

## Health Care Cybersecurity: Is There a Role for the Anesthesia Professional?

by Julian Goldman, MD, and Jeffrey Feldman, MD

Keeping patients safe during anesthesia care is a multifaceted challenge. The skills and vigilance of the anesthesia professional are necessary, but not sufficient. The ergonomics of the care environment, systems of care, communication between teams and many other factors ultimately impact patient safety. Now, it seems we need to add cybersecurity threats as another dimension to the patient safety battle.

One of the most famous health care cybersecurity breaches was the global Wannacry ransomware attack that disabled 600 organizations in the British National Health System in 2017. There were no deaths reported related to this attack, but the reduced access to health



care is well documented. The impact on patient wellness is unknown. The cost to the health system was estimated to be almost 6 million pounds.<sup>1</sup> Unfortunately, cyberattacks

continue to increase in frequency requiring hospital systems to spend significant resources to prevent any impact on patient care services. At the current time, health care institutions are predicted to experience 2-3 times the average number of attacks on other industries,<sup>2</sup> which can reach thousands of cyberattacks per month.

Attacks on health care organizations remain an international problem. One university hospital in the Czech Republic was forced by a cyberattack to delay surgery and transfer patients to other institutions for care.<sup>3</sup>

See “Cybersecurity,” Page 6

## Pharmacovigilance Applied to the Use of Sevoflurane and Desflurane: Nearly 30 years of Adverse Event Reporting

by Thomas Ebert, MD, PhD; Alex Ritchay, MD; Aaron Sandock, BA; and Shannon Dugan, BS

### SUMMARY

Sevoflurane and desflurane were introduced into the U.S. market in the early 1990s, with each having some concerns about their safety. Sevoflurane had a fresh gas flow restriction due to concerns for the formation of compound A and an associated renal tubular cell necrosis found in a rat model.<sup>1</sup> Desflurane was noted to be an

airway irritant and associated with laryngospasm, sympathetic activation, tachycardia, and hypertension.<sup>2–6</sup> We reviewed the Food and Drug Administration (FDA) adverse event reporting system to determine if these early concerns found validity after 25 years of clinical use of sevoflurane and desflurane.

### INTRODUCTION

In this report, we have explored the FDA Adverse Events Reporting System (FAERS) database for sevoflurane and desflurane seeking evidence, or lack thereof, for adverse events during clinical use of these two volatile anesthetics. The safety of modern-day volatile anesthetics is generally accepted, but concerns about their safety were debated at the time of their introduction into clinical use and thus merit further evaluation. Justifying our efforts to use FAERS database are the historical adverse events from the use of older volatile anesthetics and neuromuscular blocking drugs that were revealed after their introduc-

tion into clinical practice.<sup>7,8</sup> When new drugs are approved for broad use in the clinical settings with a diverse patient population and multiple co-morbid conditions, the time-tested process called pharmacovigilance can reveal new safety concerns.<sup>9</sup> As an example, halothane-mediated hepatitis and enflurane-induced renal concentrating defects were first identified after these anesthetic gases were placed into the clinical setting.

As background, sevoflurane was released into clinical practice in the U.S. in 1995.<sup>10</sup> The most important early safety concern with sevoflurane was the development of pentafluoroisopropenyl fluoromethyl ether (compound A), a breakdown product formed through the interaction of sevoflurane and carbon dioxide absorbents. Compound A's effects had not been thoroughly investigated in patients in FDA Phase 1–3 trials.

See “Adverse Event Reporting,” Page 8

### To Our APSF Readers:

If you are not on our mailing list, please subscribe at <https://www.apsf.org/subscribe> and the APSF will send you an email of the current issue.

## TABLE OF CONTENTS

### ARTICLES:

Health Care Cybersecurity: Is There a Role for the Anesthesia Professional?.....	Cover
Pharmacovigilance Applied to the Use of Sevoflurane and Desflurane: Nearly 30 years of Adverse Event Reporting .....	Cover
Improving Perioperative Patient Safety: A Matter of Priorities, Collaboration, and Advocacy .....	Page 3
<b>Rapid Response:</b> HEPA Filters. Do We Really Know Enough?.....	Page 11
<b>Rapid Response:</b> Breathing System Filters in the Era of COVID-19 .....	Page 12
The MHC Story: Accelerating Implementation of Best Practices Through Improved Organizational Macro-Ergonomics Updates from the Perioperative Multi-Center Handoff Collaborative (MHC) .....	Page 15
Proactive Perioperative Risk Analysis: Use of Failure Mode and Effects Analysis (FMEA) .....	Page 17
<b>Rapid Response:</b> Emergency Power and Elective Surgery .....	Page 22
Safety vs. Quality—The 2020 APSF/ASA Ellison C. Pierce, Jr., MD, Memorial Safety Lecture .....	Page 23
Enhancing a Culture of Safety Through Disclosure of Adverse Events .....	Page 25
APSF Awards 2021 Grant Recipients .....	Page 28
<b>Rapid Response:</b> What Type of Operating Room Pressure Should We Use for Patients with SARS-COV-2 Infection?.....	Page 30
<b>Rapid Response:</b> Recommendations for OR Ventilation during the SARS COV-2 Pandemic—Staying Positive.....	Page 30
Anesthesia Machine as an ICU Ventilator—A Near Miss During the COVID-19 Pandemic.....	Page 34
Perioperative Hypersensitivity: Recognition and Evaluation to Optimize Patient Safety .....	Page 36
<b>Rapid Response:</b> Unanticipated Movement of Skytron Operating Room Tables.....	Page 39
Drug-Induced MH-like Syndromes in the Perioperative Period.....	Page 41
Postoperative Anterior Neck Hematoma: Timely Intervention is Vital.....	Page 44

### LETTER TO THE EDITOR:

The Single-Provider-Operator-Anesthetist Model for Dental Deep Sedation/Anesthesia: A Major Safety Issue for Children.....	Page 33
---	---------

### APSF ANNOUNCEMENTS:

Guide for Authors .....	Page 2
APSF Newsletter Podcast: Now Available Online @ APSF.org/podcast.....	Page 5
APSF Stoelting Conference 2021: Clinician Safety: To Care is Human.....	Page 20
APSF Donor Page.....	Page 21
A Remembrance: Charles Cowles, MD, MBA, FASA .....	Page 31
Crowdfunding .....	Page 35
Legacy Members .....	Page 48
2020 Board Members and Committee Members: .....	<a href="https://www.apsf.org/about-apsf/board-committees/">https://www.apsf.org/about-apsf/board-committees/</a>

## Guide for Authors

A more detailed Guide to Authors with specific requirements for submissions can be found on line at <https://www.apsf.org/authorguide>

The APSF Newsletter is the official journal of the Anesthesia Patient Safety Foundation. It is widely distributed to a variety of anesthesia professionals, perioperative providers, key industry representatives, and risk managers. Therefore, we strongly encourage publication of those articles that emphasize and include the multidisciplinary, multi-professional approach to patient safety. It is published three times a year (February, June, and October). **Deadlines for each issue are as follows: 1) February Issue: November 15th, 2) June Issue: March 15th, 3) October Issue: July 15th.** The content of the newsletter typically focuses on anesthesia-related perioperative patient safety. Decisions regarding content and acceptance of submissions for publication are the responsibility of the editors.

1. Please include a title page which includes the submission's title, authors' full name, affiliations, conflicts of interest statement for each author, and 3–5 keywords suitable for indexing. Please include word count on the title page (not including references).
2. Please include a summary of your submissions (3–5 sentences) which can be used on the APSF website to publicize your work.
3. All submissions should be written in Microsoft Word in Times New Roman font, double-spaced, size 12.
4. Please include page numbers on the manuscript.
5. References should adhere to the American Medical Association citation style.
6. References should be included as superscript numbers within the manuscript text.
7. Please include in your title page if Endnote or another software tool for references is used in your submission.
8. Authors must submit written permission from the copyright owner to use direct quotations, tables, figures, or illustrations that have appeared elsewhere, along with complete details about the source. Any permission fees that might be required by the copyright owner are the responsibility of the authors requesting use of the borrowed material, not the APSF. Unpublished figures require permission of the author.

Types of articles include (1) Invited review articles, Pro/Con Debates and Editorials, (2) Q and As, (3) Letters to the Editor, (4) Rapid Response, and (5) Conference reports.

1. Review articles, invited Pro/Con debates, and Editorials are original manuscripts. They should focus on patient safety issues and have appropriate referencing. The articles should be limited to 2,000 words with no more than 25 references. Figures and/or tables are strongly encouraged.
2. Q&A articles are submitted by readers regarding anesthesia patient safety questions to knowledgeable experts or designated consultants to provide a response. The articles should be limited to 750 words.
3. Letters to the editor are welcome and should be limited to 500 words. Please include references when appropriate.
4. **Rapid Response** (to questions from readers), formerly known as, "Dear SIRS," which was the "Safety Information Response System," is a column that allows for expeditious communication of technology-related safety concerns raised by our readers, with input and response from manufacturers and industry representatives. Dr. Jeffrey Feldman, current chair of the Committee on Technology, oversees the column and coordinates the readers' inquiries and the response from industry.
5. Invited conference reports summarize clinically relevant anesthesia patient safety topics based on the respective conference discussion. Please limit the word count to less than 1000.

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

If accepted for publication, copyright for the accepted article is transferred to the APSF. Except for copyright, all other rights such as for patents, procedures, or processes are retained by the author. Permission to reproduce articles, figures, tables, or content from the APSF Newsletter must be obtained from the APSF.

**Individuals and/or entities interested in submitting material for publication should contact the Editors (Dr. Steven Greenberg and Dr. Jennifer Banayan) directly at [greenberg@apsf.org](mailto:greenberg@apsf.org) or [banayan@apsf.org](mailto:banayan@apsf.org).**



### The Official Journal of the Anesthesia Patient Safety Foundation

The **Anesthesia Patient Safety Foundation Newsletter** is the official publication of the nonprofit Anesthesia Patient Safety Foundation and is published three times per year in Wilmington, Delaware. Contributions to the Foundation are tax-deductible. ©Anesthesia Patient Safety Foundation, 2021.

The opinions expressed in this *Newsletter* are not necessarily those of the Anesthesia Patient Safety Foundation. The APSF neither writes nor promulgates standards, and the opinions expressed herein should not be construed to constitute practice standards or practice parameters. Validity of opinions presented, drug dosages, accuracy, and completeness of content are not guaranteed by the APSF.

#### APSF Executive Committee 2021:

Mark A. Warner, MD, President, Rochester, MN; Daniel J. Cole, MD, Vice President, Los Angeles, CA; Steven B. Greenberg, MD, Secretary, Chicago, IL; Douglas A. Bartlett, Treasurer, Boulder, CO; Lynn Reede, DNP, MBA, CRNA, FNAP, Director At-Large, Boston, MA.

#### APSF Newsletter Editorial Board 2021:

Steven B. Greenberg, MD, Editor, Chicago, IL; Jennifer M. Banayan, MD, Associate Editor, Chicago, IL; Edward A. Bittner, MD, PhD, Associate Editor, Boston, MA; JW Beard, MD, Wilmette, IL; Heather Colombano, MD, Winston-Salem, NC; Jan Ehrenwerth, MD, New Haven, CT; John H. Eichhorn, MD, San Jose, CA; Meghan Lane-Fall, MD, Philadelphia, PA; Nikolaus Gravenstein, MD, Gainesville, FL; Joshua Lea, CRNA, Boston, MA; Bommy Hong Mershon, MD, Baltimore, MD; Tricia A. Meyer, PharmD, Temple, TX; Glenn S. Murphy, MD, Chicago, IL; Steven Shafer MD, Stanford, CA; Brian Thomas, JD, Kansas City, MO; Felipe Urdaneta, MD, Gainesville, FL; Jeffrey S. Vender, MD, Winnetka, IL; Wilson Somerville, PhD, Editorial Assistant, Winston-Salem, NC. Please see the links of international editors at <https://www.apsf.org/wp-content/uploads/newsletter/APSF-International-Editors.pdf>

#### Address all general, contributor, and subscription correspondence to:

Stacey Maxwell, Administrator  
Anesthesia Patient Safety Foundation  
P.O. Box 6668  
Rochester, MN 55903, U.S.A.  
[maxwell@apsf.org](mailto:maxwell@apsf.org)

Address *Newsletter* editorial comments, questions, letters, and suggestions to:

Steven B. Greenberg, MD  
Editor, *APSF Newsletter*  
[greenberg@apsf.org](mailto:greenberg@apsf.org)

Jennifer M. Banayan, MD  
Associate Editor, *APSF Newsletter*  
[banayan@apsf.org](mailto:banayan@apsf.org)

Edward A. Bittner, MD, PhD  
Associate Editor, *APSF Newsletter*  
[bittner@apsf.org](mailto:bittner@apsf.org)

#### Online Editors:

Josh Lea, CRNA  
Felipe Urdaneta, MD

#### Send contributions to:

Anesthesia Patient Safety Foundation  
P.O. Box 6668  
Rochester, MN 55903, U.S.A.  
Or please donate online at [www.apsf.org](http://www.apsf.org).

# Improving Perioperative Patient Safety: A Matter of Priorities, Collaboration, and Advocacy

by Mark A. Warner, MD

We live in a world of competing priorities when we care for patients. On any given day, we are cajoled, pushed, and even prodded to provide cost-effective, efficient, highly productive patient care. In many environments, the faster and cheaper we provide anesthesia services, the more kudos we receive from our health care leaders. In far too many instances, there is less emphasis on providing safe care because it is assumed that the care we provide will be safe. While efficiency and safe care can be balanced effectively, we know that far too many patients are harmed during their perioperative care, including during their anesthetics, when the pressure to speed patient throughput is emphasized more than safety.

When we are patients, our priorities often might not match those of the colleagues who are taking care of us. In general, as patients we tend to place high value on perioperative safety. Yes, we want our care to be efficient and our surgical outcomes to be excellent, but getting through the perioperative period with no complications or unexpected problems is also an important patient priority.

## THE IMPORTANCE OF SETTING ANESTHESIA PATIENT SAFETY PRIORITIES

As a foundation dedicated to patient safety, the Anesthesia Patient Safety Foundation (APSF) strives to help our patients achieve their priority of receiving safe intraoperative and perioperative care. In the past decade, training requirements for many new anesthesia professionals and breadths of clinical practices in the U.S. have been extended into the full spectrum of perioperative care, evolving towards those in a number of other nations. These changes in the U.S., along with a growing emphasis on enhanced recovery pathways, have prompted opportunities to increase patient safety initiatives throughout the perioperative period.

As a consequence, anesthesia patient safety is now a remarkably broad topic, ranging from pulmonary aspiration on induction of anesthesia through postoperative issues such as opioid-induced respiratory arrest, prolonged cognitive impairment, and failure-to-rescue patients during acute physiologic deterioration. APSF has embraced this expansion of the scope of anesthesia patient safety.

Each year, the APSF committees and Board of Directors review existing and emerging perioperative patient safety issues and develop a



Dr. Mark Warner, APSF President

list of the foundation's highest priority issues. Table 1 provides a list of these priorities and actions taken by the APSF to promote and improve them during the past 5 years. Many of these issues need long-term commitment of resources and advocacy to obtain patient safety improvements.

We then use this list to drive our website and *Newsletter* content, research funding, and educational panels and forums (e.g., the annual Stoelting Conferences). While several of these priorities are specific to intraoperative anesthesia care (e.g., distractions in procedural areas), 8 of the 10 have scopes that extend throughout the full perioperative spectrum of issues. A very pertinent, timely example is hospital-acquired infections and environmental microbial contamination and transmission (e.g., COVID infection and its many ramifications on intraoperative and perioperative care and provider safety). The APSF has addressed pandemic-related issues extensively in 2020 (<https://www.apsf.org/novel-coronavirus-covid-19-resource-center/>). More than 600,000 individuals from every country worldwide have accessed our website and *Newsletter* for important COVID patient and provider safety information during the pandemic.

Prioritization matters when there are limited resources, expertise, and time. This is when teamwork becomes so vitally important. No one organization; no one health system; and no one professional society can have a positive impact on all of the important perioperative patient safety issues. It takes a team, with each member making its own unique contributions in

collaboration with others. That is why APSF and health care leaders from around the world continually discuss perioperative patient safety issues and how we can work together to solve these crucial, prioritized issues that are important to all of us. That includes every anesthesia professional who provides patient care.

What can you and the groups in which you have influence do to improve perioperative patient safety? It is incumbent on each of us to ask what we can do personally and together within the specialty and outside of it to make a difference. It includes reaching beyond our usual comfort zones of clinical practice and seeking opportunities that involve working with others who are involved in the perioperative care spectrum. For APSF specifically, it has included developing our social media capabilities such as Facebook, Twitter, and Instagram to reach anesthesia professionals around the world who otherwise would not be aware of our patient safety priorities and initiatives. We have a remarkably successful podcast initiative (<https://www.apsf.org/anesthesia-patient-safety-podcast/>) that provides important anesthesia patient safety updates on a variety of topics, including our patient safety priorities.

## PROFESSIONAL WELLNESS: AN IMPORTANT NEW APSF PRIORITY

A growing number of publications report that it is important for our anesthesia colleagues to be safe because impaired colleagues increase the risk of patient harm. Patient harm associated with impaired anesthesia professionals is a growing issue as stresses and personal health risks in anesthesia professionals have risen. The stresses associated with the current COVID pandemic provide a good example. For example, the intubateCOVID registry, partially supported by APSF, has described in July 2020 that there is a 3.1% risk of new lab-confirmed COVID-19 and an 8.4% risk of new symptoms requiring self-isolation or hospitalization in health care workers who intubated patients with suspected or confirmed COVID. (<https://www.apsf.org/news-updates/the-intubatecovid-global-registry-describes-risk-of-covid-19-outcomes-in-health-care-workers-following-tracheal-intubation-of-patients-with-covid-19/>).

The APSF has recognized the need to integrate anesthesia professional wellness into our foundation's vision. Our vision previously was "that no patient shall be harmed by anesthesia."

