anesthesia residents (Matthew Meyer, MD) and distributed to the members of the department in an electronic format. It was also made available to them online and affixed to each anesthesia machine (Figure 1). Our department participates in a quarterly QI bonus program. As a “nudge” towards the adoption of better NMBD management practices, we tied the quarterly QI bonus to the rate of documentation of twitches within the fifteen minutes prior to the administration of neostigmine. Our goal was to provide a reminder to evaluate neuromuscular blocking reversal dosing in a manner that was not intrusive, easy to implement, and easy to monitor. The initiative has succeeded in improving the documentation of TOF. We are currently in the process of evaluating its effects on clinical outcomes.

We know that residual neuromuscular blockade is a relevant problem that leads to a significant increase in respiratory morbidity and health care utilization.<sup>8,12,20</sup> However, residual neuromuscular blockade remains pervasive despite the advances in our understanding of this challenge since Dr. Viby-Mogensen's 1979 report. The fundamental issue appears to be the continued reliance by anesthesia professionals on informal and variable applications of qualitative clinical indicators rather than use of objective and quantitative TOF stimulation to determine appropriate reversal of neuromuscular blockade. The quantitative measurement of TOF stimulation is a reliable and objective measurement of adequate return of neuromuscular activity, and can be effectively used as a guide for appropriate neostigmine dosing. The QA/QI initiative at the MGH is an example of an integrated interdisciplinary approach by key stakeholders to promote sustained adoption of these best practices and improve patient safety. Broader adoption of similar evidenced-based initiatives and guidelines should provide a significant leap forward towards the elimination of the hidden universality of residual neuromuscular blockade and reduce the co-morbidities and added healthcare utilization associated with residual neuromuscular blockade.

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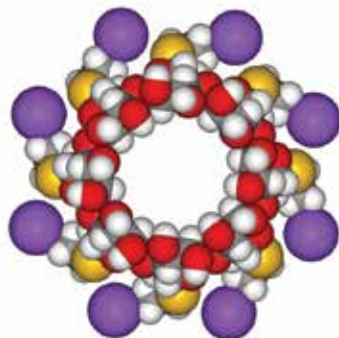
# The Development and Regulatory History of Sugammadex in the United States

by Glenn Murphy, MD

The Neuromuscular Research Group at Organon Newhouse Scotland (east of Glasgow) had been working on the development of fast-onset, short-acting, nondepolarizing steroidal neuromuscular blocking agents since the 1960s, which led to the development of pancuronium, vecuronium and rocuronium. Shortly after the launch of rocuronium, questions arose about a possible action of rocuronium on smooth muscle neurotransmission, so Dr. Anton Bom was contacted. Dr. Bom was performing smooth muscle studies at the same research site. Rocuronium is not very water soluble, so buffer solutions with a pH of 4 are required. Dr. Bom attempted to dissolve rocuronium in organic solvents that were traditionally used for smooth muscle studies, none of which were able to solubilize rocuronium. Next, he decided to examine cyclodextrins, which were demonstrated to dissolve steroidal hormones. Cyclodextrins are rigid, ring-shaped molecules composed of sugar units. The outside of the cyclodextrin is hydrophilic, which makes the molecule water-soluble. The hole in the middle of the cyclodextrin ring is hydrophobic, which allows lipophilic molecules, like steroids, to enter this cavity, creating water-soluble complexes.<sup>1</sup>

Since rocuronium has a steroidal nucleus, Dr. Bom speculated that rocuronium would form complexes with cyclodextrins. This binding would prevent rocuronium from acting on the nicotinic acetylcholine receptor and allow rapid reversal of neuromuscular blockade. His initial studies confirmed that rocuronium formed complexes with cyclodextrins. However, this binding was weak, allowing rocuronium to easily disassociate. Several modifications of the molecule were required to increase affinity. The cavity of the cyclodextrin was too small, so the cavity had to be extended by the addition of side-chains to each sugar unit. To ensure that the side-chains did not enter the cavity, negatively charged end-groups had to be attached to the side-chains. These modifications would allow a tight complex to form between the quaternary nitrogen of the rocuronium and the negatively charged ends of the side-chains. Dr. Ming Qiang Zhang, a medical chemist, then provided a long list of commercially available cyclodextrin molecules. The pharmacologists created in-vitro and in-vivo screening models, which allowed the creation of new cyclodextrin derivatives.<sup>1</sup>

Sugammadex was developed to selectively bind to rocuronium. However, other steroidal muscle relaxants, such as vecuronium and pancuronium, are bound by sugammadex, but with a much lower affinity. There is no affinity of sugammadex for other classes of muscle relaxants (i.e. succinylcholine and the benzylisoquinoliums (mivacurium, atracurium and cisatracurium). One molecule of sugammadex is able to noncovalently bind one molecule of steroidal muscle relaxant.<sup>2</sup>



Space-filling model of sugammadex sodium.

In March of 1999, the first batch of Org 25969 (now known as sugammadex) was produced. In all pharmacological screening tests, this molecule showed the desired profile.

Both the concept of using modified cyclodextrins as reversal agents and the structure and synthesis of sugammadex and related cyclodextrins were patented in 2001. The first human study was performed in healthy volunteers and published in 2005.<sup>1</sup> This investigation demonstrated that 3 minutes after the administration of a normal intubation dose of rocuronium (0.6 mg/kg), 8 mg/kg of Org 25969 could completely reverse neuromuscular blockade. Since the publication of this initial investigation, sugammadex has been administered to over 6000 patients in clinical trials. In addition, sugammadex is approved in 57 countries, with approximately 11.5 million patients receiving the drug as of March 2015.<sup>1</sup>

The first regulatory approval was in the European Union in 2008. In 2007, an application for approval to the FDA was submitted. In 2008, the FDA Advisory Committee unanimously recommended approval. However, the FDA issued a Not-Approvable Letter at this time. The FDA requested further characterization of sugammadex on repeat exposures due to concerns over hypersensitivity and anaphylactic reactions, as well as possible mechanistic causes of events. In the initial submission, there was one case of anaphylaxis and 31 cases of hypersensitivity. In addition, a small prolongation of aPTT and PT was noted in an in-vitro study.<sup>3</sup> Further studies evaluating the effects of sugammadex on surgical bleeding were also requested. Finally, the need for additional studies examining the effects of sugammadex on cardiac arrhythmias and QT prolongation was noted.

In response to the FDA's requests, 4 additional studies were conducted examining the impact of sugammadex on coagulation. These investigations demonstrated a small increase in PT and aPTT that occurred within minutes of administration, but resolved within an hour. In addition, in a large

## Safety Must Extend into Perioperative Period

“Expanding Influence,” From Page 48

undergoing procedures in body parts that have high concentrations of dwelling bacteria. Colorectal surgery is a good example.

Blood products contain much debris, including free hemoglobin and cellular stroma that can be toxic to organs such as kidneys. Processes that lead to reductions in blood transfusion are cost-effective, improve patient care in these settings, and help avoid prolonged disability, sepsis, and multi-organ failure. Approximately 40% of all blood products are transfused into surgical and procedural patients. The specialty is perfectly positioned to take lead roles in developing new algorithms or modifying existing algorithms for their specific practices and patient populations. In collaboration with transfusion medicine specialists, surgeons, and proceduralists, anesthesiologists and their care teams can work within health care settings to design and implement successful processes to reduce<sup>4,5</sup> the use of blood products and decrease perioperative complications.

**Human factors:** Each step in a clinical pathway or process, whether it has been designed or occurred naturally, increases the opportunity for human error. Anesthesiologists, working closely with their health care colleagues and system engineers, can analyze, design, assess and continuously improve perioperative care pathways and processes by eliminating unnecessary steps. It is the right thing to do financially—reducing steps decreases expenses and increases efficiency. It is the right thing to do clinically—reducing steps decreases errors. It is the right thing to do for our patients—reducing steps decreases complications and increases patient safety.

Expansion of anesthesia care beyond intraoperative management and into an encompassing perioperative setting makes sense clinically because patients will benefit. It is another step forward in expanding the influence of the specialty in the safety of patients who are anesthetized for their surgical and procedural care.

Visionary leaders of the specialty during the past generation have noted that anesthesia care must evolve. Table 3 provides several of the quotes taken from selected ASA Rovenstine Lectures. These visionary colleagues had it right—expansion of the specialty to encompass perioperative care is necessary BECAUSE IT IS THE RIGHT THING TO DO FOR OUR PATIENTS.

I propose that the APSF reconsider its vision statement, “No patient shall be harmed by anesthesia.” It is now time that the statement should read, “No patient undergoing an anesthetic shall be harmed in the perioperative period.” This is the imperative you want to follow if you wish to expand the influence of the specialty into the future. This is the imperative you want to follow if you wish to have a greater influence on patient safety. This is the imperative you wish to have followed if you are the patient.”

*Dr. Warner is Professor of Anesthesiology and Executive Dean at the Mayo Clinic College of Medicine in Rochester, Minnesota.*

See “Sugammadex” Next Page

# Sugammadex Approved After Multiple Delays

## “Sugammadex” From Preceding Page

study of patients undergoing hip or knee replacement surgery, no increase in bleeding or transfusion requirements was observed in patients randomized to receive sugammadex.<sup>3</sup> In order to address concerns related to cardiac arrhythmias, an analysis of phase 2 and 3 clinical studies was conducted, as well as an analysis of postmarketing data.<sup>4,5</sup> These study findings indicated that QTc was not prolonged in patients given sugammadex. The studies also indicated that arrhythmias did not occur with greater frequency with sugammadex compared to neostigmine, although bradycardia can occur with both agents. Finally, a randomized, double-blind, placebo-controlled study in healthy volunteers was conducted to evaluate the incidence of allergic reactions to sugammadex.<sup>6</sup>

In 2012, another submission for approval was sent to the FDA. In 2013, a Complete Response Letter was provided to the sponsor. The FDA reported that protocol violations in the hypersensitivity study had been observed, which raised data reliability issues. However, bleeding and arrhythmia risks had been adequately addressed. In 2014, the sponsor resubmitted a new hypersensitivity trial in awake volunteers. A total of 375 awake subjects were given 3 intravenous doses of sugammadex (4 mg/kg, 16 mg/kg, or saline), and patients examined for hypersensitivity or anaphylactic reactions. One case met the criteria for anaphylaxis in the 16 mg/kg dose group (no hypotension or wheezing, treated with steroids and diphenhydramine), although the mechanism was unclear (no tryptase or IgG/IgE specific for sugammadex). Furthermore, no cases of anaphylaxis were reported in 3,519 patients administered sugammadex in clinical trials. Finally, in postmarketing data, 273 reports of anaphylaxis were reported in approximately 11.5 million sugammadex exposures, with 237 of 241 patients recovering with standard therapy.<sup>6</sup>

In 2015, a second Complete Response Letter was sent to the sponsor. At one site of the hypersensitivity study, staff who dosed subjects in one cohort performed adverse assessments in a different cohort. The FDA requested additional site inspections and sensitivity analysis. In November of 2015, the FDA again convened to review the resubmitted data. After review of all submitted studies as well as postmarketing data, the FDA Advisory Committee again unanimously recommended approval.<sup>7</sup> Approximately 8 years after the initial FDA submission, sugammadex, owned and marketed by Merck, received FDA approval on December 16, 2015.

Sugammadex represents a novel and new drug, which offers several important advantages over current anticholinesterase reversal agents. Deep levels of neuromuscular blockade (train-of-four (TOF) count of 0, post-tetanic count of 1–2) can be reversed effectively with 4 mg/kg of sugammadex within 3 minutes, whereas neostigmine is ineffective in antagonizing deep blockade. At moderate levels of neuromuscular block (TOF count of 2), the mean time to achieve full recovery

(TOF ratio of 0.9) with sugammadex is 1.5 minutes versus 19 minutes with neostigmine.<sup>8</sup> Furthermore, in urgent or emergent reversal of large doses of rocuronium (1.2 mg/kg), the mean time to neuromuscular recovery is significantly faster with sugammadex (16 mg/kg) compared to spontaneous recovery with succinylcholine.<sup>9</sup> Sugammadex will allow increased flexibility of neuromuscular management in the operating room; deep blockade can be maintained until the end of surgery if required and then quickly reversed. Most importantly, the risk of residual neuromuscular blockade in the PACU can be significantly reduced if sugammadex is appropriately dosed. In the absence of consistent neuromuscular blockade monitoring with peripheral nerve stimulators and/or specified guidelines for reversal, recent data has demonstrated that the risk of residual block in the PACU can be reduced from 43% in patients given neostigmine to 0% in those given sugammadex.<sup>10</sup> Finally, data from phase 1–3 clinical studies, volunteer subject investigations and post-marketing data in over 12 million patients have demonstrated that sugammadex is safe, with a rare risk of anaphylactic reactions that are treatable with standard therapy.<sup>7</sup>

The adoption of sugammadex by hospitals, pharmacies and anesthesia providers may be impacted by cost concerns. As with all newly FDA-approved drugs, anesthesia providers should be aware that post-marketing surveillance provides a vehicle for communicating with the FDA about any concerns of adverse events that may be associated with this new drug.