See "President's Report," Next Page



From "President's Report," Preceding Page

**Table 1: APSF's 2021 Perioperative Patient Safety Priorities and Ongoing Activities.**

*The following list contains our **top 10 priorities** and the associated activities.*

*The summary of activities is not exhaustive.*

### 1. Preventing, detecting, and mitigating clinical deterioration in the perioperative period

- a. Early warning systems in all perioperative patients
- b. Monitoring for patient deterioration
  - i. Postoperative continuous monitoring on the hospital floor
  - ii. Opioid-induced ventilatory impairment and monitoring
  - iii. Early sepsis
- c. Early recognition and response to decompensating patient
- The 2019 Stoelting Conference was dedicated to this topic.
- This topic has been highlighted in 2020 APSF Newsletter issues and APSF-sponsored panels and presentations.
- APSF is collaborating with the American Society of Anesthesiologists (ASA) and other subspecialty organizations to address specific issues related to this topic.
- APSF will support prototype development for several models that may reduce failure-to-rescue.
- APSF has supported two research grants on this issue in the past 5 years.

### 2. Safety in out-of-operating room locations such as endoscopy and interventional radiology suites

- APSF has addressed this issue recently in APSF Newsletter articles (e.g., June 2020).
- APSF has supported two research grants on this issue in the past 5 years.

### 3. Culture of safety: the importance of teamwork and promoting collegial personnel interactions to support patient safety

- APSF addressed this issue in its 2017 ASA Annual Meeting workshop, as well as in APSF Newsletter articles and presentations.
- The 2019 Pierce Lecture at the ASA Annual Meeting by Dr. Jeff Cooper highlighted this issue; his remarks were published in the February 2020 APSF Newsletter.

### 4. Medication safety

- a. Drug effects
- b. Labeling issues
- c. Shortages
- d. Technology issues (e.g., barcoding, RFID)
- e. Processes for avoiding and detecting errors
- The 2018 Stoelting Conference was dedicated to this topic.
- APSF representatives presented panels at the 2019 ASA and New York State Society of Anesthesiologists' annual meetings.
- APSF will host a consensus workgroup on drug labeling in 2021.
- Multiple APSF Newsletter articles have been published on this issue in 2020.

### 5. Perioperative delirium, cognitive dysfunction, and brain health

- The APSF supports this ASA-American Association of Retired Persons initiative.

- APSF has supported two research grants on this issue in the past 5 years.
- This issue is addressed in the October 2020 APSF Newsletter.

### 6. Hospital-acquired infections and environmental microbial contamination and transmission

- APSF helped develop the 2018 Society for Healthcare Epidemiology of America (SHEA) consensus guidelines on intraoperative infection-prevention (<https://www.cambridge.org/core/journals/infection-control-and-hospital-epidemiology/article/infection-prevention-in-the-operating-room-anesthesia-work-area/66EB7214F4F80E461C6A9AC00922EFC9>).
- APSF sponsored the 2017 NYSSA and ASA panels on this topic.
- APSF made significant contributions to the development and sharing of information related to COVID in 2020 and assisted with development of pertinent shared statements, practice guidelines, and frequently asked questions.
- APSF has supported two research grants on this topic in the past 5 years.

### 7. Patient-related communication issues, handoffs, and transitions of care

- APSF serves as the collaborating organization and supporter of the Multi-Center Handoff Collaborative (<https://www.apsf.org/article/multicenter-handoff-collaborative/>).
- This was the topic of the 2017 APSF Stoelting Conference and several APSF Newsletter articles.
- APSF provides financial and infrastructure support to the Multi-center Handoff Collaborative.

### 8. Airway management difficulties, skills, and equipment

- Several APSF articles have addressed this issue in recent APSF Newsletter articles.
- APSF has supported three research grants on this issue in the past 5 years.

### 9. Anesthesia professionals and burnout

- Half of the 2016 Stoelting Conference addressed drug diversion (wellness).
- Several APSF Newsletter articles have addressed various aspects of this topic in the past two years.
- Matt Weinger, MD, immediate past Secretary of the APSF and present board member, was a major contributor to a 2019 National Academy of Sciences report on this issue (<https://www.nap.edu/catalog/25521/taking-action-against-clinician-burnout-a-systems-approach-to-professional>).
- Clinician safety (including burnout) will be the topic for the 2021 Stoelting Conference.

### 10. Distractions in procedural areas

- Half of the 2016 Stoelting Conference addressed distractions.
- Several APSF Newsletter articles have addressed various aspects of this topic.



## The APSF Collaborates with National and International Organizations to Make Perioperative Patient Care Safer

### From “President’s Report,” Preceding Page

It now reads “that no one shall be harmed by anesthesia care.” This latter version adds the well-being of anesthesia colleagues to our vision and extends our role beyond traditional intraoperative patient safety.

The 2021 Stoelting Consensus Conference on September 8th and 9th will focus specifically on anesthesia professional wellness and its potential negative impact on patient safety. This conference will discuss potential interventions to reduce patient and provider harm and provide recommendations to implement the best of these interventions.

### PRIORITIZING ANESTHESIA PATIENT SAFETY: IT TAKES EVERYONE

The APSF is fortunate to work closely with partners around the world to advocate for anesthesia patient safety. While the foundation can stimulate discussions, promote the generation of new knowledge related to perioperative safety priority issues, and develop consensus recommendations, it takes everyone working

together to advocate for anesthesia patient safety. We sincerely appreciate the outstanding efforts and contributions of partners such as the World Federation of Societies of Anaesthesiologists (WFSA); regional societies such as the European Society of Anesthesiologists, Confederation of Latin American Societies of Anaesthesiology, and others; and many national anesthesia societies that have been major leaders in anesthesia patient safety.

Examples from the past several years of these collaborations include our work with the national societies of anesthesiology in Japan, China, Brazil, Portugal, Spain, France, Columbia, Mexico, and other countries to develop translated issues of the *APSF Newsletter*. The *Newsletter* is now available in five translated languages, allowing us to reach an expanded proportion of the world’s anesthesia professionals. APSF has supported patient safety education research projects with the WFSA and the Patient Safety Movement Foundation. These education projects will lead to improved subspecialty training in low resources coun-

tries and the development and implementation of anesthesia-specific patient safety curricula for training programs and continuing education of anesthesia professionals. We’ve collaborated on clinical patient safety research grants with the Foundation for Anesthesia Education and Research and the Orthopaedic Research and Education Foundation to generate the next generation of anesthesia patient safety clinician scientists.

It is the union of these groups and their collaborative contributions that make big impacts. Please support their efforts. However, and most importantly, please advocate personally for patient safety every day and in every way. It is the right thing to do for our patients and our combined personal advocacy has the biggest positive impact of all on anesthesia patient safety.

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

*The author has no conflicts of interest.*



## APSF Newsletter Podcast

Now Available Online @ [APSF.org/podcast](https://www.apsf.org/podcast)



The APSF now offers you the opportunity to learn about anesthesia patient safety on the go with the Anesthesia Patient Safety Podcast. The weekly APSF podcast is intended for anyone with an interest in perioperative patient safety. Tune in to learn more about recent *APSF Newsletter* articles with exclusive contributions from the authors and episodes focused on answering questions from our readers related to patient safety concerns, medical devices, and technology. In addition, special shows that highlight important COVID-19 information on airway management, ventilators, personal protective equipment, drug information, and elective surgery recommendations are available. The mission of the APSF includes being a leading voice for anesthesia patient safety around the world. You can find additional information in the show notes that accompany each episode at [APSF.org](https://www.apsf.org). If you have suggestions for future episodes, please email us at [podcast@apsf.org](mailto:podcast@apsf.org). You can also find the Anesthesia Patient Safety Podcast on Apple Podcasts or Spotify or anywhere that you listen to podcasts. Visit us at [APSF.org/podcast](https://www.apsf.org/podcast) and at @APSForg on Twitter, Facebook, and Instagram.



Allison Bechtel, MD  
APSF Podcast Director

# U.S. Health Care Institutions Have Seen A Recent Increase in Cyberattacks

From “Cybersecurity,” Cover Page

This hospital was a major testing center for COVID-19 so its ability to manage the pandemic through testing was also impaired. In the United States, a heightened cyberattack threat was identified in October 2020, and there have been a number of successful attacks on health care organizations that have disrupted health care services.<sup>4</sup> For example, on October 28, 2020, the same day the *New York Times* published an article on the increased threat, a successful cyberattack incapacitated the electronic medical record system at the University of Vermont, impacting six hospitals within the care network.<sup>5</sup> While every aspect of patient care was affected and numerous patients were unable to receive care, the reported impact on patients undergoing treatment for cancer was particularly heart-wrenching. As a result of the cyberattack, all of the records describing the chemotherapy care protocols were inaccessible. Patients arriving for chemotherapy treatments were denied care simply because the care providers could not access their records and determine how to treat them safely. It took almost one month to restore the recordkeeping systems.

Cyberattacks can take different forms. Ransomware attacks are obvious as they disable workstations or EMR databases, and the perpetrators of the attack offer to restore functionality if the attacked system owners pay a fee. Although payments do not generally result in the restoration of service and are not recommended, many victims have paid the cybercriminals. If ransomware infects and encrypts a system, it also has to be assumed that data could have been stolen—or “exfiltrated”—opening the door for the abuse of patient health information (PHI). Other types of cyberattacks may not be so obvious. Many medical devices are interconnected to receive and send data on the hospital network, and are therefore vulnerable to cyberattacks. Cybercriminals can potentially alter alarms and device functionality remotely, and the change may not be apparent until a patient suffers an obvious harm.

## WHY DO CYBERCRIMINALS TARGET HEALTH CARE SYSTEMS IN PARTICULAR?

Health care data is especially valuable as a rich source of both personal and financial information and can sell on the dark web at a premium compared with simple credit card data. The high value of data combined with relatively weak cybersecurity infrastructure, makes



health care institutions very attractive targets. Unfortunately, the COVID-19 pandemic has magnified the potential impact of a successful cyberattack on patient care, creating a unique opportunity to exploit the vulnerability of health care IT systems. Indeed, the increased cyberattacks on health care organizations that followed the notice in October 2020 of an increased threat level may not be financially motivated. The recent increase in attacks targeted at health care institutions follow particularly successful efforts by U.S. government agencies to disable the ability of hackers to impact the American election process. The current increase in attacks may be a retaliation, and an effort to make it clear that these hackers are still highly effective.

Unfortunately, one cannot deny the possibility of simple malevolence directed at vulnerable populations as a motivator for these cyberattacks. Health care institutions are highly vulnerable due to the ever increasing reliance on Information Systems (IS) to provide patient care, but many lack the resources of large corporations to invest in cybersecurity. Sick patients, especially during a pandemic, provide an attractive target to criminals due to the likelihood of a negative impact on these patients, and the possibility to create fear or panic.

## CAN CYBERATTACKS BE PREVENTED?

Kevin Mitnick, one of the most successful early hackers, was active from the 1980s until 1995 when he was jailed for communication-related crimes. He has since become a computer security consultant, but the story of his days as a hacker makes for interesting reading.<sup>6</sup> One important lesson is that the strategy of “social engineering” was essential to his success and remains the primary strategy of hackers today. According to Mitnick, “Social

engineering is using deception, manipulation, and influence to convince a human who has access to a computer system to do something, like click on an attachment in an email.”<sup>6</sup>

That same approach continues to be a primary hacking strategy and can be extremely effective given the ubiquity of email use in modern institutions.

IS departments are primarily responsible for working to ensure that cyberattacks are not successful. One strategy is to use the architecture of hardware and software systems to create layers of security (called “defense in depth”) that complicate the navigation of the system by an attacker and limit the spread of malware. Implementing user policies that can reduce the success of social engineering is another important strategy. Some of the more visible IS strategies for anesthesia professionals are blocking of certain websites or access to personal email while using a network or computer at work. Commercial site-monitoring services monitor websites to identify those that may contain malware and provide vulnerable organizations with the information to block access to those sites from internal networks.

## WHAT IS THE ROLE OF THE ANESTHESIA PROFESSIONAL IN HEALTH CARE CYBERSECURITY?

The American Society of Anesthesiologists (ASA) recently formed a cybersecurity task force (CSTF) with the goal of understanding the scope of impact on anesthesia practice by cyberattacks, and collaborating with other organizations to develop recommendations for keeping patients safe. An introductory article on the task force in the *ASA Monitor* provides background on the

See “Cybersecurity,” Next Page

# Cyberattack Simulation May Help Health Care Professionals Be More Prepared For Down-Time Events

## From “Cybersecurity,” Preceding Page

scope and scale of potential risks to our patients from cyberattacks.<sup>7</sup> Given that we are not trained as information system professionals, is there a role for anesthesia professionals in keeping patients safe from the effects of cyberwarfare?

In response to the U.S. government advisory “Ransomware Activity Targeting the Health Care and Public Health Sector” jointly released by the Cybersecurity and Infrastructure Security Agency (CISA), Federal Bureau of Investigation (FBI), and Department of Health and Human Services (HHS) including the FDA,<sup>8</sup> the APSF Committee on Technology released guidance that can be adopted by every anesthesia professional to reduce the risk to patients from cyberattacks (Table 1).<sup>9</sup> The guidance includes personal strategies like email vigilance and password security as well as departmental strategies. Simulations of downtime events are recommended by the committee and should encompass all of the processes needed to maintain patient care when one or more information systems are not functioning. Consider, for example, a polytrauma patient admitted to the emergency department and found to require urgent transport to the operating room to control bleeding. Will you be able to manage the continuum of complex care required by this patient without computer systems as they move from the ED to the operating room to the ICU? How will the urgency be communicated so that the OR is ready? How will blood bank and laboratory services be coordinated? Will pharmacy supplies be available? How will you know who is on call for a particular service? What computer systems may still function? Are the paper forms adequate to support continued documentation and care processes? The results of these simulations can inform the development of procedures for care in the event of a cyberattack and provide focus for training care providers.

Fortunately, government and other agencies are actively working to identify cyberattack risks and reduce or eliminate the impact. The problem continues to grow, despite the vigilance and support of the public and private sectors to address these cybersecurity hazards. Like human viruses, malware, once introduced into cyberspace, persists as an ongoing risk to unprotected computer systems. Cybercriminal enterprises do not seem to be inhibited from victimizing health care systems.<sup>8</sup>

Given the degree to which health care depends upon computer systems and networked devices, cyberattacks will continue to be

## TABLE 1: Cybersecurity Recommendations.

In response to the ongoing threat of cyberattacks on health care institutions, the APSF Committee on Technology recommends that all anesthesia professionals take the following actions.

### STRENGTHEN DOWNTIME PROCEDURES

- Review existing downtime procedures.
- Engage other perioperative leaders in planning.
- Inform all providers about how to continue patient care using downtime procedures.
- If possible, simulate a downtime event.

### INCREASE VIGILANCE

- Manage your email! **DO NOT ENTER YOUR SYSTEM PASSWORD OR ID** in response to any request by email. Report suspicious emails to IS services.
- Cybersecurity attacks can affect any network-dependent medical device. Be vigilant for unexpected changes in settings or behavior of alarms or function of devices like IV pumps and ventilators.

### REVIEW REPORTING

- Report medical device and system performance issues ASAP to hospital IS and/or biomedical engineering.
- Extramural reporting:
  - Device manufacturers
  - FDA at [CyberMed@fda.hhs.gov](mailto:CyberMed@fda.hhs.gov) for cybersecurity concerns
  - FDA through the MedWatch Voluntary Reporting System for any type of device malfunction. Reporting form <https://www.fda.gov/safety/medical-product-safety-information/medwatch-forms-fda-safety-reporting>

More complete recommendations will be updated as they become available at <https://www.apsf.org/news-updates/the-apsf-issues-preliminary-guidance-on-cybersecurity-threats-to-u-s-health-care-systems/>

a growing patient safety concern. Individual habits managing email and websites while at work can reduce the risk of a successful attack, but, as always, it is prudent to be vigilant for medical device and information systems malfunctions, and maintain backup plans to continue to provide safe care in the event of device and system failures.

*Julian M. Goldman, MD, is an anesthesiologist at Massachusetts General Hospital; medical director of Biomedical Engineering at Mass General Brigham; director, Medical Device “Plug and Play” Interoperability & Cybersecurity Program (MD PnP); and convener, ISO/TC 121/WG 3 Cybersecurity for anaesthetic and respiratory equipment.*

*Jeffrey Feldman, MD, MSE, is chair, APSF Committee on Technology and professor of clinical anesthesiology at Children’s Hospital of Philadelphia, Perelman School of Medicine.*

*The authors have no further conflicts of interest.*

## REFERENCES

1. Ghafur S, Kristensen S, Honeyford K, et al. A retrospective impact analysis of the WannaCry cyberattack on the NHS. *npj Digit Med.* 2, 98 (2019). <https://doi.org/10.1038/s41746-019-0161-6>. Accessed December 21, 2020.

2. 2020 Healthcare Cybersecurity Report, <https://www.herjavecgroup.com/wp-content/uploads/2019/12/healthcare-cybersecurity-report-2020.pdf>. Accessed December 21, 2020.
3. Bizga A. Mysterious cyberattack cripples Czech hospital amid COVID-19 outbreak, <https://hotforsecurity.bitdefender.com/blog/mysterious-cyberattack-cripples-czech-hospital-amid-covid-19-outbreak-22566.html>. Accessed November 18, 2020.
4. Perloth, N. Officials warn of cyberattacks on hospitals as virus cases spike. *New York Times*. Oct. 28, 2020. <https://www.nytimes.com/2020/10/28/us/hospitals-cyberattacks-coronavirus.html>. Accessed November 26, 2020.
5. Barry E, Perloth N. Patients of a Vermont hospital are left ‘in the dark’ after a cyberattack. *New York Times*. November 25, 2020. <https://www.nytimes.com/2020/11/26/us/hospital-cyber-attack.html>. Accessed November 26, 2020.
6. Mitnick K. *Ghost in the wires—my adventures as the world’s most wanted hacker*. Little, Brown and Co. New York, 2011.
7. Goldman JM, Minzter B, Ortiz J, et al. Formation of an ASA Cybersecurity Task Force (CSTF) to protect patient safety. *ASA Monitor*. September 2020;84:34. <https://doi.org/10.1097/01.ASM.0000716908.49348.5a>. Accessed December 10, 2020.
8. CISA Alert (AA20-302A), October 28, 2020, <https://us-cert.cisa.gov/ncas/alerts/aa20-302a>. Accessed December 10, 2020.
9. The APSF issues preliminary guidance on cybersecurity threats to U.S. health care systems. *APSF Newsletter online*. November 2, 2020. <https://www.apsf.org/news-updates/the-apsf-issues-preliminary-guidance-on-cybersecurity-threats-to-u-s-health-care-systems/>. Accessed November 10, 2020.



## FAERS Database Used to Identify Adverse Events After Sevoflurane or Desflurane Use Over A Quarter Century

From “Adverse Event Reporting,” Cover Page

This led to a 2 liter per minute (lpm) fresh gas flow (FGF) restriction to reduce human exposure to compound A. Studies in rat models indicated that Compound A could produce dose-dependent renal injury characterized by proximal tubular necrosis at inspired levels as low as 114 parts per million (ppm).<sup>1</sup>

Phase IV trials were subsequently performed in volunteers and patients undergoing long periods of sevoflurane anesthesia to examine both the level of exposure to Compound A, as well as to seek harmful effects based on clinical markers of renal function. In one such study, purposely designed to examine prolonged sevoflurane exposure at 1 lpm FGF, maximum compound A concentrations reached  $34 \pm 6$  ppm, but no clinically significant changes in biochemical markers of renal dysfunction were found.<sup>11</sup> Continued work revealed that humans were nearly devoid of an enzyme called renal beta lyase, a key enzyme directing the biodegradation of compound A to a toxic renal thiol in rats.<sup>12</sup>

Desflurane was introduced in 1992, and its low solubility in blood afforded it a clinical advantage of a more rapid induction and emergence from anesthesia and potentially a more rapid titration to a desired anesthetic depth compared with other volatile anesthetics in use. However, after the launch of desflurane, it was discovered that desflurane could activate airway reflexes because of its extreme pungency.<sup>2</sup>

Preclinical work with desflurane had also reported unexplained tachycardia and hypertension on occasion, and, in pediatric populations, bronchospasm. Desflurane’s lack of potency necessitated higher concentrations to achieve clinical effectiveness, thereby unmasking an adverse airway effect from its pungency. The adverse airway effect was associated with sympathetic activation during initial airway exposure after induction of anesthesia and during upward transitions in concentration.<sup>2,3</sup> Our lab had demonstrated a 2.5-fold increase in sympathetic nerve activity, hypertension, and tachycardia on initiation of desflurane after induction of anesthesia and an additional neurocirculatory activation with the transition from 1.0 to 1.5 MAC.<sup>4</sup> Subsequent work indicated that nebulized lidocaine did not obtund the airway reflex response, but opioids had a dose dependent benefit in reducing the neurocirculatory activation.<sup>13,14</sup>

In this report, we have explored the FAERS database for sevoflurane and desflurane adverse events after a quarter century of clinical use in millions of patients.

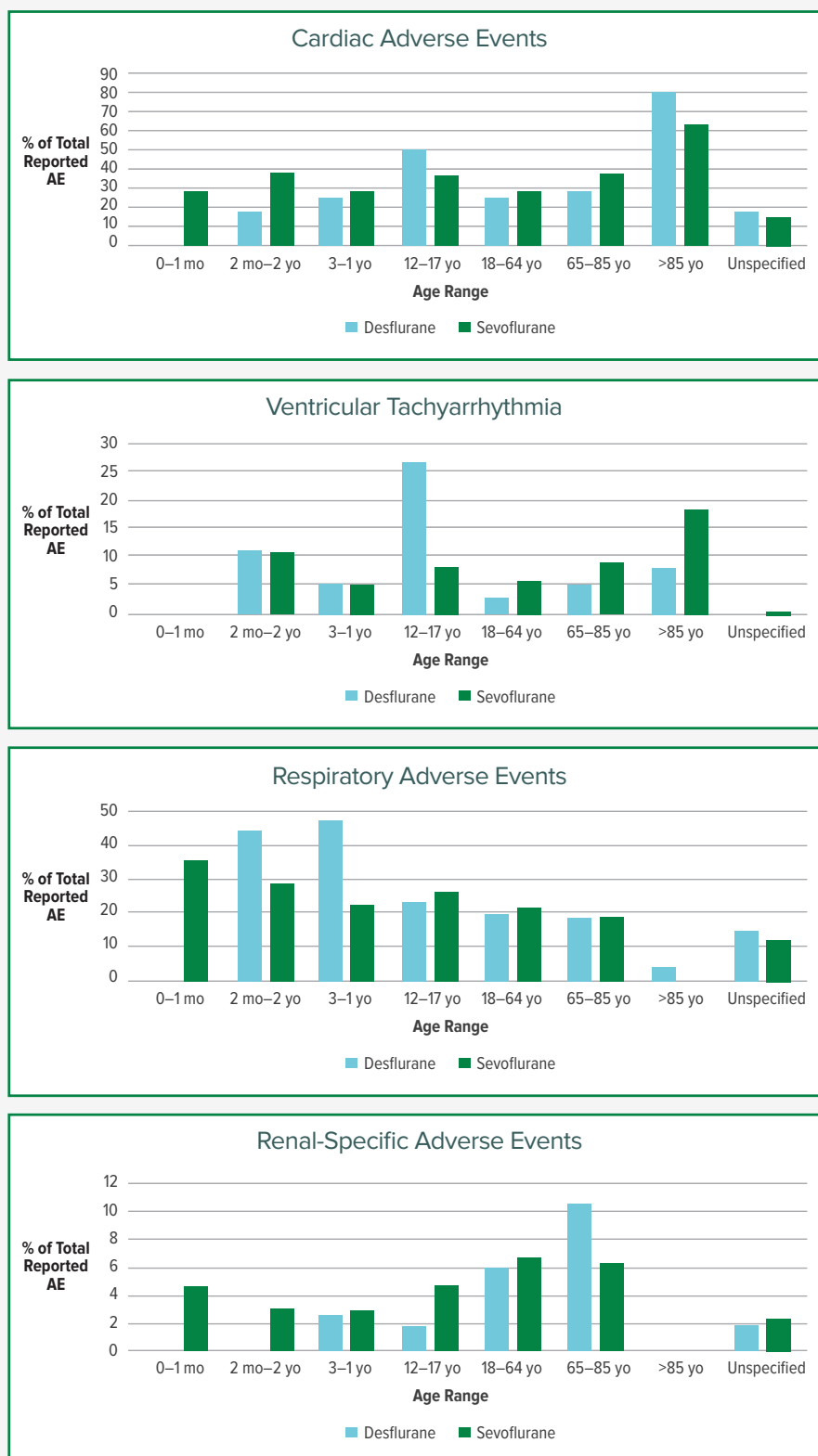


Figure 1: Adverse Events (AE) for Desflurane and Sevoflurane by Age Range.

## Injury, Poisoning, and Procedural Complications Were the Most Common Category for Both Sevoflurane and Desflurane

From “Adverse Event Reporting,” Preceding Page

We sought to determine if the self-reporting of adverse events to the FDA validated the initial concerns surrounding the safety of sevoflurane and desflurane and whether new safety concerns had been exposed during clinical use in a broad patient population.

### METHODS

In order to monitor drug safety in clinical practice, the Food and Drug Administration (FDA) has developed the FDA Adverse Event Reporting System (FAERS).<sup>15</sup> FAERS is an online database the FDA uses to monitor all approved drugs and therapeutic biologic products by assessing the quantity, severity, and overall outcomes of new medications including volatile anesthetics. The FAERS database was queried for adverse events (AEs) reported for both sevoflurane and desflurane between 1996 and December 2019. Using demographic filters, AEs were analyzed for the two volatile anesthetics with each of the following age groups filters: 0 to 1-month-old, 2 months to 2-years-old, 3 to 11-years-old, 12 to 17-years-old, 18 to 64-years-old, 65 to 85-years-old, greater than 85-years-old, and age unspecified. AEs were sorted by Reaction Group. For example, the Reaction Group Cardiac Disorder, included specific reactions such as cardiac arrest, PEA, and ventricular tachycardia among others. For this article, general reactions Cardiac Disorders, Renal and Urinary Disorders, and Respiratory, Thoracic, and Mediastinal Disorders are reported in addition to specific reactions, e.g., ventricular tachyarrhythmias (ventricular tachycardia, ventricular fibrillation, torsades de pointes). Renal-specific disorders (oliguria, anuria, acute kidney injury/renal injury, renal impairment/failure, renal tubular disorder/dysfunction, and acute tubular necrosis) were summed to reduce the incidence of other less robust urinary reactions, e.g., urinary retention. All AEs are reported as a percentage of the total reaction group number for that anesthetic within each age group.

### RESULTS

Use of desflurane yielded 1140 reported AEs with the most common category (reaction group), being Injury, Poisoning, and Procedural Complications (24.9%). The top four subcategories within this reaction group included postprocedural complications, fetal exposure during pregnancy, anesthetic neurological complications, and awareness. Cardiac AEs were second at 23.9% with the most common subcategories including bradycardia, cardiac



arrest, tachycardia, and ventricular tachycardia. Respiratory/Thoracic accounted for 19.4% with the top subcategory bronchospasm making up 2.9% of all desflurane-related AEs. The next most common were hypoxia, dyspnea, and laryngospasm.

Sevoflurane had 4977 reported AEs with the most common category being Injury, Poisoning and Procedural Complications (30.4%). The top four subcategories included anesthetic complications, postprocedural complications, anesthetic neurological complications, and awareness. As with desflurane, cardiac AEs were also the second most common reaction group for sevoflurane at 24.4%. The most common subcategories included cardiac arrest, bradycardia, tachycardia, and ventricular fibrillation. Respiratory/Thoracic events accounted for 18.7%, in similar range with desflurane. The four subcategories included pulmonary edema, hypoxia, apnea, and bronchospasm (1.6% of total sevoflurane AEs). Laryngospasm was the sixth most common subcategory in Respiratory/Thoracic complications. Of note, Renal-specific Disorders made up only 4.4% of all reported reactions for sevoflurane, compared with 5.3% for desflurane.

Figure 1 demonstrates AEs of interest for this report. Both desflurane and sevoflurane had high proportions of reported Cardiac AEs in the 85+ age group (80% and 63.6%). Ventricular tachyarrhythmia had a disproportionately high occurrence with desflurane in the age range of 12–17 at 26.8% compared to 8.2% for sevoflurane. There were very few reported adverse events in the neonatal age

group for desflurane, although it tends not to be used in those under 2 years old due to distributor recommendations. The proportion of respiratory events out of total AEs for desflurane compared to sevoflurane were notably higher in the 2 months–2 years of age and 3–11 year age groups.

### DISCUSSION

The FAERS database contained 1140 adverse events reported for desflurane and 4977 reported for sevoflurane. The frequency of AE reporting is influenced by the total number of each of the anesthetics administered in clinical practice. But the AE reporting does confirm, by prevalence of AEs for each anesthetic, a number of areas of potential concern for these two volatile anesthetics in clinical use. Cardiac AEs were the second most commonly reported “reaction group” for both anesthetics. The proportion of ventricular tachyarrhythmias was higher with desflurane in a younger population, but was noted to be higher with sevoflurane in an elderly population. Respiratory events were more prevalent than other adverse events in younger patients receiving desflurane. The greatest percentage of AEs in the Injury, Poisoning, and Procedural Complications group were awareness and neurologic AEs, likely capturing postoperative agitation and cognitive decline.

There are a number of links between the FAERS database and the clinical science for each anesthetic.

See “Adverse Event Reporting,” Next Page

# No New or Unexpected Adverse Events Were Found in the FAERS Database for Sevoflurane and Desflurane Use

From “Adverse Event Reporting,” Preceding Page

**Arrhythmias and Volatile Anesthetics:** *In vitro* studies have shown that desflurane may increase intramyocardial catecholamine release,<sup>16</sup> which could lead to the generation of arrhythmias. Desflurane has also been associated with more arrhythmias than sevoflurane after off-pump coronary artery bypass grafting,<sup>17</sup> and has been associated with a higher rate of postoperative atrial fibrillation after on-pump cardiac surgery.<sup>18</sup> The interlead variability of the QT interval, called the QT dispersion (QTd), is a marker for regional differences in ventricular repolarization and correlates better with the risk of dysrhythmia than the QT interval itself.<sup>19</sup> In healthy adults undergoing noncardiac surgery, induction of anesthesia with only desflurane (no premedication) appeared to significantly increase the QTd while induction with only sevoflurane was not associated with any changes,<sup>20</sup> but when midazolam and vecuronium were used prior to intubation, desflurane and sevoflurane both prolonged the QTd with no significant difference between the two.<sup>21</sup> While a prolonged QTd can lead to various arrhythmias, its relationship to sympathetic activation, more commonly associated with desflurane is unknown.

**Respiratory Disorders and Volatile Anesthetics:** The proportion of respiratory AEs was high in the younger age group. As mentioned earlier, within the first few years of desflurane being available clinically there were concerns about pungency and airway irritation. As seen in recent studies regarding the respiratory effects of desflurane, a clear difference exists between adults and children. In an historical study of a large cohort of 14,000 children, researchers found that the use of desflurane was a risk factor for intraoperative respiratory events of all kinds, as well as for laryngospasm in particular.<sup>5</sup> In a clinical trial of 400 healthy children who were randomized to either desflurane or isoflurane, children who received desflurane had a significantly higher frequency of airway events of any severity, laryngospasm, and coughing.<sup>6</sup> However, the results are quite different when looking at adults. One meta-analysis of 13 randomized controlled trials showed no difference between sevoflurane and desflurane in the rates of upper airway events, laryngospasm, or cough at emergence.<sup>22</sup> Another meta-analysis of seven randomized controlled trials showed no difference between sevoflurane and desflurane in the incidence of overall cough or laryngospasm in adults.<sup>23</sup>

## LIMITATIONS

The FAERS relies on the voluntary reporting of adverse events by health care professionals

and consumers in the United States, and for this reason there are important limitations to the database. First, there is no certainty that the reported adverse event was caused by the drug in question, as the FDA does not require that a causal relationship be proven. Second, the FDA does not receive every single adverse event that occurs for every single drug. There are many factors that determine whether a report will be filed, such as the severity or publicity of the event. It is expected that more serious side effects, such as cardiac arrhythmias, would be reported more frequently than other less serious reactions, such as postoperative nausea. For this reason, the database cannot be used to calculate an incidence of a given adverse event in the population. The frequency of use of sevoflurane is higher than desflurane in pediatric and adult patients.<sup>24</sup> Thus, the total number of adverse events for any one volatile anesthetic is not relevant unless the denominator is precisely known.

**Conclusions:** Unlike other anesthesia drugs where their clinical use revealed new or unexpected safety concerns such as halothane hepatitis or anaphylaxis from rapacuronium, there do not appear to be any new or unexpected adverse phenomena after nearly 30 years of use of desflurane and sevoflurane. Early research identifying the neurocirculatory changes from the airway irritant effects of desflurane and the absence of renal injury from sevoflurane have carried forward to explain the findings in the FAERS self-reported data. Desflurane had a high incidence of airway events in a younger population that did not persist in older patients. Cardiac arrhythmias were noted with both anesthetics, and a prevalence of ventricular tachycardia was noted with desflurane in younger patients.

*Thomas Ebert, MD, PhD, is a professor of anesthesiology at the Medical College of Wisconsin, Milwaukee, WI, and chief of anesthesiology at the Clement J. Zablocki Veterans Affairs Medical Center, Milwaukee WI.*

*Alex Ritchay, MD, is an anesthesiology resident at the Medical College of Wisconsin in the Department of Anesthesiology, Milwaukee, WI.*

*Aaron Sandock, BA, is a medical student at the Medical College of Wisconsin, Milwaukee, WI.*

*Shannon Dugan, BS, is a research assistant at the Medical College of Wisconsin, Milwaukee, WI.*

*The authors have no conflicts of interest.*

## REFERENCES

- Gonsowski C, Laster M, Eger E, et al. Toxicity of compound A in rats. *Anesthesiology*. 1994;80:566–573.
- Muzi M, Lopatka C, Ebert T. Desflurane-mediated neurocirculatory activation in humans: effects of concentration and

rate of change on responses. *Anesthesiology*. 1996;84:1035–1042.

- Welskopf R, Moore M, Eger E, et al. Rapid increase in desflurane concentration is associated with greater transient cardiovascular stimulation than with rapid increase in isoflurane concentration in humans. *Anesthesiology*. 1994;80:1035–1045.
- Ebert T, Muzi M. Sympathetic hyperactivity during desflurane anesthesia in healthy volunteers. *Anesthesiology*. 1993;79:444–453.
- Oofuvong M, Geater A, Chongsuvivatwong V, et al. Risk over time and risk factors of intraoperative respiratory events: a historical cohort study of 14,153 children. *BMC Anesthesiology*. 2014;14:13.
- Lerman J, Hammer G. Response to: Airway responses to desflurane during maintenance of anesthesia and recovery in children with laryngeal mask airways. *Paediatr Anaesth*. 2010;20:962–963.
- Habibollahi P, Mahboobi N, Esmaeili S, et al. Halothane-induced hepatitis: a forgotten issue in developing countries. *Hepat Mon*. 2011;11:3–6.
- Sosis MB. Further comments on the withdrawal of rapacuronium. *Anesthesia & Analgesia*. 2002;95:1126–1127.
- Sloane R, Osanlou O, Lewis D, et al. Social media and pharmacovigilance: a review of the opportunities and challenges. *Br J Clin Pharmacol*. 2015; 80:910–920.
- Smith I, Nathanson M, White P. Sevoflurane—a long-awaited volatile anaesthetic. *Br J Anaesth*. 1996;76:435–445.
- Ebert T, Frink E, Kharasch E. Absence of biochemical evidence for renal and hepatic dysfunction after 8 hours of 1.25 minimum alveolar concentration sevoflurane anesthesia in volunteers. *Anesthesiology*. 1998;88:601–610.
- Kharasch E, Jubert C. Compound A uptake and metabolism to mercapturic acids and 3,3,3-trifluoro-2-fluoromethoxypropanoic acid during low-flow sevoflurane anesthesia. *Anesthesiology*. 1999;91:1267–1278.
- Bunting H, Kelly M, Milligan K. Effect of nebulized lignocaine on airway irritation and haemodynamic changes during induction of anaesthesia with desflurane. *Br J Anaesth*. 1995;75:631–633.
- Pacentine G, Muzi M, Ebert T. Effects of fentanyl on sympathetic activation associated with the administration of desflurane. *Anesthesiology*. 1995;82:823–831.
- U.S. Food and Drug Administration. 2020. Potential signals of serious risks by FAERS. [online] Available at: <https://www.fda.gov/Drugs/GuidanceComplianceRegulatoryInformation/Surveillance/AdverseDrugEffects/ucm565425.htm> Accessed March 9, 2020.
- Park WK, Kim MH, Ahn DS, et al. Myocardial depressant effects of desflurane: mechanical and electrophysiologic actions *in vitro*. *Anesthesiology*. 2007;106:956–966.
- Hemmerling T, Minardi C, Zaouter C, et al. Sevoflurane causes less arrhythmias than desflurane after off-pump coronary artery bypass grafting: a pilot study. *Ann Card Anaesth*. 2010;13:116.
- Cromheecke S, ten Broecke PW, Hendrickx E, et al. Incidence of atrial fibrillation early after cardiac surgery: can choice of the anesthetic regimen influence the incidence? *Acta Anaesthesiol Belg*. 2005;56:147–54.
- Day C, McComb J, Campbell R. QT dispersion: an indication of arrhythmia risk in patients with long QT intervals. *Heart*. 1990;63:342–344.
- Yildirim H, Adanir T, Atay A, et al. The effects of sevoflurane, isoflurane and desflurane on QT interval of the ECG. *Eur J Anaesthesiol*. 2004; 21: 566–570.
- Kazanci D, Unver S, Karadeniz U, et al. A comparison of the effects of desflurane, sevoflurane and propofol on QT, QTc, and P dispersion on ECG. *Ann Card Anaesth*. 2009;12:107.
- Stevanovic A, Rossaint R, Fritz H, et al. Airway reactions and emergence times in general laryngeal mask airway anaesthesia. *Eur J Anaesthesiol*. 2015;32:106–116.
- de Oliveira G, Girao W, Fitzgerald P, et al. The effect of sevoflurane versus desflurane on the incidence of upper respiratory morbidity in patients undergoing general anesthesia with a Laryngeal Mask Airway: a meta-analysis of randomized controlled trials. *J Clin Anesth*. 2013;25:452–458.
- Nasr G, Davis M. Anesthetic use in newborn infants: the urgent need for rigorous evaluation. *Pediatr Res*. 2015;78: 2–6.