*Financial Disclosure: Dr. Murphy discloses that he is on the advisory board of Merck and has served as a consultant for Merck and CASMED.*

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# Large Groups Prioritize Safety Issues

## “Large Practice Groups,” From Cover

One option is for professional associations (ASA, AANA, AAAA) to adopt APSF recommendations in the form of policy statements (Standards, Practice Advisories) that would be applicable to all association members. The reality of this option is unlikely considering the widely diverse opinions and practice profiles of the members of these organizations.

The second option for APSF recommendations to become “best practices” is “spreading the word” among individual anesthesia professionals via educational materials (such as conference reports in the *APSF Newsletter*) or educational videos. Although the written word is the traditional approach, APSF also believes educational videos provide a robust model that could be more powerful than a written report for effecting change.

The third option for effecting change and the principal reason to involve large anesthesia groups and practice management groups is

**Table 1: Large Anesthesia/Practice Management Groups Represented at Conference**

American Anesthesiology
Anesthesia Associates of Massachusetts (Boston, MA)
Cleveland Clinic (Cleveland, OH)
Community Health Systems (Franklin, TN)
Department of Veterans Affairs
First Colonies Anesthesia Associates (FCAA) (Frederick, MD)
Integrated Anesthesia Associates (East Hartford, CT)
Kaiser Permanente
Linn County Anesthesiologists (Hiawatha, IA)
Mayo Clinic (Rochester, MN)
North American Partners in Anesthesia (NAPA) (Melville, NY)
Northside Anesthesiology Consultants (Atlanta, GA)
NorthStar Anesthesia (Irving, TX)
Old Pueblo Anesthesia (Tucson, AZ)
PhyMED Healthcare Group (Nashville, TN)
Sheridan Healthcorp
Southern Arizona Anesthesia (Tucson, AZ)
TeamHealth Anesthesia
Tejas Anesthesia (San Antonio, TX)
Twin Cities Anesthesia Associates (St Paul, MN)
US Anesthesia Partners
Valley Anesthesiology and Pain Consultants (Phoenix, AZ)
Vanderbilt University School of Medicine (Nashville, TN)

APSF’s hope that these entities would individually endorse and adopt selected APSF recommendations that are relevant to their practices, needs and resources.

Following these introductory comments, the attendees met in three breakout groups with members of the APSF Executive Committee to consider three questions (see below) with the goal of creating a report to present to the conference’s general session. Bullet points following the questions represent conclusions/recommendations from each of the three breakout groups and the number in parentheses represents the number of times this statement appeared independently in each group.

**1. In your practice, what do you consider to be the most important safety issues in terms of potential harm to patients?**

- Production pressures (3)
- Communication (handoffs, coordination of care, culture of ongoing learning) (3)
- Distractions in the operating room (2)
- Monitoring postoperative respiratory depression (obstructive sleep apnea) (2)
- Medication safety (2)
- Anesthesia for surgery in non-operating room locations (2)

**2. Please describe how APSF can best partner with “your practice” to advocate patient safety initiatives.**

- Disseminate information (*APSF Newsletter*, videos, social media)
- Stronger statements/recommendations
- APSF become a conduit/convenor of large anesthesia groups to share information and best practices
- Develop toolkits for safety initiatives (emergency manuals, checklists)
- Workshop on developing a “safety officer” (safety champions in each large group)
- Confront safety issues resulting from postoperative respiratory depression, production pressures, office-based anesthesia
- Design a “better” human

**3. APSF has a specific interest in the “simulation component” of MOCA based on the belief that simulation provides “practice for managing rare emergencies.” Do you believe a requirement for simulation based on “practice for rare emergencies” would bring value to members of your group?**

- Could these experiences be transmitted in different ways without requiring travel to a simulation site (online experiences to practice crisis management)?
- High value for team training more than for rare events; should not be required

In addition to the breakout group reports, the results of a Pre-conference Survey that had been sent to attendees prior to the conference (29 out of a possible 36 surveys were returned) were pre-

**See “Large Practice Groups,” Next Page**

ANESTHESIA PATIENT SAFETY FOUNDATION

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Abe Abramovich

Robert K. Stoelting, MD



# Multiple Large Anesthesia Groups Participate in Workshop and Give Input

## “Large Practice Groups,” From Preceding Page

sent to the attendees (bullet points represent survey responses).

### 1. In your practice, what do you consider to be the most important patient safety issues in terms of potential harm to patients? (responses in order of frequency)

- Distractions in the operating room
- Production pressures
- Communication (handoffs)
- Medication safety
- Postoperative respiratory monitoring, neuromuscular blocker monitoring

### 2. Please rank the importance of APSF safety initiatives in your practice.

APSF safety initiatives that were viewed as “high priority for my practice” were:

- Distractions in the operating room
- Production pressures
- Medication safety in the operating room
- How to deal with the “outlier” practitioner
- Confirming competence before using advanced medical technology

### 3. Please describe how APSF can best partner with “your practice” to advocate patient safety initiatives.

- Set priorities for large groups to “consider”
- Use large groups to “test” safety initiatives

- Develop videos of simulated “emergency situations”
- Provide “nudge” for large groups to pursue safety initiatives
- Facilitate dissemination of “best practices”

### 4. Do you perceive a downside/risk for your anesthesia group partnering with APSF to incorporate specific safety initiatives? An example would be requiring “advanced medical technology training” paralleling the published APSF recommendations.

Yes (3)                      No (25)

- Stress many are feeling over mandates
- Cost of implementing
- Recommendations based on evidence
- Maximize “brand value” of APSF

### 5. APSF has a specific interest in the “simulation component” of MOCA based on the belief that simulation provides “practice for managing rare emergencies.”

Do you believe a requirement for simulation based on “practice for rare emergencies” would bring value to members of your group?

Yes (23)                      No (4)

- Simulation is a powerful and underleveraged tool
- Endorsement of APSF would be helpful
- Logistics and cost is problematic
- Tried to mandate for our group and resistance was enormous

Based on the breakout group recommendations and the survey responses, it is concluded that high priority safety issues viewed as placing patients at risk for harm were (1) distractions in the operating room, (2) production pressures, and (3) communication issues. Medication safety, technology training, monitoring postoperative respiratory depression and monitoring neuromuscular blockade were also mentioned as safety concerns.

Overall, the attendees seemed to endorse a role for APSF in advocating best practices based on safety initiatives with reservations related to evidence to support the recommendations and cost of implementing these changes. There was agreement that simulation for “practice for managing rare emergencies” had merit, but logistics and cost were problematic.

APSF will consider the conclusions and recommendations of this conference for implementing “best practices” on a broader scale than “one anesthesia professional at a time” and for establishing priorities for future safety initiatives. APSF believes that large anesthesia/practice management groups offer an opportunity for an ongoing partnership with APSF as we pursue our mutual vision that “no patient shall be harmed by anesthesia.”

*Robert K. Stoelting, MD  
President, APSF*



## APSF Website Offers Online Educational DVDs

Visit the APSF website ([www.apsf.org](http://www.apsf.org)) to view the following DVDs and request a complimentary copy.



- Opioid-Induced Ventilatory Impairment (OIVI): Time for a Change in the Monitoring Strategy for Postoperative PCA Patients (7 minutes)



- Perioperative Visual Loss (POVL): Risk Factors and Evolving Management Strategies (10 minutes)



- APSF Presents Simulated Informed Consent Scenarios for Patients at Risk for Perioperative Visual Loss Ischemic Optic Neuropathy (18 minutes)

# EDITOR'S Q&A

## How Do I Prepare for OR Power Failure?

by Erica L. Holland, MD; Carli D. Hoaglan, MD; Martha A. Carlstead, CRNA; Ryan P. Beecher, CRNA; Grete H. Porteous, MD

### Introduction

Loss of electrical power in a hospital is a patient safety hazard that has been neglected in medical training and research.<sup>1,2</sup> The technology-rich environment of the operating room (OR) puts patients at risk should a sudden loss of power occur, as lights and critical equipment may fail without warning. Regional disasters and extreme weather events are the most common causes of power outages. Extreme weather events have become more common in the past two decades, and it is projected that regional power failures will occur more frequently and last longer in future years, despite efforts to improve power grid resiliency.<sup>3,4</sup> Hospital power failure may also be the result of a local disruption of municipal power, or be limited to a single institution. Published case reports (Appendix 1 on page 62) suggest that frequent root causes of intraoperative power loss are a failure of emergency generators to function during a widespread power outage, and hospital construction work that unmasks faults in internal electrical systems.<sup>5-11</sup> These reports underscore the fact that hospital emergency generators and back-up systems are not completely reliable. Anesthesia providers need to know as much about responding to power failure as they do about managing any other intraoperative crisis. As there is no centralized reporting system for hospital power failure events, the true incidence of this emergency is unknown. Based on anecdotal experience, we believe it may be more common than is generally appreciated.

In addition to direct effects on critical anesthesia equipment, other repercussions of power outage in the OR can be extensive (Table 1). Power failure often translates to loss of lighting in the OR and adjacent hallways. Surgeons are faced with loss of electrosurgical units, video display monitors, and suction.<sup>6,8</sup> Anesthesia machines and ventilators revert to battery power, which may last from 30 to 90 minutes depending on device and manufacturer specifications. Surprisingly, there are few reports on how well anesthesia machines function on battery power, and what can be expected when

**Table 1. Vulnerability of operating room equipment and hospital services to power failure**

This table is intended as an overview, as actual equipment performance may vary based on institution and make and model of device. Devices with limited or no battery back-up should operate if plugged into an emergency circuit ("red outlet") and generators are working.

Substantial battery back-up, or not dependent on electrical power	
Anesthesia machine/ventilator	Portable ultrasound machines
Non-desflurane vaporizers	Intra-aortic balloon pump
Portable patient monitors	Laptop computers
Portable infusion pumps	Medical gases (e.g., pipeline oxygen)
Portable suction	
Limited or no battery back-up	
Room lights	Patient warming devices
End-tidal gas analyzer	Transesophageal echocardiography machines
Automated medication dispensing devices (e.g., Cerner's RxStation®)	Wall suction and scavenging systems
Desflurane vaporizer	Da Vinci® Surgical System*
Patient monitors without battery back-up	Video towers
Electrosurgical units	Cardiopulmonary bypass machine
Fluoroscopy/portable X-ray units	Desktop computers without battery
Fluid warmers/rapid infusion devices	Cell salvage machine
Depends on institution	
WiFi/Internet access	Badge-activated door locks
Paging systems	Electronic medical record
Telephones	

\*Battery allows undocking of patient from robot.

their batteries are finally depleted. Electronic patient monitors, desflurane vaporizers, and end-tidal gas analyzers often lack battery back-up. Hospital power failure may compromise communications (telephones, pagers, WiFi), electronic medical records, access to critical medications from automated dispensing cabinets, room temperature control, sterilization capabilities, elevators, and staff access to clinical areas through badge-secured doors.<sup>12,13</sup> In some cases, operations may need to be aborted and patients evacuated. Prolonged hospital power failure eventually impacts sanitation, access to food and clean water, transportation and security.

Our anesthesia department at a tertiary-care medical center was recently faced with the challenge of preparing for electrical upgrades in a new hospital building that could temporarily compromise emergency generator power delivery to a suite of operating rooms and other critical areas. Published reports suggest that anesthesia departments should be knowledgeable about the battery life and capabilities of their equipment, should have sources of back-up lighting and monitoring immediately available, and should have a disaster plan that engages the entire OR staff. We thus embarked upon a project to review our current emergency plans, test the functionality of key anesthesia equipment during

**See "Power Failure," Next Page**

*The APSF sometimes receives questions that are not suitable for the Dear SIRS column. This Q and A column allows the APSF to forward these questions to knowledgeable committee members or designated consultants. The information provided is for safety-related educational purposes only, and does not constitute medical or legal advice. Individual or group responses are only commentary, provided for purposes of education or discussion, and are neither statements of advice nor the opinions of the APSF. It is not the intention of the APSF to provide specific medical or legal advice or to endorse any specific views or recommendations in response to the inquiries posted. In no event shall the APSF be responsible or liable, directly or indirectly, for any damage or loss caused or alleged to be caused by or in connection with the reliance on any such information.*

# OR Power Failure Can Be a Critical Event

## “Power Failure,” From Preceding Page

power failure, and develop a safety checklist and inexpensive emergency patient monitoring kit.