## RAPID Response

to questions from readers

## HEPA Filters. Do We Really Know Enough?

by Felipe Urdaneta, MD

*This article was previously published on the APSF online portal.  
The present version is updated and modified by the author for the present APSF Newsletter.*

The global crisis due to COVID-19 has permeated every aspect of our health care systems. Concerns about the biohazard of SARS-CoV-2, spread and contact transmission to patients, health care personnel, environment, and equipment have been widespread, especially with regards to procedures that generate aerosols (AGPs).<sup>1-3</sup> Transmission of the virus is primarily respiratory in nature. SARS-CoV-2 virion is approximately 120 nanometers in diameter (0.06–0.14  $\mu\text{m}$ ), and travels from person to person in biological carrier particles such as droplets or aerosols.<sup>2,3</sup> Recommendations regarding adequate levels of PPE, handwashing, surface cleaning, decontamination, and precautions during airway management procedures have been discussed extensively during the pandemic.<sup>4-6</sup> As with other respiratory transmissible diseases, we rely on two important filtering systems: circuit filters when artificial breathing systems are used in the operating room and/or intensive care units (ICU) and face-mask respirators.

However, things are a bit complicated:

1. Anesthesia machines and mechanical ventilators require filters for air quality purification and cross-contamination prevention. The efficiency standard of such filters is termed HEPA for high-efficiency particulate air/ high-efficiency particulate absorbing capacity.<sup>7</sup> The ASA recommends placement of HEPA filters between the Y-piece of the breathing circuit and the patient's mask, endotracheal tube or laryngeal mask airway.<sup>8</sup>
2. European and U.S standards to determine filter efficiency are not the same: European standards use 99.95% removal of particles with a diameter of 0.3  $\mu\text{m}$  in diameter, while the U.S uses 99.97%.<sup>9</sup>
3. Face mask efficiency is determined by the level of particle penetration. An N95 mask for example removes at least 95% of 300 nm particles using an airflow rate of 85 liters/min.<sup>10</sup> Face mask respirators are regulated according to U.S National Institute for Occupational Safety and Health (NIOSH) and internationally recognized standards and testing.



4. Filters in breathing circuits and anesthesia machines are not regulated. There is no national or international standard test for filters in breathing circuits. Since there is no standard testing, are all manufactures reporting the same when discussing the level of efficiency?<sup>11</sup>
5. Are current available filters adequate for COVID-19?
6. Because many COVID-19 patients require prolonged mechanical ventilation, how often should these filters be changed in the ICU?
7. What should health care professionals do in case of filter shortages?

These are some of the pressing questions with regards to HEPA filters that I would like to see discussed.

Thank you.

Felipe Urdaneta  
Clinical Professor of Anesthesiology  
University of Florida/NFSGVHS  
Gainesville, Florida

*The author is a consultant for Medtronic and member of the Advisory Board for Vyaire and has received speaker honoraria on their behalf.*

### REFERENCES

1. Canova V, Lederer Schlipfer H, Piso RJ, et al. Transmission risk of SARS-CoV-2 to healthcare workers—observational results of a primary care hospital contact tracing. *Swiss Medical Weekly*. 2020;150:1–5.
2. Asadi S, Bouvier N, Wexler AS, et al. The coronavirus pandemic and aerosols: Does COVID-19 transmit via expiratory particles? *Aerosol Sci Technol*. 2020;0:1–4.
3. van Doremalen N, Bushmaker T, Morris DH, et al. Aerosol and surface stability of SARS-CoV-2 as compared with SARS-CoV-1. *N Engl J Med*. 2020;382:1564–1567.
4. Asenjo JF. Safer intubation and extubation of patients with COVID-19. *Can J Anaesth*. 2020:1–3.
5. Chia SE, Koh D, Fones C, et al. Appropriate use of personal protective equipment among healthcare workers in public sector hospitals and primary healthcare polyclinics during the SARS outbreak in Singapore. *Occup Environ Med*. 2005;62:473–477.
6. Sorbello M, El-Boghdady K, Di Giacinto I, et al. The Italian coronavirus disease 2019 outbreak: recommendations from clinical practice. *Anaesthesia*. 2020;75:724–732.
7. First MW. Hepa filters. *Appl Biosaf*. 1998;3:33–42.
8. American Society of Anesthesiologists. Information for health care professionals. Published 2020. <https://www.asahq.org/about-asa/governance-and-committees/asa-committees/committee-on-occupational-health/coronavirus>. Accessed June, 2020.
9. Wikipedia. HEPA. <https://en.wikipedia.org/wiki/HEPA>. Accessed June 9, 2020.
10. Haghighat F, Bahloul A, Lara J, et al. Development of a procedure to measure the effectiveness of N95 respirator filters against nanoparticles. 2012.
11. NIOSH-Approved Particulate Filtering Facepiece Respirators. [https://www.cdc.gov/niosh/nppt/topics/respirators/disp\\_part/default.html](https://www.cdc.gov/niosh/nppt/topics/respirators/disp_part/default.html). Accessed June 9, 2020.

See “System Filters,” Next Page

## RAPID Response

to questions from readers

# Breathing System Filters in the Era of COVID-19

by Robert G. Loeb, MD

*This article was previously published on the APSF online portal.  
The present version is updated and modified by the author for the present APSF Newsletter.*

We thank Felipe Urdaneta, MD, for highlighting some confusion about the use of anesthesia breathing system filters in response to the COVID-19 pandemic. The APSF website has a page (<https://www.apsf.org/faq-on-anesthesia-machine-use-protection-and-decontamination-during-the-covid-19-pandemic/>) that summarizes current strategies for protecting the anesthesia machine from contamination by a potentially infected patient. But it does not provide some of the details behind the recommendations. This article will provide details, such as the risk of patient trans-infection via the breathing system, modes of virus transmission, filtration physics, types of filters, and standardized tests and specifications of filters, in an effort to answer Felipe Urdaneta's questions and clear up similar confusions among our readership.

### RISK OF PATIENT CROSS-INFECTION VIA THE BREATHING SYSTEM

Circle breathing systems present a hypothetical risk of patient cross-infection due to rebreathing of previously exhaled gases. Prior to the 1990s, anesthesia breathing system filters were not routinely used and it was thought that cross-infection of patients was prevented by passage of exhaled gas through the alkaline carbon dioxide absorbent.<sup>1</sup> However, breathing system filters became increasingly used in the 1990s<sup>2</sup> after a report of nine cases of cross-infection by hepatitis C attributed to contaminated anesthesia breathing systems.<sup>3</sup> There is conflicting evidence for the potential for cross-infection; almost no cases have been documented, but *in-vitro* tests demonstrate the possibility.<sup>4-6</sup> In any case, breathing system filters are recommended by a number of anesthesia societies, but only when breathing circuits are reused between patients.<sup>7,8</sup>

### MODES OF RESPIRATORY VIRUS TRANSMISSION

COVID-19 (SARS-CoV-2) is transmitted primarily via the respiratory route, as are Severe Acute Respiratory Syndrome (SARS-CoV), Middle-East Respiratory Syndrome-associated coronavirus (MERS-CoV), and other coronaviruses. It is transmitted via droplets, which are more than 20 microns in diameter, and via aerosols

which are less than 5–10 microns in diameter.<sup>9</sup> Droplets tend to fall due to gravity, whereas aerosol particles float in air and follow airstreams. Intermediate-sized particles share some properties of droplets and aerosols. Rapid evaporation of small droplets results in even smaller droplet nuclei that also follow airstreams. Droplets, aerosols, and intermediate-sized particles are generated during coughing, sneezing, and talking, whereas aerosols are primarily generated during passive breathing. An important concept in filtering pathogens is that respiratory viruses are not transmitted by isolated virus particles floating in air, but by viruses contained within larger particles. Droplets and some intermediate-sized particles can settle on surfaces, potentially leading to surface transmission.

No studies have estimated how many virus particles SARS-CoV-2 infected patients exhale. However, one study that quantified exhalation of other respiratory virus particles, found that seasonal coronavirus infected patients exhaled and coughed-out 0 to 200,000 virus particles per hour.<sup>10</sup>

While a single viral particle can theoretically result in systemic infection, the chance of infection increases with the duration and magnitude of viral exposure.<sup>11</sup>

### PHYSICS OF FILTRATION

People generally understand the physics of sieve filtration, an observable phenomenon in strainers, whereby a particle that is larger than the smallest holes cannot pass through a filter. However, other forces come into play with very small particles (e.g., diameter < 2 microns).<sup>12</sup> Very small particles tend to adhere to the filter material once they make contact, even if they could fit through openings in the filter. There are four basic mechanisms whereby particles make contact with filter material. Particles in the range of 0.11 micron can directly impact filter strands through a process called *inertial impaction*. Particles in the range of 0.05–1 micron can tangentially contact filter strands through a process called *interception*. As particles get smaller, they increasingly exhibit Brownian motion in addition to moving with air flow—and can contact filter material as a consequence of this erratic movement through a process called *diffusion*.

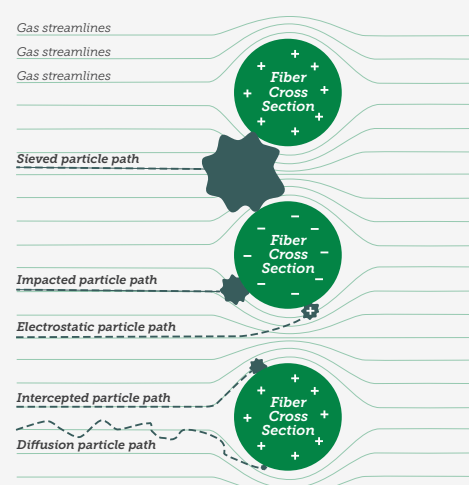


Figure 1: Filtration phenomena.

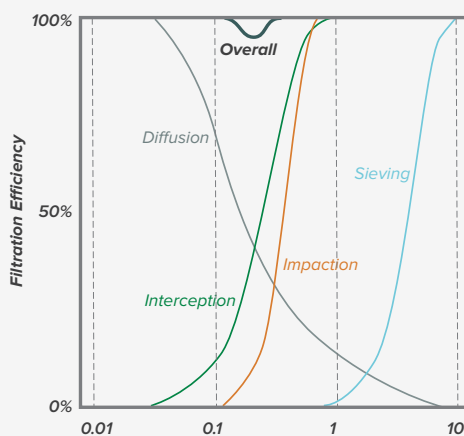


Figure 2: Individual filtration phenomena sum to yield overall filtration for different size particles. Note that the lowest efficiency is around 0.3 microns.

Finally, small charged particles can be attracted to the charged surface of filter material through a process called *electrostatic attraction*. Figure 1 illustrates each of these phenomena, and Figure 2 shows how the sum of these phenomena affects the overall filter efficiency. Note that for most air filters, particles around 0.3 microns (i.e., 300 nanometers) in size are the most difficult to trap—particles that are larger or smaller are easier to catch.

See "System Filters," Next Page

## A Variety of Filters and Testing Are Available

From "System Filters," Preceding Page

### TYPES OF FILTERS USED IN ANESTHESIA BREATHING SYSTEMS

#### Pleated mechanical filters

Pleated mechanical filters contain a thick sheet of tightly packed, randomly oriented, bonded hydrophobic fibers that capture particulates within the depth of the filter. The filter material is pleated to increase the surface area and decrease resistance to airflow. They typically have a very high filtration efficiency and may also provide some heat and moisture exchange when placed close to the airway, at a site of two-way airflow. When used in a humid environment, their filtration efficiency and resistance to airflow can get better or worse; they still tend to be highly effective when damp.<sup>13</sup> Liquids do not easily pass through pleated mechanical filters.<sup>14</sup> Mechanical filters tend to cost more, and have a higher internal volume than electrostatic filters.

#### Electrostatic filters

Electrostatic filters contain a thin sheet of less tightly woven electrostatic fibers. Their resistance to airflow is less for a given surface area, so they are not pleated. Electrostatic filters typically have 1000-fold lower filtration efficiencies than pleated mechanical filters.<sup>13</sup> Their filtration efficiency and resistance to airflow can get better or worse in a humid environment. Liquids easily pass through an electrostatic filter.<sup>14</sup>

#### Heat and moisture exchange filters (HMEF)

By themselves, heat and moisture exchange (HME) devices provide no filtering. HMEs that contain an electrostatic or a pleated mechanical filter are denoted HMEF. HMEs and HMEFs are only effective for humidification when placed close to the airway, at a site of two-way airflow, where they absorb water during exhalation and release it during inhalation.<sup>15</sup>

#### Membrane filters

A completely different type of filter is used in respiratory gas analyzers to prevent fluid entry into the analyzer chamber. While not classified as breathing system filters, hydrophobic membrane filters are commonly included in water traps because they allow gas to pass when dry, but become occlusive when wet. Membrane filters have ultra-small pores and channels that can prevent particle passage primarily by sieving.

### STANDARDIZED TESTS AND SPECIFICATIONS OF FILTERS

#### Particle Filtration

There is one single international standard for testing the filtration efficiency of breathing system filters, *ISO 23328-1: Breathing system filters for anaesthetic and respiratory use*.<sup>16</sup> The standard describes a method, the salt test method, that quantifies the number of 0.1 to 0.3 micron airborne sodium chloride particles that pass through the filter during a short-term challenge at airflow rates likely to be encountered during the intended use. Pediatric and adult filters are challenged with either 0.1 mg or 0.2 mg of sodium chloride particles at 15 L/min or 30 L/min, respectively. Filters are preconditioned in humidified air to simulate a period of clinical use before they are tested. Nonelectrostatically charged dry salt particles are used for the challenge, because they are very difficult to trap. The method does not assess the filtration performance for droplets and aerosols, nor does it purport to test the filtration performance for microorganisms. It is for comparison purposes only and has no proven clinical relevance. The standard contains no threshold for minimum performance of breathing system filter efficiency. The test results are expressed as the *percent filtration efficiency*, which is the percent of particles in the challenge that *do not* pass through the filter. For example, if the filter is challenged with 10 million ( $10^7$ ) particles, and 1000 ( $10^3$ ) particles are detected on the other side, then the percent filtration efficiency is  $100 * (1 - 10^3 / 10^7) = 99.99\%$ .

Entirely different standards are used for testing and rating other types of filters. Notably, the National Institute for Occupational Health and Safety, developed *NIOSH 42 CFR Part 84: Respiratory Protective Devices*<sup>17</sup> as a method to test and rate nonpowered air-purifying respirators. N-series respirators that are used in health care are challenged with 200 mg of nonelectrostatically charged dry sodium chloride particles that are 0.1 to 0.3 microns in size at a flow rate of 85 L/min.<sup>18</sup> This is a similar but more challenging test than ISO 23328-1 due to the higher particle mass and flow rate. Another notable filtration testing standard is *IEST-RP-CC001: HEPA and ULPA Filters*,<sup>19</sup> which tests the performance of filters used in clean air devices and clean rooms. HEPA refers to *high-efficiency particle air* filters that remove 99.97% of particles whose diameter is equal to 0.3 microns. However, it is not appropriate

to apply this term to breathing system filters because the test methods are different.

#### Microorganism Filtration

Some breathing system filter product literature contains statements about bacterial and or viral filtration efficiency. There is no standard test for determining the bacterial and or viral filtration efficiency of breathing system filters, but there are standard methods for determining this for other types of filters. One of these is *ASTM F2101-19: Standard test method for evaluating the bacterial filtration efficiency (BFE) of medical face mask materials, using a biological aerosol of Staphylococcus aureus*.<sup>20</sup> A similar procedure using biologic aerosols of *Bacillus subtilis* or MS-2 coliphage to test breathing system filters is described by Wilkes et al.<sup>21</sup> and is the same as that in Draft BS EN 13328-1 (which never got past the draft stage). In both procedures, suspensions of bacteria or viruses are aerosolized to a mean liquid particle size of 3.0 microns and drawn through the filter material by a downstream vacuum. Anything that passes through the filter is captured either into nutrient broth or onto culture plates. Percent filtration efficiency is calculated by dividing the number of cultured particles downstream of the filter by the number in the upstream challenge. At face value, these methods might seem more clinically relevant than the salt test method. They use larger sized fluid particles than the salt test method. The fluid particles may be electrostatically charged. Only viable microorganisms are counted. However, these methods are less reproducible. In general, the same filter will have greater percent filtration efficiencies for bacteria, than for viruses, than for salt particles.

### BUBBLE POINT TESTING

Membrane filters are rated by pore size, which is indirectly determined using the bubble point test. The bubble point test is based on the principle that liquid is held in the pores of the filter by surface tension and capillary forces, and that the minimum pressure required to force liquid out of the pores is related to the pore diameter. However, pore size cannot be used as a surrogate for particle or pathogen filtration efficiency. *Hydrophilic* 0.22-micron membrane filters are commonly used to sterilize pharmaceuticals, and to maintain sterility of epidural infusions, but their efficiency at filtering airborne particles has not been tested.

See "System Filters," Next Page



## RAPID Response

to questions from readers

# Clinicians Should Know Specifications for Breathing System Filters in Use

### From "System Filters," Preceding Page

Some 0.2-micron *hydrophobic* membrane filters (e.g., those in the GE D-Fend Pro, Dräger Water-Lock® 2, and Covidien FilterLine® water traps) have been independently tested, and have an airborne viral filtration efficiency of 99.99% or greater.

### CLINICAL RECOMMENDATIONS

In 2003, the United States Center for Disease Control stated, "No recommendation can be made for placing a bacterial filter in the breathing system or patient circuit of anesthesia equipment," citing now 40-year old studies that showed failure of sterile breathing circuits or breathing system filters to reduce the incidence of postoperative pneumonia.<sup>22</sup> There is no current regulation to use breathing system filters on anesthesia machines. However, it seems prudent to prevent, as best as possible, the cross-infection of patients with SARS-CoV-2 during this COVID-19 pandemic. There are sparse reports of cross-infection from contaminated anesthesia machines prior to SARS, MERS, and COVID-19, but the risk from these pathogens is not currently known. Out of an abundance of caution and informed by existing knowledge, the APSF and ASA recommend using breathing system filters, recognizing that the science is incomplete. (<https://www.apsf.org/faq-on-anesthesia-machine-use-protection-and-decontamination-during-the-covid-19-pandemic/>).

Adding breathing system filters is not without risk.<sup>23,24</sup> Depending on placement, they can add dead space which increases carbon dioxide rebreathing and slows inhalation induction and emergence. They increase resistance to inspiratory and/or expiratory flow, which increases spontaneous work of breathing, and affects pulmonary mechanics (testing methods are described in international standard ISO 9360-1).<sup>25</sup> Filters can become obstructed leading to life-threatening hypoventilation and barotrauma. They add weight to the breathing circuit and add sites for accidental disconnection.

The filtration efficiency required to prevent infection from exhaled viruses via the breathing system is not known. If a patient exhales 200,000 virus particles per hour, then an electrostatic filter that traps 99.9% of them will allow only 200 to pass. Placing two of these filters in series (e.g., one at the airway and one on the expiratory limb) will multiply the filtration efficiency to 99.9999%, making the risk of virus passage almost nil, but will double the resistance to flow. Using a single higher efficiency (e.g., 99.9999%) pleated mechanical breathing

system filter at the airway will capture the same number of viruses and introduce less airway resistance than two electrostatic filters in series, but may increase the dead space.

Clinicians should know the specifications for the breathing system filters available to them. These can be found from the manufacturer's web site or help line, in product literature, online, and in journal articles.<sup>13,14</sup> Important specifications are:

- bacterial and viral filtration efficiency (%—higher is better),
- NaCl or salt filtration efficiency (%—higher is better),
- resistance to flow (pressure drop in Pa or cmH<sub>2</sub>O at a given airflow rate in L/min—lower is better),
- how the former specifications are affected by filter conditioning in humidity,
- internal volume (ml—lower is better), and
- humidification
  - (moisture loss in mgH<sub>2</sub>O/L of air—lower is better), or
  - (moisture output in mgH<sub>2</sub>O/L of air—higher is better).

Note that some publications list evaluations that were done 10 or 20 years ago, and that products may change, or be manufactured or distributed by different companies.

Robert G. Loeb, MD, is clinical professor of anesthesiology at the University of Florida College of Medicine, Gainesville, FL.

He is employee of the University of Florida, chair of the American Society of Anesthesiologists Committee on Equipment and Facilities, and he is on the Masimo, Inc. Technical Advisory Board.

### REFERENCES

1. Murphy PM, Fitzgeorge RB, Barrett RF. Viability and distribution of bacteria after passage through a circle anaesthetic system. *Br J Anaesth*. 1991;66:300–304.
2. Atkinson MC, Girgis Y, Broome JJ. Extent and practicalities of filter use in anaesthetic breathing circuits and attitudes towards their use: a postal survey of UK hospitals. *Anaesthesia*. 1999;54:37–41.
3. Chant K, Kociuba K, Munro R, et al. Investigation of possible patient-to-patient transmission of hepatitis C in a hospital. *New South Wales Public Health Bulletin*. 1994;5:47–51.
4. Spertini V, Borsoi L, Berger J, et al. Bacterial contamination of anesthesia machines' internal breathing-circuit-systems. *GMS Hyg Infect Control*. 2011;6(1).
5. Lloyd G, Howells J, Liddle C, et al. Barriers to hepatitis C transmission within breathing systems: efficacy of a pleated hydrophobic filter. *Anaesth Intensive Care*. 1997;25:235–238.
6. Heinsen A, Bendtsen F, Fomsgaard A. A phylogenetic analysis elucidating a case of patient-to-patient transmission of hepatitis C virus during surgery. *J Hosp Infect*. 2000;46:309–313.
7. Australian & New Zealand College of Anaesthetists. PS28 Guideline on infection control in anaesthesia 2015. Available at: <https://www.anzca.edu.au/safety-advocacy/standards-of-practice/policies-statements-and-guidelines> Accessed July 6, 2020.
8. Association of Anaesthetists of Great Britain & Ireland. Guidelines: infection prevention and control 2020. [https://anaesthetists.org/Portals/0/PDFs/Guidelines%20PDFs/Infection\\_Control\\_Guideline\\_FINAL%202020.pdf?ver=2020-01-20-105932-143](https://anaesthetists.org/Portals/0/PDFs/Guidelines%20PDFs/Infection_Control_Guideline_FINAL%202020.pdf?ver=2020-01-20-105932-143) Accessed July 6, 2020.
9. Tellier R, Li Y, Cowling BJ, Tang JW. Recognition of aerosol transmission of infectious agents: a commentary. *BMC Infect Dis*. 2019;19:101.
10. Leung NH, Chu DK, Shiu EY, et al. Respiratory virus shedding in exhaled breath and efficacy of face masks. *Nat Med*. 2020;26:676–680.
11. Nicas M, Hubbard AE, Jones RM, Reingold AL. The infectious dose of variola (smallpox) virus. *Appl Biosaf*. 2004;9:118–127.
12. Hakobyan NA. Introduction to basics of submicron aerosol particles filtration theory via ultrafine fiber media. *Armen J Phys*. 2015;8:140–151.
13. Wilkes A. Breathing system filters: an assessment of 104 breathing system filters. MHRA Evaluation 04005. March 2004 <https://www.psnetwork.org/wp-content/uploads/2018/01/An-assessment-of-104-breathing-system-filters-MHRA-Evaluation-04005-2004.pdf> Accessed July 6, 2020.
14. Wilkes AR. The ability of breathing system filters to prevent liquid contamination of breathing systems: a laboratory study\* APPARATUS. *Anaesthesia*. 2002;57:33–39.
15. Wilkes AR. Heat and moisture exchangers and breathing system filters: their use in anaesthesia and intensive care. Part 1—history, principles and efficiency. *Anaesthesia*. 2011;66:31–9.
16. International Organization for Standardization. Breathing system filters for anaesthetic and respiratory use — Part 1: Salt test method to assess filtration performance. (ISO 23328-1:2003) <https://www.iso.org/standard/35330.html> Accessed July 6, 2020.
17. Department of Health and Human Services. 42 CFR Part 84 Respiratory protective devices; final rules and notice. Federal Register Volume 60, Number 110 (Thursday, June 8, 1995). <https://www.govinfo.gov/content/pkg/FR-1995-06-08/html/95-13287.htm> Accessed July 6, 2020.
18. National Institute for Occupational Safety and Health. Determination of particulate filter efficiency level for N95 series filters against solid particulates for non-powered, air-purifying respirators standard testing procedure (STP). <https://www.cdc.gov/niosh/nppt/stps/pdfs/TEB-APR-STP-0059-508.pdf> Accessed July 6, 2020.
19. Institute for Environmental Sciences and Technology. HEPA and ULPA Filters. (IEST-RP-CC001) <https://www.iest.org/Standards-RPs/Recommended-Practices/EST-RP-CC001> Accessed July 6, 2020.
20. ASTM International. Standard test method for evaluating the bacterial filtration efficiency (BFE) of medical face mask materials, using a biological aerosol of *Staphylococcus aureus*. (F2101 – 19) [https://compass.astm.org/EDIT/html\\_annot.cgi?F2101+19](https://compass.astm.org/EDIT/html_annot.cgi?F2101+19) Accessed July 6, 2020.
21. Wilkes AR, Benbough JE, Speight SE, et al. The bacterial and viral filtration performance of breathing system filters. *Anaesthesia*. 2000;55:458–465.
22. CDC Healthcare Infection Control Practices Advisory Committee. Guidelines for preventing health-care-associated pneumonia, 2003. *MMWR* 53(RR03); 1–36, 2004.
23. Lawes EG. Hidden hazards and dangers associated with the use of HME/filters in breathing circuits. Their effect on toxic metabolite production, pulse oximetry and airway resistance. *Br J Anaesth*. 2003;91:249–264.
24. Wilkes AR. Heat and moisture exchangers and breathing system filters: their use in anaesthesia and intensive care. Part 2—practical use, including problems, and their use with paediatric patients. *Anaesthesia*. 2011;66:40–51.
25. International Standards Organization. Anaesthetic and respiratory equipment—heat and moisture exchangers (HMEs) for humidifying respired gases in humans—part 1: HMEs for use with tracheostomized patients having minimal tidal volume of 250 ml (ISO 9360-2: 2001).

# The MHC Story: Accelerating Implementation of Best Practices Through Improved Organizational Macro-Ergonomics

## Updates from the Perioperative Multi-Center Handoff Collaborative (MHC)

by Bommy Hong Mershon, MD, and Philip E. Greilich, MD, MSc

Scaling and sustaining change in health care is complex and generally requires aligning the efforts of interdisciplinary groups on multiple levels. Examples include the use of participatory design to adapt a best practice to a given clinical unit, forming guidance teams to scale successful unit-based efforts throughout a hospital or health system, and incentivizing wide-spread dissemination of effective implementation strategies by medical societies, large group practices, and regulatory and funding agencies. Some of the most successful efforts to date have used a “learning collaborative” to focus on a specific patient safety priority over an extended period of time. This type of organizational macro-ergonomic facilitates alignment of context experts (clinicians), subject matter experts (e.g., human factors, implementation science, systems engineering, information technology), and organizations that promote patient safety. The Michigan Keystone Project (for central lines)<sup>1</sup> and the Safe Surgery program in South Carolina (for surgical checklists)<sup>2</sup> are two such exemplars, though other examples continue to emerge.

The Perioperative Multi-Center Handoff Collaborative (MHC) is a national learning collaborative whose primary objective is to create pragmatic, scalable, and sustainable practices that will increase the efficiency and effectiveness of handoffs and care transitions for clinicians, patients, and their families. It was formed in 2015 by a group of academic anesthesiologists who were leading pilot efforts at their respective institutions. A partnership with the Anesthesia Patient Safety Foundation (APSF) led to the planning and conduct of the first Stoelting Consensus Conference on Perioperative Handoffs in 2017. This interprofessional conference of patient safety experts achieved high levels of consensus over 50 recommendations<sup>3</sup> that laid the foundation for the formation of the MHC’s initial working group on education, implementation, and research. The collaborative relationship was solidified when APSF sponsored the MHC as its special interest group (SIG) for championing handoffs and care transitions, one of its patient safety priorities (#7 Handoffs & Care Transitions).<sup>4</sup> This support was instrumental for the launch of MHC’s website ([www.handoffs.org](http://www.handoffs.org)), which is intended to increase visibility and connect its members to other medical societies, industry, medical groups, insurers, and regulatory agencies.

As a boundary-spanning organization, the MHC seeks to accelerate the development of scalable solutions for handoffs through experimentation and thoughtful expansion of its collaborative partnerships. Although its membership now comprises a substantial interdisciplinary “brain trust” that represents more than 20 academic medical centers within the United States, strategic partnerships will be required to generate products for discovery (grants, manuscripts), multilevel education (curriculum), and implementation (tools, strategies) for both the public and private sectors. One such example is the collaborative partnership created in 2018 with Epic, the electronic medical record (EMR) vendor for over half of the institutions providing anesthesia in the United States. Given growing evidence of a relationship between number of handoffs and morbidity and mortality,<sup>5-7</sup> the MHC’s Implementation Working Group began working with an Epic Foundation team to design a platform that would improve the intraoperative anesthesia handoff process. Here we describe the process and achievements of that collaboration.

After official formation of the MHC, our EMR workgroup first met in December 2017. The core members consisted of the Epic team—Felix Lin, Adam Marsh, and Spencer Small—along with anesthesiologists from different institutions: Philip Greilich, MD (UT Southwestern, MHC founding chair), Aalok Agarwala, MD (Massachusetts General, MHC steering board member), Patrick Guffey, MD (Children’s Hospital of Colorado, Epic Steering Committee), Guy De-Lisle Dear, MD (Duke), Trent Bryson, MD (UT Southwestern), and Bommy Hong Mershon, MD (Johns Hopkins). We met monthly over the next two years, with additional members joining throughout. Our workgroup’s goal was to design an intraoperative handoff tool in Epic through this collaborative partnership.

Initially, we compared each institution’s own intraoperative handoff tools in Epic: what worked, what needed improvement, and the limitations that our local Epic programmers encountered. Led by Felix Lin (Epic), we surveyed the clinicians in our group on the critical and necessary elements that needed to be in an intraoperative handoff tool. Based on this information, our design approach was to reduce clutter, streamline the most crucial information elements essential to an intraoperative handoff, and minimize the “clicking” and “scroll-

The screenshot shows the Epic intraoperative handoff tool interface. It features a sidebar with navigation links: 'Preprocedure Note', 'Preprocedure Meds', 'Airways', 'LDAs', and 'Handoff Complete'. The main content area is titled 'Airways' and contains the following information:

- Airway**
- Mask difficulty: 1 - vent by mask
- Type: endotracheal airway
- Endotracheal airway: ETT
- Technique: direct laryngoscopy
- Blade: Macintosh
- ETT Size (mm): 7.5
- Grader: grade I - full view of glottis
- Attempts: 1

Below the 'Airways' section is the 'LDAs' section, which includes a table:

Type	Placement
Peripheral	04/13/20 1626
IV	
ETT	04/13/20 1636

Below the 'LDAs' section is the 'Situational Awareness & Planning' section, which contains a checklist of questions:

- Are you anticipating any changes?
- Does anything need to happen right now?
- Are there any labs pending?
- Do you have any concerns?

Below the 'Situational Awareness & Planning' section is the 'Postprocedure Care Plan' section, which includes checkboxes for 'Extubate vs. remain intubated (PACU vs. ICU)' and 'Analgesic plan and PONV plan'.

Below the 'Postprocedure Care Plan' section is the 'Synthesis by Receiver' section, which asks 'What questions do you have?'.

At the bottom of the interface is a 'Handoff Complete' button.

Figure 1: First version of the intraoperative handoff tool (reprinted with permission from ©2020 Epic Systems Corporation) in the Epic intraoperative record.

ing” that was prevalent when navigating within the Epic intraoperative record. It was also important that we incorporate mandatory documentation such as the staffing time grid when the handoff occurs. We applied quality improvement principles of standardizing critical information elements<sup>8,9</sup> and integrated these guidelines into the workflow to ultimately make it accessible and easy to use. However, institutions could customize the specific data points displayed within the different standardized critical information elements according to their specific workflow and preference in a process considered “adapting standard work to individual customers.”<sup>10</sup>

See “MHC Story,” Next Page

# Handoffs Can Be Integrated into the Electronic Medical Record

## From “MHC Story,” Preceding Page

We also recognized that good handoff communication is not just about information transfer. The most important factor for successful handoffs is interactive communication, supported by the cognitive load theory of working memory.<sup>11</sup> Our consensus was to add a static text box to prompt the handoff giver and receiver to engage with each other.

Within 18 months of forming this collaborative partnership, Epic was able to launch the first official version (Figure 1) of the handoff tool in August 2019. The latest version (Figure 2), released in February 2020, contains additional information elements. This handoff tool was disseminated to more than 50% of all Epic customers in this short time.

Because of limitations related to programming and internal review within Epic, these versions do not include all of the elements our group had originally designed and requested. Epic developers decided to focus on creating a tool that offered the available elements in the most user-friendly format for easier adoption by more institutions. Our group is continuing to work with Epic to further refine this tool and to develop a set of user requirements that could be adopted by other EMR vendors.

Moving forward, our goals are to 1) improve the functionality of the Epic mobile version, or Haiku, in a way that makes viewing a patient's record more clinician-centered and enables it to be used for handoffs and 2) focus on the operating room to postanesthesia care unit and operating room to intensive care unit (ICU) handoffs. Future plans include expansion to improving handoffs in other perioperative environments such as ICU, ER, floor to OR handoffs.

Complex health processes such as handoffs benefit greatly if we approach them through collaborative partnerships. Design, implementation, and dissemination of guidelines, best practices, and tools can be achieved more efficiently and effectively and thereby help improve health care at the national level. A national conference, funded by the Agency for Healthcare, Quality and Research (AHRQ), is scheduled to convene in 2021 to bring major stakeholders together to plan scalable solutions for teaching, implementing, and investigating best practices for perioperative handoffs and care transitions.

*Bommy Hong Mershon, MD, is assistant professor at the Johns Hopkins Department of Anesthesiology and Critical Care Medicine, Baltimore, MD.*

Intake	
PRBC - EMERGENT	350.00 mL
NaCl 0.45%	500.00 mL
<b>Total Intake</b>	<b>850 mL</b>
Output	
Urine	75 mL
Est. Blood Loss	10 mL
<b>Total Output</b>	<b>85 mL</b>
<b>Net</b>	
<b>Net Volume</b>	<b>765 mL</b>

Figure 2: Current version of the handoff tool (reprinted with permission from ©2020 Epic Systems Corporation) in the Epic intraoperative record. In the live Epic intraoperative record, this sidebar is shown as a continuous vertical column that can be viewed by scrolling up and down.

Philip E. Greulich, MD, MSc, is professor in the Department of Anesthesiology & Pain Management at the University of Texas Southwestern Medical Center, Dallas, TX.