## Anesthesia Equipment Testing

We tested two different anesthesia machines, one portable monitor and one infusion pump for duration of battery life and functionality on battery power (Table 2). Multiple examples of each device were tested, and all devices were charged overnight prior to testing. Anesthesia machine, ventilator, infusion pump, and portable monitor function were observed until display screens indicated “0% battery,” and then until devices failed and screens became dark.

We found that all types of equipment had a battery life longer than expected, approximately 3 to 4 hours. Anesthesia machine battery life was extended by approximately 1 hour by turning the ventilator off and using manual ventilation. Ventilators on Fabius machines continued to operate for <10 minutes after “0% battery” was displayed, but Apollo ventilators continued functioning for several hours longer. Sevoflurane vaporizer output on both types of anesthesia machines was consistent with dialed settings as long as there was fresh gas flow, and did not depend whether the anesthesia machine was using alternating current (AC) power, battery power, or had a completely depleted battery. Fresh gas flow, rotometers, and the oxygen flush valve were unaffected by AC power loss or battery depletion. These observations are consistent with the manufacturer’s specifications, except that battery life was consistently longer than the 30–90 minutes advertised for these machines (Dräger anesthesia machine user manuals courtesy of Dräger Medical, Inc). Alaris pumps failed within minutes of “battery failure” warning screens. Their fluid volume output was no different whether on battery or AC power. Phillips monitors also failed within about 15 minutes of a “0% battery” indicator screen. In general, displays on all devices underestimated actual battery life. It is unsurprising that manufacturers err on the side of caution in displaying this value to the user, particularly for critical medical devices. All types of devices displayed increasingly loud, visible, and difficult-to-ignore warnings when close to battery failure (Figure 1). No device failed without warning during testing. It is important to note that complete battery depletion during tests such as these can adversely affect subsequent battery function, so repeated tests are not advised.

Table 2. Results of anesthesia equipment testing

Device	Testing mode	Devices Tested	Hours to “0% battery” display Mean (Range)
Dräger Apollo® anesthesia machine	Ventilator on	2	4.8 (4.3–5.5)
	Ventilator off	1	5.6
Dräger Fabius® anesthesia machine	Ventilator on	2	3.5 (3.2–3.7)
	Ventilator off	2	4.6 (4.4–4.8)
Phillips IntelliVue x2® portable monitors	With BP cuff	3	3.0 (2.6–3.6)
	Without BP cuff	1	3.4
Alaris PC® infusion pumps	2 channels	4	4.2 (3.9–4.5)

*Anesthesia machines on battery power were tested both with ventilator on (set to tidal volume of 500 mL and respiratory rate 10 breaths per minute), or ventilator off (simulating a “manual ventilation” state). Fresh gas flow was set to 2 L/min, sevoflurane was dialed to 2%, and end-tidal sevoflurane was measured. Alaris pumps were set-up to run two channels, simulating a carrier infusion at 150 mL/hour and a phenylephrine infusion at 25 mcg/min. In addition to measuring infusion pump battery life, the function of infusion pumps was measured by comparing pump output in mL/hour for devices on battery power compared to alternating current (AC) power. Phillips monitors were tested for battery life both with a non-invasive blood pressure (NIBP) cuff cycling every 5 minutes, and with no NIBP cuff measurements.*

## Emergency Monitoring Supplies

While it is helpful to know how anesthesia equipment will generally perform during a crisis, it is also wise to plan for contingencies. In order to be prepared for a worst-case scenario in which patient monitors fail and portable monitors are unavailable, we designed and distributed “Emergency Monitoring Kits” to carts in every anesthetizing location. Figure 2 shows the contents of the \$60 kits, of which the most important are an inexpensive pulse oximeter and a light-emitting diode (LED) headlamp.

The kits are sealed with break-away tags to discourage component theft, and batteries in headlamps, pulse oximeters, and LED flashlights kept in all anesthesia machines are replaced every 6 months. A paper anesthetic record is included not only for anesthesia charting, but as a critical part of patient identification and documentation during an evacuation.

## OR Power Failure Checklist

Checklists are useful cognitive aids for clinicians that have been proven to increase patient

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Figure 1. Screens displayed on Dräger Apollo and Fabius GS anesthesia machines at time of battery failure.



## Preparedness and Institutional System Are Important Steps

### “Power Failure,” From Preceding Page

safety in numerous areas of medicine.<sup>14,15</sup> For anesthesiologists and nurse anesthetists, checklists are particularly helpful guides for patient management during rare, life-threatening intraoperative events such as malignant hyperthermia and local anesthetic systemic toxicity.<sup>16-18</sup> In published reports, anesthesia providers have had variable responses to operating room power failure, including switching to manual ventilation and discontinuing volatile anesthetics.<sup>6,7</sup> These actions may be appropriate in some power failure situations, and inappropriate in others.

As we were unable to find any published checklists on crisis management for OR power failure, we created our own (Figure 3). Based upon the results of equipment testing and multiple simulations, we decided that the crucial first step during power failure was to determine whether the anesthesia machine and ventilator were functional, and if so, to continue using them. This step allows the clinician's hands to be free to perform other necessary tasks, allows continued delivery of a reliable anesthetic, and minimizes the chance of barotrauma and respiratory alkalosis from manual ventilation. Confidence that volatile anesthetic will continue to be delivered removes the immediate burden on the anesthesia provider to urgently convert to a total intravenous anesthetic (TIVA) in the dark. Furthermore, as electronically controlled medication dispensing stations are not operational without power, supply of intravenous sedatives and anesthetics may be rapidly depleted if multiple ORs are affected. Another crucial element of the checklist involves repeated steps to assure the delivery of oxygen to the patient. In the case of a disaster such as an earthquake, pipeline oxygen supply may be damaged or turned off as a fire control measure. We also include prompts for the anesthesia provider to confirm that critical equipment is plugged into a generator-powered circuit (“red outlets”), to communicate with the surgical team and nursing staff regarding prioritization of help for patient care, and to prepare for patient evacuation if necessary.

### Discussion

Operating room power failure is a critical event that merits advance preparation to prevent catastrophic patient harm. Hospitals are rightly subject to rigorous regulations regarding emergency generator power testing and reliability, and required to develop plans for power failure emergencies.<sup>19</sup> In most cases, it is likely that in the event of intraoperative power loss, approximately 10 seconds (or longer) of darkness will be followed by restoration of power by generators. Return of electrical power does not

mean the end of a crisis, however, as sophisticated medical equipment may be damaged by power surges or forced to undergo a prolonged restarting process. Recently at our institution, municipal power interruption of less than a second caused by an accident at a local electrical substation resulted in unanticipated problems: damage to delicate electronics in some fluoroscopy equipment, malfunction of a transesophageal echocardiography machine during a cardiac case, and loss of video imaging for several minutes during a da Vinci<sup>®</sup> robot-assisted laparoscopic case in which significant bleeding was occurring. A delay of care for several minutes as equipment reboots during a critical part of a procedure can be dangerous. Regardless of whether a crisis is brief or prolonged, or whether generators work or not, patients remain at significant risk whenever power is interrupted.

Management of intraoperative power failure should be part of a coordinated medical facility response. While preparedness within the operating room is important, it is equally important to develop an institutional system for disaster response that allows for a clear chain of command with recognized roles and protocols, rapid assessment of patient needs, and deployment of resources. The Hospital Incident Command System (HICS)<sup>20</sup> is the basis of our institution's efforts to build a robust emergency preparedness program. Within the HICS system, protocols in perioperative areas are being developed that allow staff to rapidly assess operating room needs and triage care even in the presence of darkness and loss of normal avenues of communication. Individual operating room needs are triaged by color to direct assistance to the most critical, and gauge

OR readiness to receive patients during an emergency.

This project has allowed us to explore our capabilities “in the dark” as an anesthesia service practicing in an earthquake hazard area, and has also allowed us to engage the entire medical center in preparations and simulations for disaster planning. Anesthesiologists, nurse anesthetists, and anesthesia technicians should learn about the battery capabilities of their equipment and the projected impact of a power outage on key services necessary for patient care. Anesthesia departments should have extra equipment for patient monitoring readily available, most importantly, LED headlamps and battery-powered pulse oximeters. A checklist may help clinicians remember to perform key steps when the lights go out: finding alternative light sources, preventing hypoxemia, and confirming that critical equipment is plugged into generator-powered outlets. We continue to refine and practice this checklist and our disaster response protocols, and hope that others may use our experience as a starting point for discussing preparedness for power failure and other emergencies at their own institutions.

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**Figure 2. Emergency patient monitoring kits.** Kits contain an LED headlamp, sphygmomanometer, stethoscope, pulse oximeter, colorimetric CO<sub>2</sub> detector, paper anesthetic record, and copy of the power failure emergency checklist.

# Power Out?

## Is Ventilator Still Working?

**YES**

Call for HELP while doing the following...

- Continue normal use of ventilator & non-desflurane vaporizers
- Change FiO<sub>2</sub> to 100% @ 2 L/min

**NO**

Call for HELP while doing the following...

- Adjust APL and manually ventilate utilizing pipeline O<sub>2</sub> or E-cylinder @ 100% FiO<sub>2</sub>
- O<sub>2</sub> flush valve may need to be pressed multiple times to refill circuit to manually ventilate
- O<sub>2</sub> flowmeter & O<sub>2</sub> flush valve will still function
- Non-desflurane vaporizer will still function at approximate dialed setting

- Obtain additional light source if not already done (e.g., flashlight, headlamp, laryngoscope, cell phone)
- Open emergency monitoring kit in bottom drawer of anesthesia cart. Apply manual patient monitors (pulse ox, NIBP). Listen for breath sounds, use colorimetric CO<sub>2</sub> detector as needed.
  - o If available, use portable transport/"brick" monitors
  - o Check patient vital signs and chart every 5 minutes on paper anesthetic record
- Confirm Ambu-bag available and O<sub>2</sub> E-cylinder on back of anesthesia machine is at 2000 psi
  - o If pipeline O<sub>2</sub> fails, utilize O<sub>2</sub> E-cylinder on back of machine
  - o Anticipate possible need to switch to Ambu-bag with auxiliary O<sub>2</sub> tank or room air
- Notify anesthesia attending, anesthesia tech, & charge anesthesiologist of situation
- Communicate with surgical team regarding status & determine patient triage category: Red, Yellow, Green, Blue, or Black (see "Patient Triage Guidelines" in binder)
- Confirm that critical room equipment is plugged into RED outlets
- Obtain additional propofol, opioids, and midazolam, if needed
- Maintain 100% FiO<sub>2</sub> at 2 L/min unless contraindicated
- Anticipate possible upcoming need for IV anesthesia (see "Quick Propofol Drip Guide" in binder)
- Prepare for possible patient evacuation (see "Patient Evacuation Kit" in binder)
- Anticipate that anesthesia machine battery and Alaris pumps may last as long as 3 hours (not guaranteed)
  - o Consider transition from controlled to spontaneous ventilation to conserve battery

### TROUBLESHOOTING VENTILATOR

- If ventilator fails to operate, try turning machine Off/On
  - o Fabius switch location: back lower right corner (Figure 4)
  - o Apollo switch location: front lower right corner, hold for 3 sec (Figure 5)
- Attempt to plug ventilator into different red outlet
- If difficulties manually ventilating, try pressing O<sub>2</sub> flush valve several times to fill circuit

### "Power Failure," From Preceding Page



Figure 4: Fabius On/Off Switch (back of machine).



Figure 5: Apollo On/Off Switch (hold for 3 sec).

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# Preparedness and Institutional System Are Important Steps

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## Supplemental Materials

### PATIENT TRIAGE GUIDELINES

<b>Red</b>	Needs immediate help and/or evacuation within 30 minutes, unstable patient, mechanically ventilated (outside of OR environment), or requiring significant cardiac or pulmonary resuscitation
<b>Yellow</b>	Can wait 30 min–2 hr for evacuation, relatively stable patient but requiring ongoing supportive care or continuation of procedure beyond 30 min
<b>Green</b>	Can abort or finish procedure within 30 min...OR...can wait > 2 hr for evacuation, patient otherwise stable
<b>Blue</b>	Can be discharged home within 30 min, stable patient
<b>Black</b>	Deceased

### Quick Propofol Drip Guide

(To Approximate 100 mcg/kg/min)

Route	50 kg Patient	100 kg Patient
Intermittent Syringe Bolus	2.5 ml every 5 min	5 ml every 5 min
Mini-drip (60 drop/ml)	1 drop every other second	1 drop every second

### PATIENT EVACUATION KIT

<input type="checkbox"/> Ambu-Bag	<input type="checkbox"/> Manual Monitors	<input type="checkbox"/> Propofol
<input type="checkbox"/> Mask	<input type="checkbox"/> Full O <sub>2</sub> Tank	<input type="checkbox"/> Midazolam/Opioid
<input type="checkbox"/> Emergency Binder	<input type="checkbox"/> Extra Gloves	<input type="checkbox"/> Muscle Relaxant
<input type="checkbox"/> Oral Airway	<input type="checkbox"/> Extra IV Fluids	<input type="checkbox"/> Phenylephrine
<input type="checkbox"/> LMA #4	<input type="checkbox"/> Extra Syringes	<input type="checkbox"/> Ephedrine
<input type="checkbox"/> ETT/Stylet	<input type="checkbox"/> Extra Needles	<input type="checkbox"/> Atropine
<input type="checkbox"/> Laryngoscope	<input type="checkbox"/> Tape	<input type="checkbox"/> Code Epinephrine Box (100 mcg/ml)

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EDITOR’S Q&A

**Appendix 1. Reports of intraoperative power failure.** Abbreviations: OR – operating room; PACU – post-anesthesia care unit; ESU – electrosurgical unit; ICU – intensive care unit; CABG – coronary artery bypass graft; CPB – cardiopulmonary bypass; ACT – activated clotting time; TOF – train-of-four; TIVA – total intravenous anesthesia.  
<sup>†</sup>Year of publication.

Year <sup>†</sup>	Scenario	Root Cause	Outcome	Recommendations
2010	<ul style="list-style-type: none"> <li>Complete loss of power on two consecutive days</li> <li>9 operations in progress</li> <li>Outage lasted 13 minutes on day 1 and 9 minutes on day 2</li> </ul>	<ul style="list-style-type: none"> <li>Fault within the switching panel that controlled whether the hospital used municipal power or emergency generator power</li> <li>Unclear if generators worked</li> </ul>	<ul style="list-style-type: none"> <li>Anesthesia monitors failed and “clinical monitoring” was used until portable transport monitors arrived</li> <li>Video towers and imaging systems failed</li> <li>Surgical lights, ventilators, gas delivery systems and CPB continued because of built-in batteries</li> </ul>	<ul style="list-style-type: none"> <li>An uninterruptible power supply system for the OR should be installed as this would allow at least one hour of power in the ORs in order to complete ongoing procedures</li> <li>Staff should be familiar with power requirements of equipment<sup>5</sup></li> </ul>
2010	<ul style="list-style-type: none"> <li>Partial hospital power failure with loss of power to emergency (generator) system</li> <li>8 operations in progress, including a craniotomy, Whipple procedure, and kidney transplant</li> <li>Outage lasted 15 minutes</li> </ul>	<ul style="list-style-type: none"> <li>During construction, a phase loss relay in main hospital circuit became dislodged, simulating loss of municipal power</li> <li>A critical branch transfer switch then connected hospital power to an emergency generator that was disabled for servicing</li> <li>“Red outlets” that were supplied by generator lost power</li> </ul>	<ul style="list-style-type: none"> <li>Most anesthesia providers switched to manual ventilation, while two continued to use the battery-powered anesthesia machine ventilator</li> <li>3 providers switched from desflurane to sevoflurane or isoflurane. One switched to propofol infusion with midazolam</li> <li>All patient monitoring was interrupted except in the one room where anesthesia equipment was erroneously not plugged into red outlet. Portable monitors were brought into rooms</li> <li>Room lights continued to function except in one room</li> <li>ESUs and automated drug supply cabinets failed</li> </ul>	<ul style="list-style-type: none"> <li>Communication should be improved by notifying staff of potential power loss during possible service interruption and developing a “batch paging” system to notify key personnel during an emergency</li> <li>Anesthesia providers should focus on “ABCs”, call for help, utilize emergency equipment and ensure delivery of anesthesia to the patient</li> <li>All rooms should have portable backup lights</li> <li>If some equipment is functional in a room, consider plugging failed equipment into different outlets</li> <li>Phase loss relay component should be secured to avoid a similar accident in future<sup>6</sup></li> </ul>
2005	<ul style="list-style-type: none"> <li>Complete loss of hospital power</li> <li>Emergency generators failed in wing of hospital with operating room, but functioned elsewhere</li> <li>Complex oral and maxillo-facial operation in progress</li> <li>Outage lasted days</li> </ul>	<ul style="list-style-type: none"> <li>Multistate power outage (Northeast blackout of 2003)</li> </ul>	<ul style="list-style-type: none"> <li>Room lights failed</li> <li>Anesthesia machine display and monitors worked, but ventilator bellows could not be seen in the dark</li> <li>TIVA initiated. Patient ventilated with self-inflating resuscitation bag and tank oxygen</li> <li>Once portable lights confirmed normal bellows function and pipeline gas supply, anesthesia machine resumed ventilation with volatile agent</li> <li>Operation was suspended, patient was left intubated and transported to PACU</li> <li>Operation completed the next day in a different building which had generator power</li> </ul>	<ul style="list-style-type: none"> <li>Anesthesiologists have a critical leadership role in the OR during crisis. Clear communication and thoughtful planning are key to avoiding panic</li> <li>Daily equipment checks should include flashlights and batteries in every room</li> <li>The battery life of anesthesia equipment should be determined</li> <li>Consider resuming spontaneous ventilation under anesthesia as a safety precaution in case anesthesia machine battery fails<sup>7</sup></li> </ul>
2001	<ul style="list-style-type: none"> <li>Complete loss of hospital power</li> <li>3 operations in progress: ankle fusion, pelvic extension, and radical neck dissection</li> <li>Outage lasted &gt;1 week, requiring evacuation of all hospital patients</li> </ul>	<ul style="list-style-type: none"> <li>Fire in electrical vault</li> <li>Electricity still supplied to building by municipal power but unable to be distributed throughout hospital</li> <li>Main and backup generators destroyed by fire</li> </ul>	<ul style="list-style-type: none"> <li>Flashlight used for light source in ORs</li> <li>Anesthesia machines continued to function on battery</li> <li>Wall suction failed and portable suction unit used</li> <li>Electrosurgical units failed and battery-powered bipolar eye electrosurgery units and vessel ligation were used to achieve hemostasis</li> <li>Automated drug supply cabinets failed</li> <li>All operative procedures were near completion and incisions were closed</li> </ul>	<ul style="list-style-type: none"> <li>Create emergency staffing plan that identifies specific staff member responsibilities and roles</li> <li>Battery operated ESUs and suction should be available</li> <li>Perform mock disaster drills quarterly</li> <li>Pharmacy services should have a plan to ensure availability of medications to operating rooms</li> <li>Flashlights and paper intraoperative records should be available in ORs<sup>8</sup></li> </ul>
2000	<ul style="list-style-type: none"> <li>Complete loss of hospital power</li> <li>Both emergency generators failed</li> <li>Carotid endarterectomy in progress</li> <li>Outage lasted 30 minutes</li> </ul>	<ul style="list-style-type: none"> <li>Construction workers accidentally drove a steel pile through the hospital’s main incoming power cables</li> <li>The first generator did not start at all. The second generator started, but was quickly overloaded and then failed</li> </ul>	<ul style="list-style-type: none"> <li>Room lights failed except for one light with a back-up battery</li> <li>Anesthesia machine ventilator continued to function</li> <li>Patient monitors failed, including gas analyzer and capnography. Surgeon watched pulsations of the carotid artery until a portable monitor was available</li> <li>Capnography and agent monitoring remained unavailable</li> <li>The case was aborted, and the patient was taken to the ICU</li> </ul>	<ul style="list-style-type: none"> <li>Emergency generator planning should take into account the load placed on one generator in case a second generator fails<sup>9</sup></li> </ul>
1995	<ul style="list-style-type: none"> <li>Complete loss of hospital power</li> <li>Ongoing cardiac case with patient on CPB</li> <li>Outage lasted 53 minutes</li> </ul>	<ul style="list-style-type: none"> <li>Loss of municipal power during heat wave</li> <li>Emergency generators started, then failed after 15 minutes</li> </ul>	<ul style="list-style-type: none"> <li>Room lights, CPB machine, communications (intercom, pager), patient monitors, and suction failed</li> <li>Roller head in CPB circuit was manually cranked to maintain a venous saturation &gt; 70%</li> <li>Flashlights and laryngoscope lights were used for illumination</li> <li>Portable monitors and suction brought to room</li> <li>Measurement of ACT performed manually with flashlight and stopwatch</li> <li>Not possible to rewarm patient. Came off CPB on dopamine. CPB reinstated when power restored</li> </ul>	<ul style="list-style-type: none"> <li>Hand-cranking a CPB machine is exhausting, and relief staff must be brought in for this purpose immediately</li> <li>The capabilities of various functions of the CPB machine and battery life must be determined in advance of a crisis</li> <li>When communications fail, all available anesthesia personnel should systematically check each OR to determine priority needs</li> <li>Battery powered lighting in hallways, workrooms and PACU is also necessary to find equipment and prevent staff injury</li> <li>Staff in ORs must be assessed periodically for heat exhaustion when air conditioning fails during a heat wave<sup>10</sup></li> </ul>
1993	<ul style="list-style-type: none"> <li>Operating room loss of power. No mention of other hospital areas</li> <li>Ongoing laparotomy</li> <li>Emergency generators worked for approximately 3 minutes, then failed</li> <li>Outage lasted 45 minutes</li> </ul>	<ul style="list-style-type: none"> <li>Regional power outage (likely Hurricane Hugo)</li> <li>Generator cooling system had been accidentally deactivated. When the generator activated in response to the power failure, it quickly overheated and failed</li> </ul>	<ul style="list-style-type: none"> <li>All lighting, ventilator and monitors except for pulse oximeter failed</li> <li>Ventilation was continued manually via anesthetic circle system</li> <li>Portable monitors were used, including manual BP cuff, esophageal stethoscope, TOF monitor, oxygen analyzer, pulse oximeter and EKG</li> <li>Flashlights used, but inadequate for continuation of surgery. When power returned 45 min later, surgery resumed</li> </ul>	<ul style="list-style-type: none"> <li>Clinicians should be ready to use manual monitors and physical exam to monitor patients if battery-powered devices fail</li> <li>Develop a plan for OR power outage and rehearse it<sup>11</sup></li> </ul>

## Dear SIRS

# Incorrect Network Connection Simultaneously Crashes Multiple Anesthesia Machines

## S AFETY I NFORMATION R ESPONSE S YSTEM

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

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### Dear SIRS:

I work in Kalispell, Montana, as an anesthesiologist and head of our group of 20 anesthesiologists. We have two adjoining hospitals, one that functions as an outpatient surgery center, the other an acute care hospital and trauma center. We recently had an incident involving our Mindray anesthesia machines and monitors. Six (6) Mindray A5 anesthesia machines and eight (8) DPM 7 patient monitoring systems were in use delivering anesthesia care at the time of the incident. We have both Mindray anesthesia machines and a few Fabius Gas machines. All of our monitoring is Mindray.

While one of the Mindray machines was being moved from one anesthetizing location to another, a network connection was made incorrectly by an anesthesia technician, who plugged both ends of the network cable into the network receptacle rather than one end into the network receptacle and the other end to the anesthesia machine. This network was installed for the exclusive use of the Mindray equipment, thus no other equipment was affected. This misconnection resulted in a loop where the network traffic consumed 100% of the bandwidth. When the misconnection occurred, no other Mindray anesthesia machines or patient monitors were able to communicate with the network. As a result, every Mindray machine and patient monitor in both buildings simultaneously shut off and refused to turn back on as long as they were connected to the network. It was discovered that if the machine was disconnected from the network, the machine and monitor returned to normal function. Word spread to all anesthesiologists to unplug the machines from the network and, within 15 to 20 minutes, everything was back in service, but disconnected from the network. Fortunately, there were no untoward sequela for the patients, but every patient had their anesthetic, monitoring, and mode of ventilation changed. Hospital information technology found the source of the excessive network traffic and broke the loop by unplugging the offending cable from the network. The network operation was returned to normal within a few hours.

Carl Tinlin D.O.  
Kalispell, MT

### Mindray Reply:

On May 19, 2015, Mindray was notified of a situation involving six (6) A5 and eight (8) DPM 7 systems which unexpectedly shutdown; the result

of a cabling error where a Kalispell anesthesia technician inadvertently connected a cat5 cable from one wall connection to another wall connection, forming a loop on the Kalispell-installed and maintained hospital network. Mindray determined the cause of the shutdown was due to overwhelming network broadcast traffic. The issue was resolved by disconnecting the Ethernet to EMR cable. The systems then restarted and functioned normally. No patient injury was reported.