*The authors have no conflicts of interest.*

## REFERENCES

- Reames BN, Krell RW, Campbell DA, et al. A checklist-based intervention to improve surgical outcomes in Michigan. *JAMA Surg*. Published online 2015. doi:10.1001/jama-surg.2014.2873 Accessed January 11, 2021.
- Donahue B. In South Carolina, proof that surgical safety checklist really works. *Outpatient Surgery Magazine*. [http://www.outpatientsurgery.net/newsletter/eweekly/2017/04/18/in-south-carolina-proof-that-surgical-safety-checklist-really-works#:~:text=At the heart of Safe,incision of the skin \(%22time](http://www.outpatientsurgery.net/newsletter/eweekly/2017/04/18/in-south-carolina-proof-that-surgical-safety-checklist-really-works#:~:text=At the heart of Safe,incision of the skin (%22time) Accessed July 21, 2020.
- Agarwala AV, Lane-Fall MB, Greulich PE, et al. Consensus recommendations for the conduct, training, implementation, and research of perioperative handoffs. *Anesth Analg*. Published online 2019. doi:10.1213/ANE.0000000000004118 Accessed January 11, 2021.
- APSF's Perioperative Patient Safety Priorities. *apsf.org*. Published 2018. <https://www.apsf.org/patient-safety-initiatives/> Accessed November 12, 2020.
- Hyder JA, Bohman JK, Kor DJ, et al. Anesthesia care transitions and risk of postoperative complications. *Anesth Analg*. Published online 2016. doi:10.1213/ANE.0000000000000692 Accessed December 21, 2020.
- Jones PM, Cherry RA, Allen BN, et al. Association between handover of anesthesia care and adverse postoperative outcomes among patients undergoing major surgery. *JAMA*. Published online 2018. doi:10.1001/jama.2017.20040 Accessed December 21, 2020.
- Saager L, Hesler BD, You J, et al. Intraoperative transitions of anesthesia care and postoperative adverse outcomes. *Anesthesiology*. Published online 2014. doi:10.1097/ALN.0000000000000401 Accessed December 21, 2020.
- Rozich JD, Howard RJ, Justeson JM, et al. Standardization as a mechanism to improve safety in health care. *Jt Comm J Qual Saf*. Published online 2004. doi:10.1016/S1549-3741(04)30001-8 Accessed December 21, 2020.
- Quisenberry E. How does standard work lead to better patient safety. <https://www.virginiamasoninstitute.org/how-does-standard-work-lead-to-better-patient-safety/> Accessed December 21, 2020.
- Goitein L, James B. Standardized best practices and individual craft-based medicine: a conversation about quality. *JAMA Intern Med*. Published online 2016. doi:10.1001/jamainternmed.2016.1641 Accessed December 21, 2020.
- Young JQ, Wachter RM, Ten Cate O, et al. Advancing the next generation of handover research and practice with cognitive load theory. *BMJ Qual Saf*. Published online 2016. doi:10.1136/bmjqs-2015-004181 Accessed December 21, 2020.



# Proactive Perioperative Risk Analysis: Use of Failure Mode and Effects Analysis (FMEA)

by George Tewfik, MD, MBA, CPE

Failure mode and effects analysis (FMEA) is an invaluable tool that has been used in industry to identify potential points of failure in a process, to evaluate their causes and effects, and to determine ways to decrease risks.<sup>1</sup> Patient safety initiatives have incorporated strategies such as FMEA in addition to other techniques, e.g., root cause analysis (RCA) and the safety assessment code (SAC). The patient safety program at the Dept. of Veterans Affairs (VA)<sup>2</sup> dates back nearly 30 years; approaching error reduction on a systemic basis in the VA was associated with a significant reduction in MRI hazards and cardiac pacemaker malfunction, supporting the role of proactive analysis.<sup>2</sup> Systemic analysis for patient safety improvement has a long history, including such programs as the Safer Patients Initiative launched in the United Kingdom (2004–2008), which in its first year saw a decrease of adverse events from 7% to 1.5% per 1,000 patient days by improving reliability in general ward care, critical care, perioperative care, and medication management.<sup>3</sup>

Risk assessment using FMEA has been used effectively in hospitals to minimize medical errors; it has been deployed in many different settings.<sup>4,5,6</sup> One study of administration of unfractionated heparin identified hundreds of potential failures with a hundred more causes, and deployed dozens of countermeasures to improve medication administration safety.<sup>7</sup> After an extensive study at a 367-bed academic pediatric hospital, 233 potential points of failure were identified with the administration of unfractionated heparin including mathematical errors, unknown requirements for administration, incorrect timing, difficulties accessing information from hospital EMR, poor patient education, and the ability to administer incorrect dosages.<sup>7</sup> The application of countermeasures for the process steps identified as having the highest Risk Priority Number yielded a statistically significant improvement in the scores with resultant improvement in safety for the administration of unfractionated heparin.<sup>7</sup>

FMEA has been successfully deployed to enhance the safety of radiotherapy,<sup>8-10</sup> hospital or community pharmacy processes,<sup>11,12</sup> clinical laboratory processes,<sup>13</sup> blood transfusion,<sup>14</sup> and clinical trials.<sup>15</sup> Deployment of FMEA across a unit or service has also been demonstrated to improve such processes as transfers of care, lab/radiology requests or admission in Emergency Departments,<sup>16,17</sup> and overall systemic functionality in intensive care units (ICUs).<sup>18</sup> Finally, FMEA has been successful at attempts to not only improve systemic processes, but also to identify points of failure leading to hospi-

**Table 1: Examples of Anesthesia and Perioperative Processes to which failure mode and effects analysis (FMEA) may be applied.**

Medication Safety	Equipment	Clinical care	Hospital processes
Allergy avoidance	Routine check	Airway management	OR Scheduling
Ordering	Equipment failure	Avoid laryngospasm	Patient transport
Administration	Availability	Prevention of PONV	Bed management
Postadministration monitoring	Emergency equipment	Perioperative pain management	OR turnover
		Surgical site infection prevention	
Pre-operative workup	PACU processes	Regional Anesthesia	
Case booking	Patient monitoring	Consent/Scheduling	
PAT booking	Patient evaluation	Equipment preparation	
Consultations	PONV management	Catheter management	
Labs/testing	Pain management		
Anesthesia evaluation			

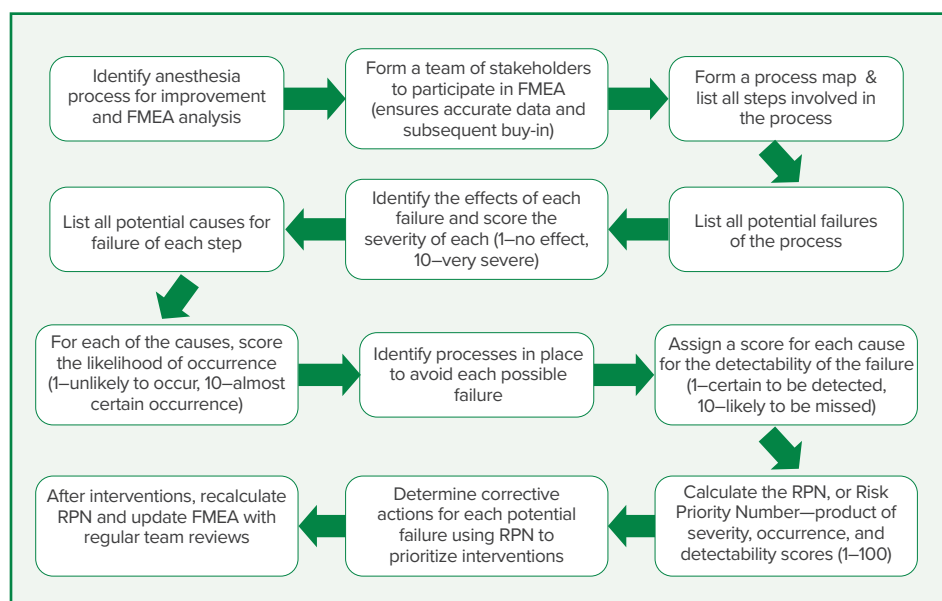


Figure 1: Application of FMEA and the steps involved for an anesthesia process.

tal complications such as posture syndrome of thyroid surgery<sup>19</sup> or venous thromboembolic disease in critically ill patients.<sup>20</sup>

Despite its demonstrated benefit, there is sparse literature examining the role of FMEA in anesthesiology. Past studies have been limited to examining maintenance and repair of anesthesia equipment,<sup>21</sup> avoiding medication errors in pediatric anesthesia,<sup>6</sup> and enhancing safety of propofol sedation in endoscopy.<sup>22</sup> However,

the practice of anesthesiology, which is a systems-based specialty with numerous processes that have similarities to manufacturing, lends itself to the use of FMEA to both identify potential adverse outcomes resulting from errors and to improve productivity. Table 1 illustrates categories and subcategories of anesthesia processes to which FMEA could be applied.

See “FMEA,” Next Page

## FMEA Can Be Applied to a Variety of Anesthesia Related Practices

### From “FMEA,” Preceding Page

The steps involved in conducting an FMEA for an anesthesia process are demonstrated in Figure 1. The first two steps are critically important for success—namely the identification of the process for optimization and assembly of a team for involvement in the analysis and subsequent interventions. The necessary stakeholders in any complicated system must be involved to ensure adequate input during analysis so that buy-in is present when corrective actions are identified. For example, “Prevention of postoperative nausea and vomiting” is a process that likely will require corrective actions that involve the pharmacy, surgical services, and preoperative nursing, without whose participation remedies might not be successfully deployed.

The next step is also critical: Creating a list of all steps in the process. It’s usually helpful to create a process map. For each step, all potential modes of failure are listed and the possible

effect of failure is recorded. Next, the severity of each failure is scored (1—least severe to 10—most severe), the potential causes for each failure are identified, and the likelihood of occurrence is scored (1—least likely to 10—near certain occurrence). Any “controls” to prevent the failure are identified and the levels of potential detection are scored (1—certain detection to 10—unlikely detection). The Risk Priority Number (RPN) is determined by multiplying the severity, occurrence, and detection scores; this number can be used by the working group to prioritize which steps to mark for corrective actions and re-evaluation. A higher RPN score indicates an area of more urgent need for intervention and process improvement, whereas a lower RPN denotes a task or step of less immediate importance.

### APPLYING FMEA TO PRE-ANESTHESIA EVALUATIONS

At University Hospital in Newark NJ, we performed an FMEA for the process of pre-anes-

thesia evaluations. Those are conducted for outpatients at the Pre-Admission Testing Clinic, who are referred for evaluation by surgeons’ offices after cases have been booked. Table 2 shows a simplified version of the FMEA analysis we conducted in the first two months of 2020 to evaluate the process. The process begins with booking an appointment in the clinic and ends with giving the patient instructions for the day of surgery. Each of the process functions are displayed in Column 1 with subsequent analysis using the steps above to calculate an RPN for each function. As shown in Table 2, the functions with the three highest RPN scores are: “Patient present for evaluation,” “Available staff,” and “Consults.” This information has allowed the senior leadership to focus efforts to make the most impact to improve the process of obtaining a thorough pre-anesthesia evaluation.

See “FMEA,” Next Page

**Table 2: An Example of FMEA Analysis Done at University Hospital in Newark, NJ Analyzing the Steps Involved in Obtaining a Pre-anesthesia Evaluation at the Pre-Admission Testing Clinic, Run by the Anesthesiology Department.**

Severity scored 1–10 (1—least severe to 10—most severe), Occurrence scored 1–10 (1—least likely to 10—near certainty) and Detectability scored 1–10 (1—certain detection to 10—unlikely detection); RPN is the product of Severity, Occurrence, and Detectability scored 1–100 and is used to prioritize processes to avoid failure and deploy appropriate resources/manpower for improvement (highest scores given most urgent attention).

### Pre-Anesthesia Evaluation (in Pre-Admission Testing Clinic)

Process Function	Potential Failure	Effect of Failure	Severity	Potential Cause of Failure	Occurrence	Process Controls	Detectability	RPN
Booking an appt for Pre-Anesthesia Evaluation	Unable to book appt	No Pre-Anesth eval prior to Day of Surgery	7	Poor comm. from Surgery to book appt	3	Auto-booking of all surgical patients in Pre-Anes Clinic	1	21
Reminder for appt	Reminder doesn't reach patient	No-show	6	No phone, email etc	3	Reminder by phone, text, email; Surgeon's office reminds pt. for appt	1	18
Patient presents for evaluation	No-show for appt	No Pre-Anesth eval	7	Failed transport, no vehicle	5	Medical transport, Family transport, Ride-sharing svc.	1	35
Available NP, resident, CRNA or physician anesthesiologist for evaluation	None available	Delayed or no eval	7	Staff shortages, unexpected call-outs	4	Hiring additional NP, increase tele-visits by residents	1	28
Accurate history	Incorrect info	Poor quality eval	4	Language/ cognitive barrier	2	Translator, family	1	8
Consults	Not obtained	No consult received	8	Unable to schedule, pt no show	3	Anes follow up	1	24
Labs drawn	Not drawn	Labs not available	3	Veins, pt not cooperative	3	Venipuncture train	1	9
Lab referrals	Not given	CXR, TTE, etc not ready	5	Rx, communication w/ pt	3	Office F/U	1	15
Instructions for DOS	Not done	Not prepared for Sx	5	Language/ cognitive barrier	2	Translator, family	1	10

## FMEA May Improve Patient Safety While Optimizing Efficiency

### From “FMEA,” Preceding Page

Steps that have been implemented, or are in the process of implementation, include improving patient transport to appointments and confirmation of transport with patients when booking with office staff. To address a lack of available staff to evaluate patients in clinic, an anesthesia resident is assigned for a pre-anesthesia evaluation clinic rotation to see patients in addition to the two nurse practitioners who routinely staff it. In addition, plans are being made to deploy telemedicine to replace many of the in-person evaluations, which will likely improve efficiency of visits, and relieve the strain of limited staff. Finally, we addressed possible failures in obtaining timely consults, such as cardiology to evaluate for congestive heart failure (CHF) or pulmonology to evaluate worsening or uncontrolled chronic obstructive pulmonary disease (COPD), by improving communication with the consultants' offices and scheduling consult appointments through anesthesia, instead of relying on patients. In addition, anesthesia office staff follow up with consultants to ensure patient presence for appointments and enlist surgeons' offices to also assist with this process.

FMEA is a powerful tool to improve health care facility processes and can be particularly effective in perioperative medicine. After deployment of each intervention and corrective action, the analysis can be repeated; rescoring of the RPN will elucidate success or failure of such actions. In addition, an updated score will allow leaders to redeploy resources including time and money to process functions that have the highest failure potential. For example, using

the model in Table 2, the process function “booking in clinic” may emerge as the most significant potential failure once the three most problematic processes have been improved.

Despite its established potential for identifying risks and process failures in health care, FMEA does not appear to be as widely employed as might be expected generally and there are few applications in perioperative medicine and anesthesiology. There are several possible reasons for its lack of regular use, such as the tedious nature of the steps involved, requiring a multidisciplinary team and detailed information-gathering.<sup>23</sup> Franklin et al. recommend a more targeted approach using FMEA, emphasizing the significance of the multidisciplinary mapping process and its potential for further analysis and intervention.<sup>23</sup> The authors further raise a critical limitation of the RPN, in that all three variables from which the score is derived (severity, occurrence and detectability) are equally weighted, resulting in situations where RPNs may be the same for different process steps, but the underlying factors significantly consequential.<sup>23</sup>

In 2013, Liu H-C et al. conducted an extensive review concerning FMEA use in health care and showed that the most common major shortcomings cited in the literature include not considering the relative importance of occurrence, severity, and detectability, difficulty assessing the three risk factors, inability to evaluate similar RPNs with different underlying scores, and a questionable equation used to calculate RPN amongst numerous other limitations.<sup>1</sup> A possible alternative to FMEA may be Healthcare Failure Mode and Effects Analysis (HFMEA)

developed by the National Center for Patient Safety and implemented by the VA National Center for Patient Safety.<sup>24</sup> This approach differs from traditional FMEA by combining detectability and criticality steps of FMEA into a decision-making algorithm and replaces the RPN with a hazard score, yielding a process in which deliberation on interventions for potential failures is simpler and more responsive to user input/expertise.<sup>24</sup>

An important consideration when using FMEA is that hospital systems often have unique process functions that differ greatly between institutions, necessitating individualized analysis for each facility. For example, an examination of steps to prevent surgical site infections may find that surgical residents place orders for preoperative antibiotics, and that antibiotics are kept in a central drug-dispensing machine. In such a scenario, compliance with perioperative antibiotic administration requires the successful placement of the order, a nurse to check the order, the nurse to retrieve the medication and deliver it to the anesthesia team, and anesthesia to administer the medication, with numerous additional substeps and potential failures for each. This differs from many other institutions where anesthesia professionals may be responsible for determining antibiotic administration and those antibiotics are stored in anesthesia carts in the operating rooms. The mapping of an institution's process may not translate to other facilities.

### CONCLUSION

Although FMEA has its limitations, it is a valuable tool for proactive process analysis to improve both patient safety and optimize efficiency. Assembling a multidisciplinary team to conduct an FMEA enables leadership to focus on the most problematic and high-impact steps of a process that may fail and to assign resources to those functions to bring about corrective action. FMEA further enables a team to continually assess the usefulness of interventions and redeploy resources where they will continue to make the biggest impact. This author strongly recommends its use in anesthesiology and perioperative medical processes to assist in improving quality and safety via a systematic process to identify where attention and resources will be most effective.