The customer requested an investigation as to why Mindray's devices were unable to withstand the problem caused by the user error. The results of the investigation are as follows:

- Mindray was initially unable to reproduce the issue using the specific Kalispell LAN settings provided, but upon further examination of Kalispell's network topology, Mindray was able to recommend specific LAN switch settings that would disable any switch port that received network broadcast or multicast traffic at a rate that would cause Mindray's A5 or DPM 7 systems to shut down.
- Mindray Engineering and Kalispell Biomedical Engineering concurrently but independently determined that turning off the Cisco port-fast feature would enhance the solution.
- When reproducing the identified issue in the Mindray lab, it was observed that while the A5 User Interface did go blank, the ventilator continued to ventilate as intentionally designed.

We appreciate the collaborative nature of the effort put forth by the Kalispell staff to work with Mindray's engineering team. Through this process we have identified the cause of the shutdown and made recommendations for Kalispell's network. Additionally, Mindray will make software enhancements to strengthen the network interface and will continue to develop and incorporate, where possible, future product and software enhancements to provide additional protection against unanticipated broadcast or multicast traffic, as our goals include providing the safest and most reliable products possible.

Rich Cipolli  
Vice President, Product Development  
Mindray, North America  
Mahwah, New Jersey

**mindray**  
NORTH AMERICA

# Anesthesia Patient Safety Foundation

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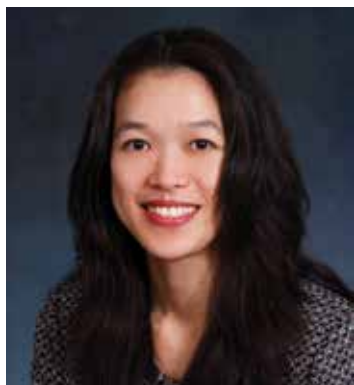
# APSF Awards 2016 Grant Recipients

by Steven K. Howard, MD

The APSF's mission statement explicitly includes the goal to improve continually the safety of patients during anesthesia care by encouraging and conducting safety research and education. Since 1987, the APSF has funded safety projects totaling over 9 million dollars.

In 2015, the APSF investigator-initiated grant program had 43 letters of intent (LOIs). Members of the APSF Scientific Evaluation Committee reviewed and invited the top eight scoring grants to submit full proposals—six full proposals were submitted for final review and discussion on October 24, 2015 at the ASA Annual Meeting in San Diego, CA. Two proposals were recommended to the APSF Executive Committee for funding and both received unanimous support. This year's recipients were Jean Wong, MD, from the Department of Anesthesia at the University of Toronto, and Sallie Weaver, PhD, from the Armstrong Institute for Patient Safety and Quality, the Department of Anesthesiology and Critical Care Medicine at Johns Hopkins University School of Medicine.

The principal investigators of this year's APSF grant provided the following description of their proposed work.



## Jean Wong, MD, FRCPC

Associate Professor, Department of Anesthesia  
University of Toronto

Dr. Wong's Clinical Research submission is entitled "*Prevention of Delirium in Elderly with Obstructive Sleep Apnea (PODESA)*"

**Background:** Delirium is one of the most common postoperative complications in elderly patients after major surgery. It is an extremely distressing problem for elderly patients and their families, and increases their risk for other serious complications, including death. The pathophysiology of delirium is poorly understood, but is believed to be a multifactorial process resulting from a combination of predisposing and precipitating factors. Recent studies show that patients with obstructive sleep apnea (OSA)—a sleep disorder characterized by repeated episodes of complete or

partial upper airway obstruction—are at a greater risk of developing postoperative delirium. The prevalence of OSA increases with age, yet elderly individuals with this condition often remain undiagnosed. Unrecognized OSA may be a treatable cause of postoperative delirium. However, no studies have investigated whether diagnosing and treating OSA preoperatively reduces the incidence of postoperative delirium.

**Aims:** The primary objectives of this multicenter, randomized, controlled trial are to determine whether identifying OSA using a portable diagnostic device—and treating OSA with auto-titrating continuous positive airway pressure (CPAP)—will prevent the occurrence of delirium in elderly patients undergoing knee- and hip-replacement surgery. We will also determine whether auto-titrating CPAP treatment of OSA will decrease the incidence of other OSA-related perioperative complications. All patients will be evaluated for the development of postoperative delirium after surgery.

**Implications:** Delirium is associated with increased morbidity and mortality, and higher healthcare costs. Our study will increase knowledge of the effect of OSA on postoperative delirium, and may reduce the risks for delirium and other OSA-related perioperative complications. The results of our study may be used to design future delirium prevention and management strategies to improve the safety and surgical outcomes of this at-risk population since there are few effective preventative interventions for delirium.

**Funding:** \$149,262 (January 1, 2016 – December 31, 2017). This grant was designated as the APSF/American Society of Anesthesiologists (ASA) President's Research Award. Dr. Wong is also the recipient of the Ellison C. "Jeep" Pierce, Jr., MD Merit Award, which provides an additional, unrestricted amount of \$5,000.



## Sallie J. Weaver, PhD

Assistant Professor

Armstrong Institute for Patient Safety and Quality  
Department of Anesthesiology and  
Critical Care Medicine,  
Johns Hopkins University School of Medicine

Dr. Weaver's educational submission is entitled "*Development and Evaluation of an Online Improvement Project Implementation Course for Anesthesia Trainees*"

**Background:** Developing anesthesia providers with the skills and experience necessary for implementing and leading patient safety improvement work is crucial for delivering reliably safe care. Patient safety improvement methods are key components of ACGME Systems-Based Practice and Practice-Based Improvement milestones for residents. Education developing the knowledge, skills, and attitudes underpinning successful completion and evaluation of improvement interventions is still emerging as an important component of many residency programs. While semi-structured faculty mentoring is critical, formal training in project development, management, and evaluation stands to strengthen the capacity of residents and other trainees to implement successful safety improvement projects from the ground up.

**Aims:** In line with APSF's mission to create young safety scientists and practitioners, this project will develop and evaluate an online training module tailored to anesthesia residents and trainees that will provide instruction and practical tools for planning, implementing, and evaluating a patient safety improvement project. The first phase includes a semi-structured needs analysis to elicit key safety improvement competency areas identified by a national panel of experts and development of the course. Phase two includes implementation and a multilevel evaluation that will examine learner reactions, cognitive and affective learning, transfer, and the quality of resident-led patient safety projects. Results will inform refinements and public dissemination of the online course.

**Implications:** This work has the potential to improve the safety of patients in the care of anesthesia providers by strengthening resident and trainee competencies in patient safety improvement, project management, and evaluation. Additionally, through partnerships with the APSF, American College of Medical Quality and other partners, this project will result in educational resources available to residency programs and individual trainees seeking to strengthen their knowledge and skills in patient safety improvement.

**Funding:** \$149,944 (January 1, 2016–December 31, 2017). This grant was designated as the APSF/American Society of Anesthesiologists (ASA) Endowed Research Award.

Dr. Howard is Professor of Anesthesiology, Perioperative and Pain Medicine at Stanford University School of Medicine and Chair of the APSF Committee on Scientific Evaluation.



# APSF Sponsors Workshop on Implementing Emergency Manuals

by Robert C. Morell, MD and Jeffrey B. Cooper, PhD

On September 9, 2015, in Phoenix, Arizona, the APSF convened an experts' workshop entitled *Implementing and Using Emergency Manuals and Checklists to Improve Patient Safety*. The background for this conference addressed the need for anesthesia professionals and other members of the perioperative care team to move towards the acceptance of cognitive aids (emergency manuals, checklists) and away from the traditional reliance on memory and the cultural perception of individual perfection. Cognitive aids include a variety of physical and electronic representations of knowledge "in the world" designed to assist those responsible for perioperative care in executing complex decision-making in dynamic settings. The reality is that no one can function as the lone expert recalling every procedure and drug dose from memory. Successful care of the patient in the perioperative period, particularly during critical events, has previously been considered to be the exclusive responsibility of an individual's knowledge and skill. This is now being recognized as not optimal because human memory is limited and fallible, especially under stress. A recognized principle of human factors research is the use of both knowledge "in the head" (memory) and "knowledge in the world" (presented externally) combined with inter-professional teamwork. The combination of these may allow the best opportunity for optimal outcome, particularly in crisis situations.

The goals of this conference focused on the practical aspects of systematically implementing Emergency Manuals/Cognitive Aids and Checklists in the perioperative setting. With Dr. Robert Stoelting, APSF President, and Dr. David Gaba serving as conference co-moderators, Dr. Stoelting opened the conference, welcoming the over 100 participants representing diverse stakeholders including anesthesiologists, CRNAs, anesthesia associates, surgeons, OR nurses and technicians, insurance providers and several healthcare companies with anesthesia interests.

The program began with a series of informational podium presentations, followed by panel discussions and culminating in small group breakout sessions, which led to a number of recommendations.

Dr. Gaba, who provided background information addressing why crisis management cognitive aids are needed in anesthesia and perioperative care, delivered the first presentation. Some reasons included that "even smart people need help in dynamic settings" and that oftentimes factors such as subconscious complacency and premature closure may play roles in limiting optimal performance when dealing with diagnosis, planning and treatment. Dr. Gaba also provided perspective obtained from Dr. Gawande's Checklist Manifesto, simulation-based studies of manual use and the role of the reader, and the Emergency Manual Implementation Collaborative (EMIC). Following



Speakers from the first panel of the workshop, seated left to right, include Matti E. Lehtonen (GE Healthcare); Laura E. Schleelein, MD (Assistant Professor of Clinical Anesthesiology, Children's Hospital of Philadelphia, Perelman School of Medicine, University of Pennsylvania); Steven K. Howard, MD (Professor of Anesthesiology, Perioperative and Pain Medicine, Stanford University School of Medicine, and Chair, APSF Committee on Scientific Evaluation); and David L. Hepner, MD, MPH (Associate Professor of Anesthesia, and Associate Director of the Weiner Center for Preoperative Evaluation, Brigham and Women's Hospital, Harvard Medical School).

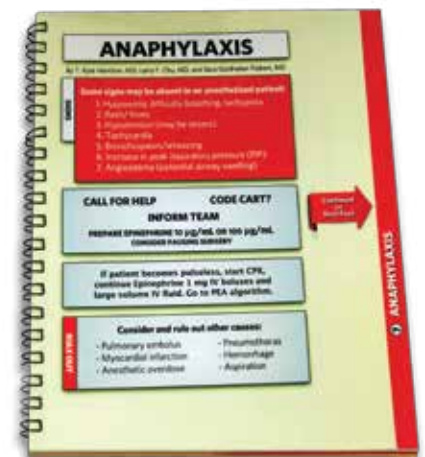
Dr. Gaba's presentation audience response data demonstrated that 82% of participants felt that every site of perioperative care should have one or more emergency manuals (EMs) readily accessible.

## Historical Background Provided

David Hepner, MD, MPH, from the Brigham and Women's Hospital in Boston, presented a review of relevant literature. He noted a 1924 historical report of such a manual by Babcock. Yet, it was many years until the concept gained serious interest in hospitals. Runciman, in 2005, introduced the idea of a crisis management algorithm based on studies of anesthesia critical events. A Stanford team led by Gaba and colleagues in 2006, reported on the use of cognitive aids on laminated cards. Those who used cognitive aids during simulated emergencies were more effective in performing critical steps compared with those who did not use such aids. Dr. Hepner provided a number of examples of studies demonstrating the value of cognitive aids, including a 2012 study by Dr. Joseph Neal demonstrating improved trainee performance during a simulated episode of local anesthetic toxicity using the ASRA checklist. Dr. Hepner also discussed how Pronovost reported on the use of checklists to reduce central line infections in the ICU setting. In addition, Zieacz et al., published their study of the use in simulation of a surgical crisis checklist, which garnered national attention.

## Hard Copy Manuals Tend to Disappear

Dr. Steven Howard, from Stanford and a co-author of the 1994 book that holds what may be the first extensive compilations of emergency procedures in anesthesia, described the advantages of using hardcopy versions of an EM. Hard copies are familiar to all clinicians, relatively easy to



create, don't require special revisions dependent on a specific platform or operating system (vs. electronic systems), and can be easily modified by adding or replacing pages. In addition hard copy can withstand power failures and Wi-Fi outages. However, he noted that there are problems intrinsic to the hard-copy model, including the need to identify an obvious place to put them where they are accessible, yet not in the way. Most challenging is that hard copies can and do easily disappear from the OR. The concept of hard copy vs. electronic was studied in simulation. Interestingly, one third of people didn't use the cognitive aid despite good instruction in its use. The hard copy seemed to be favored somewhat over the electronic version. Dr. Howard also shared his perspective that other issues are much more important than the format of the tool. These important issues include "training with the tool," cultural acceptance, practitioner acceptance, and determining how best to

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# Implementation of Emergency Manuals Presents Challenges and Risks

## “Manual Workshop,” From Preceding Page

use while recognizing potential pitfalls. Audience participation results revealed that 84% of participants felt that hard copy manuals had several advantages over electronic versions. In addition, 92% of participants believed that more studies are necessary to determine how to best utilize emergency manuals.

### Pros and Cons of Electronic EM Explored

Laurie Schleelein, MD, from the Children’s Hospital of Philadelphia, described how electronic apps could be used on personal devices for accessing an emergency manual. Advantages of electronic versions include the ability to interact with the user, for which some improvement in performance during resuscitations has been reported. The interaction can include a form of checklist that branches depending on what is done or observed. An electronic version also allows the input of patient specific information, such as entering the patient’s weight, to allow a weight-based dose. It can include a clock to enable decision-making based on elapsed time and warn when critical times are passed. An app can be used to record what has been done, which can be used for debriefing and to facilitate learning from prior events.

Emergency manual apps can be updated automatically via a server. Mobile phones and tablets are now widely used, so downloading to a very large population of users is possible. That is

already happening based on the world map of downloads of the application demonstrated by Dr. Schleelein. Electronic platforms have disadvantages as well. Technology failures are possible, it can be difficult to navigate, easy to accidentally jump to the wrong place and struggle to get back, and the display size can be limited. Electronic apps are expensive to make and need to be operating system compatible. It can be cumbersome to hold a device, which might be overcome with a reader. Research about electronic vs. hard-copy aids is conflicting, so it’s currently unclear which is the most desired approach. Audience participation results showed that 41% of participants agreed and 40% disagreed that the advantages of electronic apps far outweigh the disadvantages, while 74% of participants felt that there is a risk cognitive aids will distract the team from the emergency situation.

Matti Lehtonen of GE Healthcare subsequently discussed how emergency manuals could be embedded in clinical equipment. This has the advantage of enabling patient-specific data being accessible as part of the EM algorithm. He thinks it may be possible to build some intelligence into technology that can actually give early warning of an impending crisis to avoid it. His engineering team has many pilots; they study what’s been learned and what’s being done in aviation. Embedded, paperless versions of checklists are being integrated into new aircraft. This potential technology raises several questions. If the checklist is integrated, where should it be displayed? Is a

central display for everyone to see or a personal device preferred? These questions remain unanswered. Preliminary work suggests many advantages to an embedded EM, e.g., the interface will be familiar, and real-time patient data can be accessed. But such systems could limit individual adjustments to EMs if they are standardized by a manufacturer. The audience strongly agreed that a central visible display (83%), context-sensitive information (85%), and predictive algorithms (85%) would be beneficial in crisis management situations. In addition, 86% of the audience believed that combining electronic patient information with caregiver input would allow more appropriate and efficient checklists. 62% of the audience felt that the primary barrier to utilizing EMs and checklists is cultural, while only 9% believed barriers to be technological. 76% of the audience thought that a trained reader of the manual should be designated during the time-out.

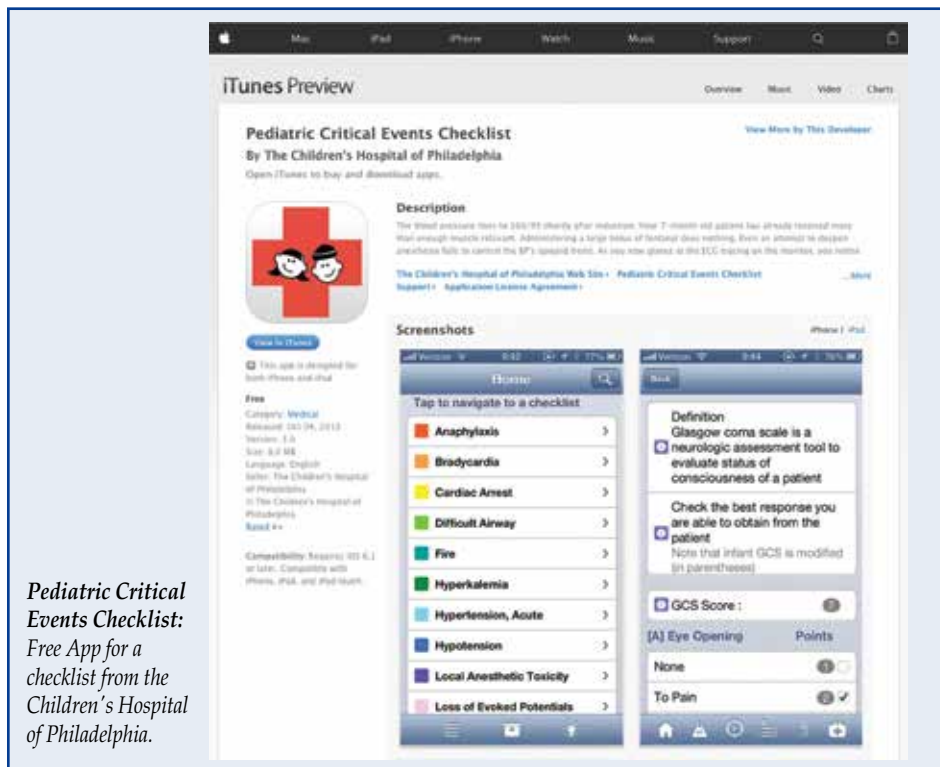
### EM Use Can Have Pitfalls

Following a short break, APSF Executive Committee member Maria van Pelt, PhD, CRNA, moderated the second session, which began with Dan Raemer, PhD, from Massachusetts General Hospital (MGH) who spoke about the pitfalls and risks associated with the use of emergency manuals. He explained that he had been a proponent of EMs for many years; however, he has shifted his thinking, having seen many real and simulated anesthesia crises and instances where the EMs have not been as helpful as hoped and perhaps harmful. He acknowledged that he did not have data to support his concerns, rather anecdotes from his observations.

Dr. Raemer illustrated pitfalls with examples he has seen. In one case of septic shock, the team perseverated on a diagnosis of malignant hyperthermia (MH). This occurred after someone suggested MH as a possibility and turned to that page in the manual. This was an example of a fixation by being on the wrong page. In another case of a mixed diagnosis with possible components of anaphylaxis and/or transfusion reaction, the team went back and forth between pages and to other pages without getting to a correct course of treatment. In yet another case, the correct diagnosis was septic shock, for which there is no page in the manual. This team became distracted and did not provide appropriate treatment.

A relevant audience response question revealed that 99% of participants believed that the introduction of EMs, like any new technique or technology in medicine, presents unanticipated risks and potential complications.

Amanda Burden, MD, of Cooper Medical School of Rowan University, made the next presentation. Dr. Burden described ways to mitigate



**Pediatric Critical Events Checklist:**  
Free App for a checklist from the Children’s Hospital of Philadelphia.

See “Manual Workshop,” Next Page



## Simulation Can be Vehicle to Implement Emergency Manuals

### “Manual Workshop,” From Preceding Page

the risks of using checklists and the role of a reader during crisis management. She reviewed the history of checklists in aviation, beginning around WWII. Despite the evidence of the effectiveness of checklists, pilots were resistant to them because of their culture of independence and reliance on their skills. She went on to review how stress and expansion of knowledge impact the ability of physicians to do the right things during critical situations. The kinds of stresses and challenges in aviation and perioperative medicine are similar and the resistance to using checklists was the same during the introduction in aviation, as they appear to be now in health care. In aviation, the solution was to do research and training to both optimize their use and teach people to use them effectively. She presented a number of pitfalls and possible solutions including the development of better checklists, the use of a reader, use of crisis resource management (CRM) skills, team training and a supportive culture.

The audience response indicated that only 19% of participants believed that limitations of checklists must be overcome before their use should be widely adopted. Similarly, 92% of respondents disagreed with the position that if teams and individuals practice CRM, checklists are not necessary.

### Consensus Building is Not Easy

Dr. William Berry, one of the early pioneers in introducing the concept of checklists into perioperative care, addressed the question if a standardized EM should be developed. He described how he and his colleagues got involved with the topic of checklists based on an adverse surgical event experienced by a surgical colleague. He took the opportunity to describe the efforts of EMIC. He acknowledged that, currently, there are many different tools from different groups; there is no consensus on what items should be included in an EM, on the format, or on needed training. The process of implementing a checklist locally is a great benefit for getting people to consider how to prepare for, and how to manage emergencies. He gave an example of how one hospital developed their own new checklist for bronchospasm, which was not in some other manuals. Much more innovation and creativity are needed to optimize the use of EMs. It would be very challenging to create a standard manual, to reach consensus on what belongs in such a manual, the steps for each situation, and then be able to maintain the product. He does not feel the time has come to do that, nor believe that it may ever come to fruition. 87% of the audience agreed that there are a number of questions that need to be answered prior to creating a single standardized manual.

Dr. Paul Preston from the Permanente Medical Group took a somewhat different position from

Dr. Berry. He asked what would it take to standardize? His rationale was, in part, that there is a cost to each hospital creating its own manual. It would be easier to implement if less time was needed to select an EM and thus more time could be available for training. Having standardization would enable EM integration into an electronic record, current vendors of which do not allow much customization. He also sees a great advantage for those who travel between institutions, although of course some local information, such as phone numbers, would be different. In audience response, 86% agreed that it would be helpful to have a standardized set of EMs, which could be tailored and used for regular emergency drills. Only 35% of the audience felt it would be important for each institution to design its own set of EMs to reflect their clinical situation.

Dr. Sara Goldhaber-Feibert from Stanford shared her expertise and extensive experience in implementing and studying EMs. She elucidated some of the best practices for implementation. Champions, leadership buy-in and local teams are keys to success. Local adaptation and customization has been shown to be vital, as well as learning from what others have done. She stressed that it is important to avoid aiming for perfection. It is important to synergize the EM implementation with other patient safety goals and context. Having the EM can be an incentive to beginning full OR teamwork training. Getting input and buy-in from multidisciplinary leaders is another piece of the successful implementation puzzle. Success is also aided by a diverse training plan that includes getting buy-in to do it, what goes into it and then how to use the manual and implement it. Encouraging self-review and educational use is also very effective. She also stressed the importance of publicizing success stories and bright spots in anthropological terms. It was made clear that there is much to be learned in the growing field of implementation science. The steps noted above are generally used in other fields so there is evidence that they have some science behind them. There are also many reports in health care regarding successful implementations of patient safety and quality interventions. 96% of the audience agreed that there are many steps between an individual downloading a useful EM and an institution effectively implementing it clinically. 66% agreed that literature on EM implementation and clinical use is accurately described as “nascent.” Interestingly, only 31% of respondents agreed that the greatest barrier to implementing EMs and checklists seems to be the belief that their use denotes some sort of failure on the part of the anesthesia professional.

Dr. Bill Paulsen moderated the final series of presentations, which began with Dr. Alex Hannenberg describing ideas for how to make a



*Dr. Hannenberg shares his perspective with workshop participants.*

“team sport” of the use of EMs. Dr. Hannenberg is a member of the board of directors of the Council on Surgical and Perioperative Safety, which is a multidisciplinary coalition of 7 associations representing professionals involved in surgical care. He sees simulation as being a vehicle to introduce emergency manuals to all the players on the team. In his experience, the process of introducing EMs locally can help identify system weaknesses. Each discipline sees weaknesses that are invisible to the others. He emphasized the importance of involving all of the specialties in the process of creating, editing, implementing, and training for EM introduction and use. In this way, a “team of champions” is created, all of who own the product. Dr. Hannenberg advised that we create a “we use checklists” mentality, the idea being that good clinicians use cognitive aids. He wants the nurse to be able to say, “Dr. Hannenberg, do you want me to bring the code cart in here, do you want me to get the Emergency Manual?” He told the story of how one of his senior surgical colleagues, when asked how he’d feel about being asked to read the manual, replied, “You have no idea how it feels when your patient is dying on the table and there’s nothing you’re involved in doing about it. I’d happily read out the checklist.” Dr. Hannenberg quoted a 2012 Study from the *Annals of Surgery* demonstrating that the success of implementation of a safety checklist was improved when a multidisciplinary team led the process, rather than when a single staff member led it. Audience response revealed that 79% agreed that anesthesia professionals should lead the development of the content

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# Breakout Sessions Lead to Constructive Ideas

## “Manual Workshop,” From Preceding Page

for cognitive aids for OR emergency management; however, 96% disagreed that only anesthesia professionals should call for the use of an EM.