*George Tewfik, MD, is an assistant professor and director of Quality Assurance in the Department of Anesthesiology at Rutgers-New Jersey Medical School in Newark, NJ.*

*The author has no conflicts of interest.*

See “FMEA,” Next Page





## FMEA References

### From "FMEA," Preceding Page

#### REFERENCES

1. Liu H-C, Liu L, Liu N. Risk evaluation approaches in failure mode and effects analysis: a literature review. *Expert Systems with Applications*. 2013;40:828–838.
2. Bagian JP, Gosbee J, Lee CZ, et al. The Veterans Affairs root cause analysis system in action. *Jt Comm J Qual Improv*. 2002;28:531–545.
3. Improvement IfH. Safer patients initiative leads to reductions in mortality and adverse events in the United Kingdom. <http://www.ih.org/resources/Pages/ImprovementStories/SaferPatientsInitiativeLeadstoReductionsInMortalityandAEsintheUK.aspx>. Published 2006. Accessed July 19, 2020.
4. Asgari Dastjerdi H, Khorasani E, Yarmohammadian MH, et al. Evaluating the application of failure mode and effects analysis technique in hospital wards: a systematic review. *J Inj Violence Res*. 2017;9:51–60.
5. Aranaz-Andrés JM, Bermejo-Vicedo T, Muñoz-Ojeda I, et al. Failure mode and effects analysis applied to the administration of liquid medication by oral syringes. *Farm Hosp*. 2017;41:674–677.
6. Martin LD, Grigg EB, Verma S, et al. Outcomes of a failure mode and effects analysis for medication errors in pediatric anesthesia. *Paediatr Anaesth*. 2017;27:571–580.
7. Pino FA, Weidemann DK, Schroeder LL, et al. Failure mode and effects analysis to reduce risk of heparin use. *Am J Health Syst Pharm*. 2019.
8. Frewen H, Brown E, Jenkins M, O'Donovan A. Failure mode and effects analysis in a paperless radiotherapy department. *J Med Imaging Radiat Oncol*. 2018;62:707–715.
9. Giardina M, Cantone MC, Tomarchio E, et al. A review of healthcare failure mode and effects analysis (HFMEA) in radiotherapy. *Health Phys*. 2016;111:317–326.
10. Xu Z, Lee S, Albani D, et al. Evaluating radiotherapy treatment delay using failure mode and effects analysis (FMEA). *Radiother Oncol*. 2019;137:102–109.
11. Castro Vida M, Martínez de la Plata JE, Morales-Molina JA, et al. Identification and prioritisation of risks in a hospital pharmacy using healthcare failure mode and effect analysis. *Eur J Hosp Pharm*. 2019;26:66–72.
12. Stojković T, Marinković V, Jaehde U, et al. Using failure mode and effects analysis to reduce patient safety risks related to the dispensing process in the community pharmacy setting. *Res Social Adm Pharm*. 2017;13:1159–1166.
13. Jiang Y, Jiang H, Ding S, Liu Q. Application of failure mode and effects analysis in a clinical chemistry laboratory. *Clin Chim Acta*. 2015;448:80–85.
14. Lu Y, Teng F, Zhou J, Wen A, Bi Y. Failure mode and effect analysis in blood transfusion: a proactive tool to reduce risks. *Transfusion*. 2013;53:3080–3087.
15. Mañes-Sevilla M, Marzal-Alfaro MB, Romero Jiménez R, et al. Failure mode and effects analysis to improve quality in clinical trials. *J Healthc Qual Res*. 2018;33:33–47.
16. Sorrentino P. Use of failure mode and effects analysis to improve emergency department handoff processes. *Clin Nurse Spec*. 2016;30:28–37.
17. Taleghani YM, Rezaei F, Sheikhbardsiri H. Risk assessment of the emergency processes: healthcare failure mode and effect analysis. *World J Emerg Med*. 2016;7:97–105.
18. Yousefinezhadi T, Jannesar Nobari FA, Behzadi Goodari F, et al. A case study on improving intensive care unit (icu) services reliability: by using process failure mode and effects analysis (PFMEA). *Glob J Health Sci*. 2016;8:52635.
19. Zhang L, Zeng L, Yan Y, et al. Application of the healthcare failure mode and effects analysis system to reduce the incidence of posture syndrome of thyroid surgery. *Medicine (Baltimore)*. 2019;98:e18309.
20. Viejo Moreno R, Sánchez-Izquierdo Riera J, Molano Álvarez E, et al. Improvement of the safety of a clinical process using failure mode and effects analysis: Prevention of venous thromboembolic disease in critical patients. *Med Intensiva*. 2016;40:483–490.
21. Rosen MA, Lee BH, Sampson JB, et al. Failure mode and effects analysis applied to the maintenance and repair of anesthetic equipment in an austere medical environment. *Int J Qual Health Care*. 2014;26:404–410.
22. Huergo Fernández A, Amor Martín P, Fernández Cadenas F. Propofol sedation quality and safety. failure mode and effects analysis. *Rev Esp Enferm Dig*. 2017;109:602–603.
23. Dean Franklin B, Shebl NA, Barber N. Failure mode and effects analysis: too little for too much? *BMJ Qual Saf*. 2012;2:607–611.
24. Safety VNCfP. The basics of healthcare failure mode and effect analysis. U.S. Dept. of Veterans Affairs. <https://www.patientsafety.va.gov/docs/hfmea/HFMEAIntro.pdf>. Published 2001. Accessed July 20, 2020.

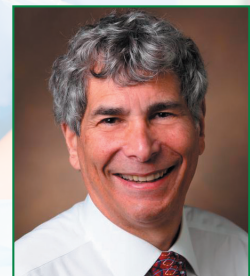
## APSF 2021 Stoelting Conference Clinician Safety: To Care is Human Hosts:



Patricia Mullen Reilly, CRNA



Brian Thomas, JD



Matthew Weinger, MD

**September 8–9, 2021**

**Royal Palms Resort and Spa, Phoenix, AZ**

For registration and conference inquiries, please contact  
Stacey Maxwell, APSF Administrator (maxwell@apsf.org).  
Hotel reservation block to be opened at a later date.

# Anesthesia Patient Safety Foundation

Founding Patron (\$360,000)  
American Society of Anesthesiologists (asahq.org)



American Society of  
**Anesthesiologists**<sup>™</sup>

## 2021 Corporate Advisory Council Members (current as of December 21, 2020)

### Platinum (\$50,000)



Acacia Pharma  
(acaciapharma.com)



GE Healthcare

(gehealthcare.com)



Fresenius Kabi  
(fresenius-kabi.us)



Masimo  
(masimo.com)

### Gold (\$30,000)



ICU Medical  
(icumedical.com)



Merck (merck.com)



Medtronic  
(medtronic.com)



Preferred Physicians  
Medical Risk  
Retention Group  
(ppmrg.com)

### Silver (\$10,000)

Senzime

### Bronze (\$5,000)

Ambu Codonics Dräger  
Medasense Respiratory Motion, Inc. Smiths Medical

**Special recognition and thank you to Medtronic for their support and funding of the APSF/Medtronic Patient Safety Research Grant (\$150,000); The Doctor's Company Foundation for their support and funding of APSF Patient Safety Prototype Development Project (\$100,000); and Merck for their educational grant.**

For more information about how your organization can support the APSF mission and participate in the 2021 Corporate Advisory Council, go to: [apfsf.org](https://apfsf.org) or contact Sara Moser at: [moser@apfsf.org](mailto:moser@apfsf.org).

## Community Donors (includes Specialty Organizations, Anesthesia Groups, ASA State Component Societies, and Individuals)

### Specialty Organizations

#### \$5,000 to \$14,999

American Academy of  
Anesthesiologist Assistants

#### \$2,000 to \$4,999

Society of Academic Associations of  
Anesthesiology and Perioperative  
Medicine  
The Academy of Anesthesiology

#### \$750 to \$1,999

American Society of Dentist  
Anesthesiologists  
Society for Airway Management  
Society for Pediatric Anesthesia

#### \$200 to \$749

Florida Academy of Anesthesiologist  
Assistants

### Anesthesia Groups

#### \$15,000 and Higher

US Anesthesia Partners

#### \$5,000 to \$14,999

Associated Anesthesiologists, PA  
North American Partners in  
Anesthesia  
NorthStar Anesthesia

#### \$2,000 to \$4,999

Madison Anesthesiology  
Consultants, LLP  
TeamHealth

#### \$200 to \$749

Anesthesia Associates of Columbus,  
GA  
Children's of Alabama (in honor of  
Jennifer Dollar, MD)  
Hawkeye Anesthesia, PLLC  
Perfect Office Solutions, Inc.  
UNC Student College of Clinical  
Pharmacy  
Wichita Anesthesiology Chartered

### ASA State Component Societies

#### \$5,000 to \$14,999

Indiana Society of Anesthesiologists

Minnesota Society of  
Anesthesiologists

Tennessee Society of  
Anesthesiologists

#### \$2,000 to \$4,999

Massachusetts Society of  
Anesthesiologists  
North Carolina Society of  
Anesthesiologists  
Wisconsin Society of  
Anesthesiologists

#### \$750 to \$1,999

Arizona Society of Anesthesiologists  
District of Columbia Society of  
Anesthesiologists  
Florida Society of Anesthesiologists  
Georgia Society of Anesthesiologists  
Illinois Society of Anesthesiologists  
Iowa Society of Anesthesiologists

Missouri Society of Anesthesiologists

Nebraska Society of  
Anesthesiologists, Inc.

Ohio Society of Anesthesiologists

Oregon Society of Anesthesiologists

South Carolina Society of  
Anesthesiologists

Texas Society of Anesthesiologists (in  
memory of Sigurdur S. Sigurdsson,  
MD)

Washington State Society of  
Anesthesiologists

#### \$200 to \$749

Arkansas Society of  
Anesthesiologists  
Colorado Society of  
Anesthesiologists  
Hawaii Society of Anesthesiologists  
Maine Society of Anesthesiologists  
New Mexico Society of  
Anesthesiologists  
Rhode Island Society of  
Anesthesiologists  
Virginia Society of Anesthesiologists

### Individuals

#### \$15,000 and Higher

Steven J. Barker, MD, PhD

#### \$5,000 to \$14,999

Mrs. Isabel Arnone (in memory of  
Lawrence J. Arnone, MD, FACA)  
Mary Ellen and Mark A. Warner, (in  
honor of Alan D. Sessler, MD)

#### \$2,000 to \$4,999

Robert Caplan, MD  
Susan E. Dorsch, MD  
Steven Greenberg, MD  
Dr. Eric and Marjorie Ho  
James J. Lamberg, DO  
Patty Mullen Reilly, CRNA  
James M. Pepple, M.D.

Joyce Wahr, MD (in honor of Mark  
Warner)

#### \$750 to \$1,999

Donald E. Arnold, MD, FASA  
Doug Bartlett (in memory of Diana  
Davidson, CRNA)

Allison Bechtel

Casey D. Blitt, MD

Fred Cheney, MD

Daniel J. Cole, MD

Jeffrey B. Cooper, PhD

Mrs. Jeanne and Robert A. Cordes,  
MD

Karen B. Domino, MD

Kenneth Elmiasian, DO, FASA (in  
memory of Dr. Archie Attarian)

David M. Gaba, MD, and Deanna  
Mann

James D. Grant, MD, MBA

Beverly and Marty Greenberg (in  
honor of Dr. Steven Greenberg)

Allen Hyman, MD (in honor of Robert  
Epstein, MD)

Catherine Kuhn, MD

Meghan Lane-Fall, MD, MSHP

Lorri A. Lee, MD

David P. Maguire, MD

Mark C. Norris, MD

Parag Pandya, MD

Gianna Pino Casini

Elizabeth Rebello, MD (in honor of  
Drs. Mark Warner and Jerome  
Adams)

Lynn Reede, CRNA

Drs. Ximena and Daniel Sessler

Ty Slatton, MD

Robert K. Stoelting, MD

Brian J. Thomas, JD (in honor of  
Matthew B. Weinger, MD)

Lynn and Laurence Torsher

Stephanie Wolfe Heindel

#### \$200 to \$749

Amolek Abcejo, MD  
Aalok Agarwala, MD, MBA

Shane Angus, AA-C

Douglas R. Bacon, MD, MA (in honor  
of Mark Warner)

Marilyn L. Barton (in memory of  
Darrell Barton)

William A. Beck, MD

David and Samantha Bernstein (in  
honor of Jeff Cooper)

K. Page Branam, MD (in memory of  
Donna M. Holder, MD)

Graham W. Bullard

Matthew W. Caldwell

Marlene V. Chua, MD

Jerry A. Cohen, MD

Jeremy Cook, MD

Christian David Cunningham

John K. DesMarteau, MD

Andrew E. Dick, MD

Richard P. Dutton, MD, MBA

Thomas Ebert, MD

Steven B. Edelstein, MD, FASA

Mary Ann and Jan Ehrenwerth, MD

Bola Faloye, MD

Thomas R. Farrell, MD

Steven Frank

Anthony Frasca, MD

Ronald George, MD

Ian J. Gilmour, MD

Linda K. Groah

Allen N. Gustin, MD

Alexander Hannenberg, MD (in honor  
of Mark A. Warner)

Gary Haynes, MD, PhD, FASA and  
Debra Haynes

John F. Heath, MD

Thomas Hennig, MD (in honor of R. K.  
Stoelting, MD)

Michael Hofkamp

Steven K. Howard, MD

Jeffrey Huang, MD

Rebecca L. Johnson, MD

Robert E. Johnstone, MD

Mark C. Kendall, MD (in honor of  
Joseph W. Szokol, MD)

Kevin King, DO

Ann Kinsey, CRNA

Gopal Krishna, MD

Laurence A. Lang, MD

Joshua Lea, CRNA

Michael C. Lewis, MD, FASA (in honor  
of David Birnbach MD)

Della M. Lin, MD

Dr. Martin London

Michael Loushin

Fredric Mattlin, MD

Edwin Mathews, MD

Stacey Maxwell

Gregory McComas, MD

Sharon Merker, MD

Emily Methangkool, MD (in honor of  
Drs. Mark Warner, Marjorie Stiegler,  
and Amy Pearson)

Jonathan Metry

Tricia Meyer, PharmD

Michael D. Miller, MD

Sara Moser (in honor of Matthew B.  
Weinger, MD)

David Murray, MD

Robert F. Olszewski, Jr., MD, FASA

Ducu Onisei MD

Dr. Fredrick Orkin

Frank Overdyk, MD

Lee S. Perrin, MD

Aaron N. Primm, MD

Sheila Riaz

Drew Emory Rodgers, MD (in honor  
of Fred Spies, MD)

David Rotberg, MD

Brad and Allison Schneider (in honor  
of Dr. Steven Greenberg)

Scott Segal

Adam Setren, MD

Emily Sharpe, MD

Ms. Sandra Kniess and David  
Solosko, MD

Marjorie A. Stiegler, MD

Steven L. Sween, MD (in honor of Drs.  
Mary Ellen and Mark Warner)

Joseph W. Szokol, MD (in honor of  
Steven Greenberg, MD)

Paul Terna, MD

Ellen and Butch Thomas

Benjamin D. Unger, MD

Gregory Unruh

Richard D. Urman, MD, MBA (in honor  
of Jeffrey Cooper, PhD)

Bruce Van Dop

Andrea Vannucci, MD

Siva Sai Voora

Matthew B. Weinger, MD

Andrew Weisinger

James M. West, MD

Richard N. Wissler (in memory of Jerry  
Model)

Jennifer Woodbury

Arpad Zolyomi

### Legacy Society

[https://www.apfsf.org/  
donate/legacy-society/](https://www.apfsf.org/donate/legacy-society/)

Dan and Cristine Cole

Karma and Jeffrey Cooper

Dr. John H. and Mrs. Marsha Eichhorn

Burton A. Dole, Jr.

David and Deanna Gaba

Drs. Alex and Carol Hannenberg

Drs. Joy L. Hawkins and Randall M.  
Clark

Dr. Eric and Marjorie Ho

Drs. Michael and Georgia Olympio

Dr. Ephraim S. (Rick) and Eileen Siker

Robert K. Stoelting, MD

Mary Ellen and Mark Warner

Matthew B. Weinger, MD, and Lisa  
Price

**Note: Donations are always welcome. Donate online (<https://www.apfsf.org/donate/>) or mail to APSF, P.O. Box 6668, Rochester, MN 55903. (Donor list current as of December 1, 2019–November 30, 2020.)**

# RAPID Response

## Emergency Power and Elective Surgery

to questions from readers

### Dear Rapid Response:

I read your safety guidelines often for answers, but I could not find one that addresses the question of what types of procedures should be done when only emergency power is available. Specifically, is there any information about the advisability of performing an "elective" surgery during a known black-out and using a back-up generator?

I am aware of a surgeon who is planning elective surgery during power outages related to wildfires and relying solely on back-up power sources for the day.

The surgeon wants some sort of published guidelines stating it is a bad idea to do elective surgery on backup power. Do you know of any?

Thank you for any helpful information you can provide.

Sincerely,

Chante Buntin, MD  
Diplomat of the American Board of Anesthesiology  
Board Certified in Anesthesia, Pain Medicine, Addiction (tbc), Palliative Care and Hospice

*The author has no conflicts of interest.*

### Reply:

Dear Dr. Buntin,

We are not aware of any specific guidelines indicating that doing elective procedures under conditions of emergency power is a "bad" idea. That said, emergency power systems are limited in capability when compared with the power available under normal conditions and should be used to prioritize the needs for urgent and emergent care. The limitations imposed by emergency power will vary from institution to institution. So, your local capabilities become important in determining what you can or cannot do safely. In general, when power is limited, using the power for non-essential services will have an impact on the power available to provide urgent or emergent care.

The National Fire Protection Association (NFPA) authors standards and codes for power requirements in health care facilities which are followed in the U.S. by the Center for Medicare & Medicaid Service and the Joint Commission.<sup>1</sup> All health care facilities are required to have 2 independent sources of power with one being

on site. Usually these sources are the utility company and a generator. As for the generator capabilities, the requirements for electrical capacity and available fuel supplies to support run times are addressed by NFPA codes but ultimately determined by your local authorities.

There is an established hierarchy for prioritizing power distribution, which is determined by the NFPA's National Electrical Code (NEC).<sup>1</sup> Power to the *life safety branch*, is first and includes power to exit signs, door unlocking mechanisms, alarms, and emergency hallway lighting. Next is the *critical branch*, which is for the well-being of patients and includes clinical equipment plugged into "red outlets" present in the operating rooms, ICU, nursery, nurse call systems, and pharmacy storage. Last is the *equipment branch*, which is everything else.

Understanding the capabilities of on-site generators is essential to making an informed decision about what type of activities can be supported when the utility power is not available. All generators have a rated capacity in kilowatts. One generator may be able to provide emergency power to the hospital but will be limited by its maximum capacity. Two or more generators is desirable as it provides redundancy in the event that one of the generators fail. Generators also will be limited by the available fuel supply.