Matt Weinger, MD, Vanderbilt University professor and Director of the Center For Research and Innovation in Systems Safety, spoke to the question of what research is needed to evaluate the safety and effectiveness of EM use. He presented preliminary results from a large study of board-certified anesthesiologists who were participating in MOCA simulation courses at 10 different U.S. sites. In a highly organized, controlled study, experts rated 364 CRM scenarios. Only 74% of all critical items were actually performed. For some critical actions, as few as 7% of anesthesiologists performed a task that experts had determined was critical in that situation. Only 54% actually used the MH protocol during the simulated MH event. For overall performance, the average score was in the middle of the scale, or just average performance. These results were supportive of the need for significant improvement and the potential benefit of training with, and implementation of, emergency manuals and CRM.

## Not Feasible to Conduct Ideal Study

Dr. Weinger generated numerous questions that that needed to be addressed with further research. He focused on the design of an ideal outcome study, introducing cognitive aids into practice and measuring patient outcome. With an estimated event rate and effect size, he estimated it would require 1.6 million patients and over three years to conduct such a study. His conclusion is that it just is not feasible to conduct such a study for EMs. Conversely, such a study could be done for the WHO checklist introduction, since it is used in all cases, not just rare emergencies. Dr. Weinger recommends that large prospective studies have to focus on teamwork interventions and that cognitive aids need to be used, but not studied as the cause of the outcomes. There was strong agreement with Dr. Weinger’s conclusion that studying outcome improvement resulting from EM introduction is not likely useful.

Dr. John Eichhorn’s presentation followed, in which he suggested actions APSF could take to further implement using EMs to improve patient safety. Dr. Eichhorn, as founding editor of this newsletter, recommended that the APSF should work to dispel the message that the use of cognitive aids is a weakness, but rather is a strength. He also noted that the APSF had been highly influential in the success of widespread use of simulation. In discussing how the APSF could effect change, he suggested that efforts should primarily be via education and advocacy. Dr. Eichhorn reminded the audience that the APSF

does not set standards; rather this organization can spread the word via the *APSF Newsletter*, which is the most widely disseminated anesthesia publication in the world. He also suggested videos and visibility in the APSF booths at the ASA and AANA annual meetings. Further, the APSF could lobby its constituents. He noted that APSF recommendations about audible alarms were adopted by the ASA. The question of supporting a new standard of care would necessitate the ASA as the best pathway. It’s not likely that new standards will be created, but guidelines are possible.

A large majority of the audience felt that the APSF should take a leading role in promoting EMs; however, the audience was split on the question of whether EMs should ever become a standard of care with only 67% voicing that opinion. Many of these issues were discussed and revisited during the final panel discussion.

Finally, the small group breakout sessions resulted in very creative and constructive ideas and recommendations. Some examples follow:

- Create an APSF education/advocacy package, including a video and a PowerPoint about implementation and use of EMs along with a “toolkit” for interested individuals/champions.
- Develop, implement, and maintain a strong social media presence for proper use of EMs.
- Recommend that a part of the pre-surgical timeout should consist of the verification of the presence of an emergency manual, to remind

the team that anyone can suggest its use, and that a reader be designated as appropriate to the situation.

- Invest in research and career development that improves implementation science related to the use of checklists.
- Advocate for the processes and education it takes to successfully engage local environment teams to implement the use of unified checklists.
- Use research to determine how one could design an EM that is so simple that no training is required.
- Use research to examine the effect of a manual or checklist focused on a single more common event (intraoperative hypotension) on composite patient outcomes.
- Determine if the APSF should play a leading role in developing and testing a new national crisis event management curriculum intended for all perioperative learners.

The conference demonstrated that we are on the right track, but much work needs to be done.

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**Anesthesia Patient Safety Foundation**  
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**DEADLINE TO SUBMIT THE LETTER OF INTENT (LOI)  
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# FDA Issues Drug Safety Communication About Epidural Corticosteroid Injections

by Joan Christie, MD

In April 2014, the U.S. Food and Drug Administration (FDA) issued a drug safety communication entitled "FDA requires label changes to warn of rare but serious neurologic problems after epidural corticosteroid injections (ESI) for pain."<sup>1</sup> In May 2015 an expert panel convened by the FDA published their recommendations to prevent neurologic complications after ESI.<sup>2</sup> The purpose of this article is to review the FDA warning and to summarize the expert panel recommendations.\*

## Timeline:

**2009:** The FDA begins evaluating serious neurologic events (SNE) associated with ESI. Cases in the medical literature and FDA adverse event reporting system (FAERS) included stroke, paralysis, spinal cord infarction, seizures, nerve injury, brain edema, loss of vision, and death.

**2011:** The FDA Safe Use Initiative facilitated the formation of an external advisory committee. The working group was to develop recommendations for minimizing risk of SNE with ESI.

**2014 May:** FDA Drug issues a Safety Communication requiring label change to warn of SNE after ESI.

**2014 Nov.:** FDA confers with the FDA's Anesthetic and Analgesic Drug Products Advisory Committee to discuss the necessity of further regulatory actions. Concerns were raised by the FDA advisory committee regarding particulate steroids (methylprednisolone, triamcinolone, betamethasone) in suspension having a higher risk for SNEs than non-particulate steroids (dexamethasone) in solution, but there was not clear agreement on the best course of action from the advisory committee. The FDA did not modify the safety communication warning.

**2015 May:** The FDA Safe Use Initiative multidisciplinary and national organization working group publishes their consensus report and recommendations in a paper entitled "Safeguards to Prevent Neurologic Complications after Epidural Steroid Injections".<sup>2</sup> This report addresses numerous potential safety issues including sedation level, technique, use of fluoroscopy or other imaging guidance, injection of contrast prior to injection of steroid and avoidance of particulate steroids for injection, particularly in the cervical region.

**2015 Oct:** FDA publishes "Serious Neurologic Events after Epidural Glucocorticoid Injection—The FDA's Risk Assessment,"<sup>3</sup> explaining their rationale for not differentiating the warning for particulate versus non-particulate steroids.

\*The FDA warning and consensus panel recommendations did not include cases of contamination of compounded products reported in 2012.

## Challenges:

Both the FDA and the external consensus panel were confronted with numerous confounding variables and a striking lack of scientific data to illuminate the myriad issues surrounding SNE after ESI. The FDA recognized potential causes of SNE including technique-related issues such as intrathecal injection, epidural hematoma, direct nerve or spinal cord injury, and embolic infarction. Patient- and procedure-related contributors included selection criteria, anatomy, spinal level, approach (interlaminar or transforaminal), the degree of patient sedation, and use of fluoroscopy. A central question was the role of glucocorticoid preparations themselves including particulate steroid suspensions and non-particulate solutions. The vast majority of SNEs with infarction were associated with particulate steroid suspensions, which was supported by two animal studies. The FDA database with 1.3 million Medicare ESIs found that 80% utilized suspensions thereby making the relative frequency of this rare event with the different steroid preparations unclear. The use of solutions increased from 5% to 15% in younger patients and 4% to 9% in Medicare recipients between 2009 and 2013. However, there were SNEs with both suspensions and solutions during that review period.

The Safe Use Initiative consensus group was charged with reviewing the existing scientific evidence and assembling clinical considerations aimed at reducing the risk of severe neurologic complications after ESI. The members of the Safe Use Initiative committee consisted of experts from many disciplines and stakeholder national medical organizations, and the consensus group generated their specific clinical practice parameters without any decision-making input from the FDA.

The group concluded that adherence to specific practice recommendations should lead to a reduction in the incidence of neurologic injuries after ESI.

## The FDA Warning:<sup>1</sup>

*Facts, information for patients, information for health care professionals*

### Facts:

- Injectable corticosteroids include methylprednisolone, hydrocortisone, triamcinolone, betamethasone, and dexamethasone.
- Corticosteroids are not approved by the FDA for injection into the epidural space.

### Information for Patients:

- Rare but serious problems have occurred after injection of corticosteroids into the epidural space of the spine to treat neck and back pain

and radiating pain in the arms and legs. These serious problems include loss of vision, stroke, paralysis, and death.

- The effectiveness and safety of injection of corticosteroids into the epidural space of the spine have not been established, and the FDA has not approved corticosteroids for this use.
- Discuss the risks and benefits of ESI with your health care professional along with the benefits and risks associated with other possible treatments.
- Seek emergency medical attention if you experience any unusual symptoms after receiving ESI, such as loss of vision or vision changes, tingling in your arms or legs, weakness or numbness of your face, arm, or leg on one or both sides of the body, dizziness, severe headache, or seizure.
- Report any side effects following ESI to the FDA MedWatch program using the information in the "contact FDA" box: Visit [www.FDA.gov/medwatch](http://www.FDA.gov/medwatch) or call 1-800-FDA-1088.

## Information for Health Care Professionals:

- Rare but serious neurologic events have been reported with ESI including spinal cord infarction, paraplegia, quadriplegia, cortical blindness, stroke, and death.
- These serious events have been reported with and without the use of fluoroscopy.
- The effectiveness and safety of epidural corticosteroid administration have not been established, and the FDA has not approved corticosteroids for this use.
- Discuss with patients the risks and benefits of ESI and other possible treatments.
- Counsel patients to seek emergency medical attention immediately if they experience symptoms after receiving ESI such as loss of vision or vision changes, tingling in arms or legs, sudden weakness or numbness of face, arm, or leg on one or both sides of the body, dizziness, severe headache, or seizure.
- Report adverse effects following ESI to the FDA MedWatch program using the information in the "contact FDA" box.

## Statements and Clinical Considerations of the Safe Use Working Group<sup>2</sup>

1. Cervical interlaminar ESIs are associated with a rare risk of catastrophic neurologic injury.
2. Transforaminal ESI using particulate steroid is associated with a rare risk of catastrophic neurovascular complications.

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# FDA and Advisory Committee Address Risks of Epidural Steroid Injections

## “Corticosteroid” From Preceding Page

3. All cervical interlaminar ESIs should be performed using image guidance with appropriate AP, lateral, or contralateral oblique views and a test dose of contrast medium.
4. Cervical transforaminal ESI should be performed using contrast medium under real-time fluoroscopy or digital subtraction imaging, using an AP view before injecting any substance that may be hazardous to the patient.
5. Cervical interlaminar ESI are recommended to be performed at C7-T1, but preferably not higher than C6-C7 level.
6. No cervical interlaminar ESI should be undertaken at any segmental level without reviewing, prior to the procedure, prior imaging studies showing adequate epidural space for needle placement at the target level.
7. Particulate steroids should not be used in therapeutic cervical transforaminal injections.
8. All lumbar interlaminar ESIs should be performed using image guidance with appropriate AP, lateral, or contralateral oblique views and a test dose of contrast medium.
9. Lumbar transforaminal ESI should be performed using contrast medium under real-time fluoroscopy or digital subtraction imaging using an AP view before injecting any substance that may be hazardous to the patient.
10. A nonparticulate steroid (e.g., dexamethasone) should be used for the initial injection in lumbar transforaminal epidural injections.
11. There are situations where particulate steroids could be used in the performance of lumbar transforaminal epidural steroid injection.
12. Extension tubing is recommended for transforaminal ESIs.
13. A face mask and gloves must be worn during the procedure.
14. The ultimate choice of what (interlaminar vs. transforaminal ESI) to use should be made by the treating physician by balancing potential risks vs. benefits with each technique for each given patient.
15. Cervical and lumbar interlaminar ESIs can be performed without contrast in patients with documented contraindication to the use of contrast (e.g., significant history of contrast allergy or anaphylactic reaction).
16. Transforaminal ESIs can be performed without contrast in patients with documented contraindication to use, but in these circumstances particulate steroids are contraindicated and only preservative-free, particulate-free steroids should be used.
17. Moderate to heavy sedation is not recommended for ESI but if light sedation is used, the patient should remain able to communicate pain or other adverse sensations or events.

## Discussion

The FDA drug safety communication is important to help clinicians and patients understand the FDA perspective and database experience with epidural steroid injections. Between 1997 and 2014, a total of 90 serious and sometimes fatal neurologic events were reported to the FDA Adverse Reporting System (FAERS) excluding contaminated compounded products. Statistics for Medicare and IMS Health suggested almost two million ESIs were performed from 2009 to 2013. Thus, clearly these catastrophic adverse events are rare. Both the advisory committee and FDA concurred that these events do occur. The FDA acknowledges ambiguity surrounding the effectiveness of ESI in their information for patients and information for health care professional sections of the warning.<sup>4,5</sup> In November 2014, after the warning had already been released, the FDA asked their advisory committee on Anesthetic and Analgesic Drug Products whether a contraindication was warranted to restrict the injection of glucocorticosteroids into the epidural space.<sup>3</sup> The FDA considered the advisory committee feedback and decided not to modify the warning which states that the “effectiveness and safety of injection of corticosteroids into the epidural space of the spine have not been established, and the FDA has not approved corticosteroids for this use.” The FDA also did not find that the available data warranted either a contraindication or warning focused on cervical transforaminal injection of particulate steroid suspension preparations. There was a concern that data did not support labeling non-particulate steroid solutions safer than particulate steroid suspensions and that such labeling might encourage practitioners to use solutions even though their relative safety and effectiveness remain an open question.<sup>3</sup> The Safe Use expert panel overwhelmingly felt that particulate steroids were the culprit in transforaminal approaches.<sup>6</sup> The FDA safety warning urges clinicians to discuss the risks and benefits of ESIs and alternative therapy with patients presumably as a part of the pre-procedure informed consent process.

The multispecialty external working group from the FDA Safe Use Initiative contended with numerous scientific obstacles and clinical uncertainties inherent in the data surrounding ESI. There were 13 organizations voting to agree, disagree, or abstain with the clinical recommendations. The largest degree of disagreement was 11 in agreement and 2 disagreeing or unable to reach consensus (85% agree). The document is clinically oriented and the recommendations are quite specific including some that may not be ubiquitously followed by all at present. There was a focus on the particulate steroid suspensions as being a major harmful factor in spinal cord infarctions, and the group recommended to restrict particulate steroid suspension use, particularly in the cervical region.<sup>2</sup> Recommendations include the use of particulate versus non-

particulate steroid formulations, imaging prior to and during the procedure, radiocontrast test doses, degree of sedation, approach, etc.

The Safe Use Initiative working group consensus recommendations were published in an anesthesiology journal although ESIs are also performed by specialists from other disciplines. Areas not addressed in the recommendations include the use of a local anesthetic test dose, patient selection criteria, the anticoagulated patient, chlorhexidine in alcohol for skin preparation, and the use of specific needle types.

The two documents begin from the position that significant neurologic injury may rarely occur after ESI. They diverge as a function of different areas of focus. The FDA’s job was to warn patients and doctors of these rare events. The FDA did not endorse the use of ESIs for chronic pain, a specific approach (transforaminal versus interlaminar), a specific formulation (particulate steroid suspension or non-particulate steroid solution), or the use of fluoroscopy or other type of imaging. The Safe Use Initiative working group complimented the FDA warning by delineating clinically substantive relevant recommendations which could reduce SNE after ESI. Although research is needed to clarify issues, the low incidence of these events may preclude detection in even very large studies. The SafeUse Initiative authors conclude “Our hope is that these clinical considerations will help every practitioner who performs epidural injections of steroids to become familiar with the risk of neurologic complications and to adopt the best safeguards to avoid complications and provide the safest care for their patients”.<sup>3</sup>

*Dr. Christie reports no financial disclosures related to this article or topic.*

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# Residual Neuromuscular Blockade (NMB), Reversal, and Perioperative Outcomes

by Karl E. Hammermeister, MD; Michael Bronsert, PhD; Joshua S. Richman, MD, PhD; and William G. Henderson, PhD

## Historical

The earliest description of curare, a naturally occurring predecessor of the neuromuscular blocking agents commonly used today in anesthesia, has been attributed to Sir Walter Raleigh in his 1596 book, *The Discoverie of the Large, Rich, and Beautiful Empire of Guiana*, in which he describes, "the most strong poyson on their arrows" used by an indigenous tribe of Guiana.<sup>1</sup> However, Ibanez cites numerous descriptions by Spanish explorers of lethally tipped arrows used by natives of northern South America in the century preceding the publication of Raleigh's book.<sup>2</sup>

Although Ibanez also describes therapeutic uses of what may have been curare, it was not until 1932 that West described experiments in patients with rigidity disorders at the Hospital for Epilepsy and Paralysis in Maida Vale, London; he concluded, (there was) "a definite, measurable reduction in the muscular rigidity resulting from diseases of the pyramidal and extrapyramidal motor system...[at] doses which produce no detectable signs of weakness."<sup>3</sup> An early therapeutic use in humans to prevent fractures occurring with convulsive therapy for depression was described by Bennett in 1940.<sup>4</sup> The earliest description of the use of curare in general anesthesia to achieve muscle relaxation during surgery we have found was at the Homeopathic Hospital of Montreal by Griffith, published in 1942.<sup>5</sup> In 1954, Beecher and Todd, both at Harvard and the Massachusetts General Hospital, reported their massive study of 599,548 anesthetics in 10 university hospitals in the U.S. between 1948 and 1952.<sup>6</sup> They undertook this study because of their, "...belief that anesthesia has an unnecessarily high death rate." All deaths were classified by a surgeon and anesthesiologist at each hospital; however, precise criteria for cause of death were not provided. A muscle relaxant was used in 2.8% (16,560), which

was tubocurarine in 55%, decamethonium bromide in 37%, and succinylcholine in 4% of cases. They found 6 times as many anesthetic deaths were associated with "curare," compared to patients managed without. Recognizing the need for risk-adjustment, 13,204 patients sampled in 1952 were classified as "good or poor physical status" (this was not the ASA classification, which had been published in 1941,<sup>7</sup> but rather a seven-point scale devised by the authors, which was effectively similar to the ASA classification). The distribution of this scale was similar between patients receiving a NMB and those not.

## Contemporary Studies

Residual NMB postoperatively has been known for more than 35 years,<sup>8</sup> and occurs commonly despite reversal with neostigmine with a reported incidence of 4 to 50%.<sup>9,10</sup> Studies prior to 2005, suggested residual neuromuscular block should be defined by a train-of-four ratio (TOFR) of <0.7. However, subsequent studies have discovered that residual neuromuscular blockade can occur at TOFR  $\geq$ 0.9, as per the review by Murphy and Brull in 2010.<sup>11</sup> These authors concluded that, "Residual neuromuscular block is an important patient safety issue and that neuromuscular management affects postoperative outcome."<sup>11</sup>

## Reversal of NMB

Acetylcholinesterase inhibitors, such as neostigmine, are commonly used to reverse NMB at the conclusion of surgery; however, they may have unwanted side-effects such as tachycardia, nausea, confusion, constipation, and dry mouth.<sup>12</sup> More importantly, when used without appropriate nerve stimulator monitoring and dosing, they may actually increase NMB by creating very high concentrations of acetylcholine at the neuromuscular junction, which can have an antagonistic effect.<sup>13</sup>

There are surprisingly few publications of adequate sample size examining the effect of NMB with and without a reversing agent on substantive outcomes important to the patient. Two of the largest studies examining this issue had significant limitations with respect to propensity matching for patient co-morbidities and/or for administration of neostigmine. These issues limit the clarity of the associations between poor outcomes and the use of NMB agents, reversal, inadequate monitoring, and inadequate reversal. These relationships are difficult to study in a retrospective manner with incomplete datasets and variable practice patterns and are better examined in large prospective studies.<sup>14,15</sup> While some providers may believe that near complete spontaneous recovery does occur by the end of a surgical procedure without the use of NMB reversal agents, a variety of studies contradict this notion. One most notable large clinical trial by Debaene and colleagues in more than 500 patients suggested that 45% of patients examined after a single dose of an intermediate acting NMB (without a NM reversal agent) had a TOFR <0.9 in PACU.<sup>16</sup> In addition, even 2 hours after administration of a single intermediate acting NMB, the TOFR was <0.7 in 10% of patients and <0.9 in 37% of the patients studied. Therefore, cautious titration of NMB reversal by using NM monitoring may reduce the risk of residual neuromuscular blockade.

## Current Practice

Naguib and colleagues conducted an internet survey of active members of the Anesthesia Patient Safety Foundation and the European Society of Anaesthesiologists in 2008; 2,636 completed surveys were received.<sup>17</sup> We did not find a more recent survey of U.S. anesthesiologists. The majority of both U.S. and European respondents estimated the incidence of clinically significant postoperative residual neuromuscular weakness to be <1%. Routine pharmacologic reversal was reported by 18% of respondents in Europe and 34% in the U.S.

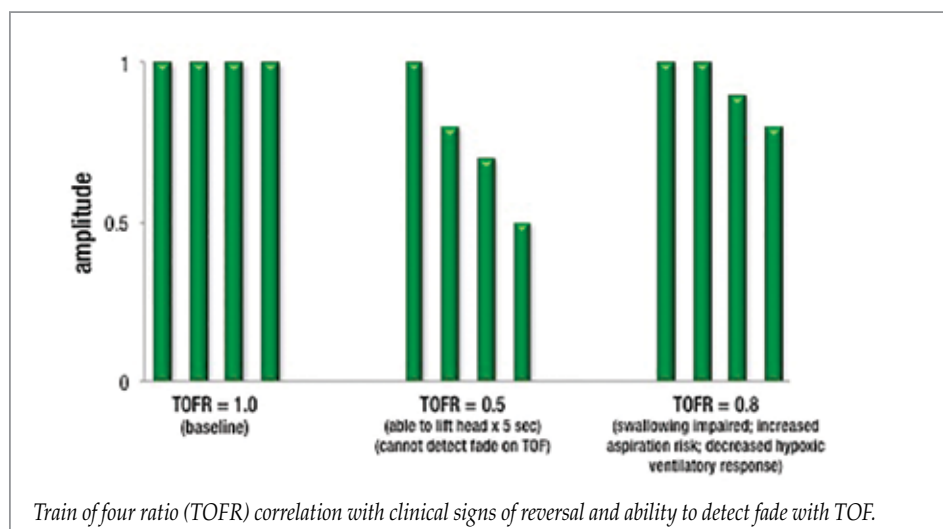
## Conclusions

There is a consensus in the recent literature that residual neuromuscular blockade is common and is associated with an increased risk of adverse outcomes, particularly respiratory. It is also clear that the use of NMB monitoring and appropriate reversal with neostigmine is highly variable among anesthesia providers and is thought to be primarily responsible for the high incidence of residual NMB in the recovery room.

*The authors report no financial conflicts of interest related to this article and topic.*

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# Reversal of NMB Highly Variable Among Anesthesia Providers

## “Residual NMB,” From Preceding Page

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## Letter to the Editor:

# The Structure and Process of PACU Handoff—How to Implement a Multidisciplinary PACU Handoff Checklist

### To the Editor:

We would like to thank Tan and colleagues for their response to our study, “Improving Post Anesthesia Care Unit (PACU) Handoff by Implementing a Succinct Checklist.”<sup>1,2</sup> They address many of the important challenges in standardization of healthcare processes and we are happy to continue the discussion. This topic is of growing concern among anesthesia providers as evidenced by several studies published in the past year that have examined the benefit of a standardized handoff.<sup>3,4</sup> Tan and colleagues bring up two important topics that we would like to emphasize in this letter: the *structure* and *process* of PACU handoff.

At their institution, Tan and colleagues found that: “following a rigid checklist may elicit resistance among more experienced clinicians because it interferes with the ‘flow’ of their practiced, yet not necessarily complete, handoff reports.” A less-structured handoff/checklist may appeal to experienced clinicians; however, at Medstar Georgetown University Hospital (MGUH), the majority of PACU handoffs are completed by trainees (residents and student nurse anesthetists). Patient handoff is a clinical skill that we expect all of our trainees to master. Reinforcing this structured format of PACU handoff establishes a culture of patient safety that will continue as our trainees graduate into practice. Our experienced clinicians may adopt a similar handoff structure described by Tan and colleagues with a verbal “story” preceding a “Read and Verify” review of the checklist, although a structured reading of the

checklist is encouraged. Even the most experienced clinicians are at times distracted or leave out important information.

We agree with another point emphasized by Tan and colleagues—it is not sufficient to address the content of PACU handoffs, we must also address the process. We are now engaged in a PACU handoff initiative that includes our surgical colleagues. This multidisciplinary PACU handoff will bring all parties to the (bedside) table to ensure complete, efficient handoff of care in the PACU. Our multidisciplinary handoff allows for a structured handoff, starting with “Patient Admission and Assessment,” where each of the three handoff teams engages in specific activities to ensure a quick, efficient admission to the PACU. This first step addresses patient safety and stability prior to focusing on face-to-face handoff.

We are encouraged that Tan and colleagues include a surgical handoff on their checklist and we wonder whether it is included in a structured handoff effort or whether the two handoffs exist independently. At MGUH, one of the keys to success in an organized multidisciplinary handoff effort is the support we have received from PACU nursing as well as both anesthesia and general surgery departments. The appointment of “local champions” has been cited as an important ingredient to success in previous successful checklist endeavors.<sup>5</sup> We feel that strong support, from both the resident leaders and department faculty, has been integral in our overall success.

We would like to thank Tan and colleagues for providing their thoughtful feedback. We welcome continued discussion as we improve the exchange of information during the crucial moments of PACU handoff.

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