The amount of time the generators will be able to supply power will be determined by the available fuel and the power requirements that will need to be satisfied. While NFPA does not prescribe the minimum run time required, language in the NFPA guidelines provides direction for hospitals to determine their needs. NFPA 110 is the standard for emergency and standby power for different types of facilities. Hospitals are considered Class X facilities and are provided the flexibility to determine minimum needed run times based upon their needs and local codes. NFPA 99 is the standard governing fire and life safety requirements for health care facilities. NFPA 99 includes the following statement to guide the minimum run time for generators: *"The hospital should determine the appropriate run time for the emergency electrical supply and size the fuel tanks accordingly. Careful consideration should be given to the potential types of outages anticipated and the availability of fuel. It should be noted that in some situations it might be permissible to size the fuel system to accommodate less than 48*

*hours of fuel. If life safety systems will need emergency power, other codes and standards might specify minimum durations of required operation."*<sup>1</sup> Interviews with experts from NFPA indicate that 48 hours of generator capacity is a good target for run times, but in some locations (e.g., earthquake zones) 96 hours is desirable.

While generators are a mature technology, unfortunately, they are well known to fail. For example, during Hurricane Sandy in 2012, a number of hospitals encountered problems with their generators when utility power stopped, including complete power failure in a major academic center.<sup>2</sup>

We would suggest that you engage the local facilities management to understand the capabilities of the emergency electrical supply. To make an informed decision, you will need to know the maximum power of the generators relative to the anticipated power needs, whether or not there is more than one generator in case of failure, how long the generators will run with the available fuel supply, and the anticipated needs for power to care for existing patients and support any urgent and emergent care needs.

Jeffrey Feldman, MD, MSE, is professor of clinical anesthesiology, Children's Hospital of Philadelphia, Perelman School of Medicine, University of Pennsylvania, Philadelphia, PA, and chair of the APSF Committee on Technology.

Charles E. Cowles, Jr., MD, MBA, FASA, was associate professor and chief safety officer at the University of Texas MD Anderson Cancer Center, Houston, TX.

Jan Ehrenwerth, MD, is professor emeritus at Yale University School of Medicine, New Haven, CT.

*The authors have no conflicts of interest.*

### REFERENCES

1. Overview of NFPA codes and standards that apply to emergency power systems in healthcare facilities. <https://nfpa.org/Codes-and-Standards/Resources/Standards-in-action/NFPA-resources-for-CMS-requirements-on-NFPA-99-and-NFPA-101/Action-for-emergency-power-in-Florida> Accessed December 21, 2020.
2. Lessons learned from Hurricane Sandy and recommendations for improved healthcare and public health response and recovery for future catastrophic events. American College of Emergency Physicians, Dec 22, 2015. <https://www.acep.org/globalassets/uploads/uploaded-files/acep-by-medical-focus/disaster/lessons-learned-from-hurricane-sandy-webpage.pdf> Accessed December 21, 2020.



# Safety vs. Quality—The 2020 APSF/ASA Ellison C. Pierce, Jr., MD, Memorial Safety Lecture

by Matthew B. Weinger, MD, MS

To watch the Ellison C. Pierce, Jr., MD, Memorial Safety Lecture in its entirety, please visit:

<https://www.apsf.org/asa-apsf-ellison-c-pierce-jr-md-memorial-lecturers/>

This piece summarizes the content of the 2020 Ellison C. Pierce, Jr., MD, Memorial Patient Safety Lecture, which was presented on October 3, 2020, at the American Society of Anesthesiologists Annual Meeting (held virtually). It highlights the conflict between quality and safety, and is a call to action for anesthesia professionals to recognize their important role in improving health care safety. My presentation first reviews the emerging role of the anesthesia professional in today's health care safety environment. I then explore an important yet under-appreciated consequence of unsafe work environments—the impact of dysfunctional systems on clinicians. Next, I talk about the push for greater health care quality in the U.S., followed by a summary of conflicting approaches to safety and quality efforts. Finally, I review principles in human factors engineering and human-centered design which may contribute to the solution of this dilemma.

## PATIENT SAFETY

Based on my review of the literature, it appears that about one-half of perioperative deaths are preventable. While primarily anesthesia-related mortality is quite low, surgical mortality is at least 100-fold higher. Thus, anesthesia professionals can and must play a greater role in reducing not just anesthesia, but surgery-related morbidity and mortality. Toward this goal, for example, we need to take more responsibility for reducing surgical infections through correct and timely prophylactic antibiotics, as well as better sterile technique by anesthesia professionals when administering intravenous drugs, especially during induction.<sup>1</sup> Maintaining effective mean blood pressure throughout perioperative care is another way anesthesia professionals can improve surgical outcomes.

More than two decades ago, I introduced to health care the concept of a “non-routine event” (or NRE). We define an NRE as anything that's undesirable, unusual, or surprising for a particular patient in their specific clinical situation. My colleagues and I have demonstrated that NREs: 1) are common—ranging from 20–40% in various perioperative settings; 2) are multifactorial; 3) can contribute to and/or be associated with adverse patient outcomes and, importantly, 4) provide addressable evidence for improving defective processes and technology within care systems.<sup>2</sup>

A key problem with the current view of patient safety (Safety 1.0) in most health care organizations is its focus on detecting and analyzing adverse events or aggregate poor outcomes to drive mitigation or improvement. While useful, the effectiveness of such an approach is limited due to hindsight bias and its inability to provide sufficient insight as to how best to prevent *future* adverse events. So, instead, in health care as in other industries, patient safety professionals need to study how experienced clinicians are successful despite the dysfunctional processes and systems in which they must work and then design processes and technology to support and foster these resilient behaviors (Safety 2.0).

## CLINICIAN SAFETY

Degraded clinician well-being and burnout is more likely when a hospital unduly emphasizes production, has dysfunctional processes and technology that predispose to unsafe care, or has a culture and leaders that inadequately understand and support front-line clinicians' needs. Studies show that clinician burnout is associated with adverse effects not only on the clinicians, but on patient safety and organizational performance.<sup>3</sup> Further, many of the system factors associated with an increased risk of burnout are the same factors associated with the risk of NREs and preventable adverse events.

## SAFETY VS. QUALITY

Data suggest that health care in the United States, when compared with other developed countries, is generally of lower quality, is often less safe, and has a higher proportion of total expenditures going toward activities that don't directly benefit patients (see numerous articles and figures at [www.commonwealthfund.org](http://www.commonwealthfund.org)). Thus, there is tremendous pressure to increase value in health care, here defined as the quality of the care delivered divided by the cost of providing that care. Because cost is the dominator in the value equation, the effectiveness and efficiency of care have become a predominant focus in most organizations' quality initiatives.

Table 1 shows the contrasts between an organization that is primarily production- or value-focused versus one where safety and reliability are the predominant focus. I modified this table from the work of Landau and Chisholm.<sup>4</sup> To summarize just a few of the contrasts, a production focus emphasizes optimization, wanting to have

just the right amount of personnel, tools, and supplies available just when they are needed. In contrast, safety or high reliability organizations want built-in redundancy and have a “just in case” mentality. The production organization treats adverse events as anomalies while the safety organization views adverse events as valuable information about potential system dysfunctions. The production organization tends to have a “shame and blame” culture, whereas, in the safety organization, those who report errors or issues are praised and even rewarded. Thus, with a production orientation, the system is more error prone while in a safety organization, it is error tolerant, and *more importantly*, will be resistant to serious accidents through better error detection and recovery.

**Table 1: Production vs. Safety Focused Health Care Organizations.**

Production Focus	Safety/Reliance
Optimization (Just in Time)	Redundancy (Just in Case)
Promote standardization	Accept diversity/variability
Resistant to change	Adaptive and flexible
Adverse events as anomalies	Adverse events as information
Optimism about outcomes	Pessimism about outcomes
Shoot the messenger	Reward the messenger
Error prone	Error tolerant

Conflict between production and safety often occurs in procedural areas which are high cost (and potentially high revenue). Here, there is constant organizational pressure to improve productivity (i.e., throughput) and financial performance. Both of these can be easily measured whereas we can only infer safety—when accidents happen, we know we are in unsafe territory. However, when there have been no accidents, the organization can have a false sense of safety. There will thus be a tendency to “push the [safety] envelope” over time increasing the risk of harm events. To date, the only perioperative “safety meter” we have is individual clinicians—your willingness to speak up, to stop the line, and to advocate for patient and clinician safety.

See “Pierce Lecture,” Next Page

## Human Factors Engineering Provides Methods for Designing Safer Delivery of Patient Care

From “Pierce Lecture,” Preceding Page

**Design for Safety.** Human factors engineering (or HFE) provides methods to design processes, technology and systems to achieve higher levels of safety and quality. HFE is the scientific and practical discipline of understanding and improving systems to increase overall safety, effectiveness, efficiency and user satisfaction.<sup>5</sup>

The Human- (or User) Centered Design Cycle (Figure 1) is how HFEs design, evaluate and deploy any new or revised tool, technology, process, or system.

The cycle starts with gaining a full understanding of the problem you’re trying to address. This user research leads to a full description of users’ needs. Next, you specify the use-related design requirements. Working through multiple iterations of design and evaluation yields an optimized product or intervention that meets the desired requirements. You then assess, prior to full implementation, whether the resulting product or intervention actually meets your users’ needs. In the presentation, I provided examples of each phase of the human-centered cycle based on our prior research (see, for example, references 6–9).

POPTEC (PeOple, Processes, Technology, Environment, and Culture) is how HFEs think about the performance-shaping factors that affect the risk of non-routine and adverse events. POPTEC thus provides a framework, not only for user research, but to guide design and evaluation throughout the entire HCD cycle.<sup>5</sup>

### CONCLUSION

To improve patient safety, the health care organization needs to create resilient human-centered systems. Individuals and teams should be trained in serious event management. Standardization is important for both quality and safety. But, especially for safety, it must be *flexible* and open to continual refinement. Processes and technology need to be engineered to be safety-oriented, error-tolerant, and facilitate error recovery. A robust event-reporting system will encourage reporting and provide feedback. All meaningful events need to be analyzed to identify the most important safety problems. Then, potential interventions should be developed and evaluated using HFE principles. This difficult work must be multidisciplinary and collabora-

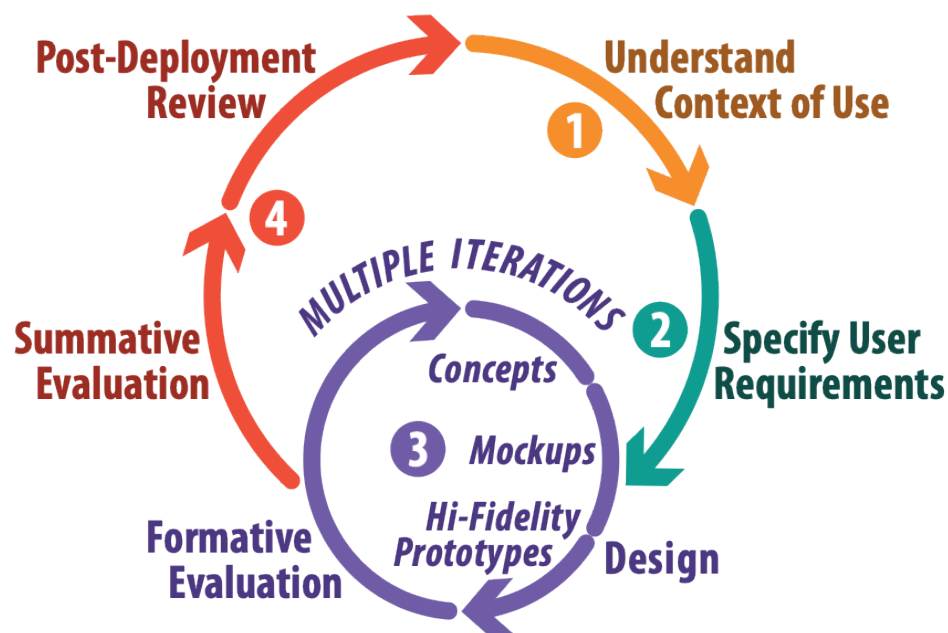


Figure 1: Human-Centered Design Cycle.

tive and should fully engage all relevant clinicians and other stakeholders. Finally, an organization needs enlightened leaders who actually understand and prioritize patient and worker safety, and who put real effort into creating a robust safety culture.

In closing, anesthesia professionals must not simply be “the people who put people to sleep.” We have the training, knowledge, and skills that make us uniquely suited to be the safety leaders in our organizations. To have an impact, we need to take a broader view of our role in health care to fully realize our potential to improve both safety and quality.

*Matthew B. Weinger, MD, MS, is the Norman Ty Smith Chair in Patient Safety and Medical Simulation and professor of anesthesiology, biomedical informatics and medical education at the Vanderbilt University School of Medicine, Nashville, TN. He also is the director, Center for Research and Innovation in Systems Safety, Vanderbilt University Medical Center, Nashville, TN.*

*Dr. Weinger is a founding shareholder and paid consultant of Ivenix Corp., a new infusion pump manufacturer. He also received an investigator-initiated grant from Merck to Vanderbilt University Medical Center to study clinical decision making.*

### REFERENCES

- Loftus RW, Koff, MD, Birnbach DJ. The dynamics and implications of bacterial transmission events arising from the anesthesia work area. *Anesth Analg*. 2015;120:853–860.
- Liberman, JS, Slagle JM, Whitney, G, et al. Incidence and classification of nonroutine events during anesthesia care *Anesthesiology*. 2020;133:41–52.
- Committee on Systems Approaches to Improve Patient Care by Supporting Clinician Well-Being, National Academies of Science, Engineering, and Medicine. Taking action against clinician burnout: a systems approach to professional well-being. Washington, DC: The National Academies Press, October 2019, 334 pp. [doi.org/10.17226/25521](https://doi.org/10.17226/25521). ISBN: 978-0-309-49547-9.
- Landau M, Chisholm D. The arrogance of optimism: notes on failure-avoidance management. *J Contingencies Crisis Manage*. 1995;3:67.
- Weinger MB, Wiklund M, Gardner-Bonneau D. (editors): Handbook of human factors in medical device design. Boca Raton, FL: CRC Press, 2011.
- Anders S, Miller A, Joseph P, et al. Blood product positive patient identification: comparative simulation-based usability test of two commercial products. *Transfusion*. 2011;51: 2311–2318.
- Anders S, Albert R, Miller A, et al. Evaluation of an integrated graphical display to promote acute change detection in ICU patients. *Inter J Med Inform*. 2012; 81: 842–51.
- Weinger M, Slagle, J, Kuntz A, et al. A multimodal intervention improves post-anesthesia care unit handovers. *Anesth Analg*. 2015;121:957–971.
- Weinger MB, Banerjee A, Burden A, et al. Simulation-based assessment of the management of critical events by board-certified anesthesiologists. *Anesthesiology*. 2017;127:475–89.

# Enhancing a Culture of Safety Through Disclosure of Adverse Events

by Christopher Cornelissen, DO, FASA; R. Christopher Call, MD; Monica W. Harbell, MD, FASA; Anu Wadhwa, MBBS, MSc, FASA; Brian Thomas, JD; Barbara Gold, MD, MHCM

## CLINICAL VIGNETTE

It is Friday evening and you are preparing to hand off a femoral-popliteal bypass case to the night team when you receive a page from your trainee that the “heparin isn’t working.” You proceed to the room and learn that your trainee has given 5,000 units of heparin per surgeon request with a resultant rise in the activated clotting time (ACT) value from 121 to 128. The surgeon requests an additional 3,000 units be given and a second ACT returns at 126. Reviewing the situation, you notice an opened vial of tranexamic acid (TXA) on the anesthesia cart. You inquire about the vial, and the trainee acknowledges that he accidentally swapped (TXA) for heparin. The surgeon, who had not overheard your conversation, asks your opinion as to why the ACT has not risen. How do you answer? Should the case continue? Should this event be disclosed to the patient? If so, when should the disclosure occur and who should be present? What support is available for care team members affected by this event?

This clinical scenario provides an opportunity for the anesthesia team to model, through behavior and actions, a culture of safety as it pertains to the disclosure of adverse events. We will review guiding principles of disclosure which may be applied by anesthesia professionals when harmful events occur. We will also examine how a culture of safety serves as the foundation for adverse event disclosure, identify leading practices, and outline resources that facilitate patient-centered disclosure.

## HOW A CULTURE OF SAFETY RELATES TO ADVERSE EVENT DISCLOSURE

A culture of safety reflects the shared values, commitments, and actions that promote patient safety within an organization. It is the product of individual and group attitudes, competencies, and patterns of behavior that determine the organization’s commitment to quality and patient safety. It is not just what is thought or said, but what is demonstrated by behaviors and actions.<sup>1</sup> In work environments with a robust culture of safety, there is no fear in discussing near misses, errors, and patient harm,

but rather there exists a supportive environment to learn from experiences with the goal of preventing errors and improving care for future patients. The Agency for Healthcare Research and Quality (AHRQ) highlights the following four key features that define a culture of safety:<sup>2</sup>

1. Recognition of the high-risk nature of health care with a commitment to “achieve consistently safe operations”
2. A blame-free environment where individuals can report errors or near misses without fear of reprimand or punishment
3. Teamwork across ranks and disciplines to address patient safety problems
4. Commitment from the organization to provide resources to address safety concerns.

The Joint Commission, which accredits health care organizations throughout the United States, requires that health care facilities create a safety program that promotes reporting adverse events and near misses and learning from them.<sup>3</sup> Disclosure to the patient is required when the adverse event 1) has a perceptible effect on the patient that was not discussed in advance as a known risk; 2) necessitates a change in the patient’s care; 3) potentially poses an important risk to the patient’s future health, even if that risk is extremely small; 4) involves providing a treatment or procedure without the patient’s consent.<sup>2</sup>

## ANESTHESIA CARE AND DISCLOSURE WITHIN A CULTURE OF SAFETY

Anesthesia professionals aspire to minimize risk, prevent harm, and learn from errors. This principled mindset has helped establish anesthesia professionals as leaders in patient safety.<sup>4</sup> However, in complex systems, errors and harm will continue to occur despite our best efforts. When an error does occur, it is imperative that we respond in an equally principled manner. This includes disclosing what is known, committing to a thorough review, and sharing what is learned with our patients, while being mindful that all organizational quality improvement protections are adhered to. With this process, patients come to understand that the organization learned from their experiences and that conclusions drawn from the review will lead to reforms that support the “learning culture” emblematic of a safety culture.<sup>1</sup>

**Table 1: Summary of the Key Components for an Effective Disclosure of a Medical Error.**

Preparation
Review the event with the involved parties.
Plan your discussion with patient or family in advance.
Select a quiet and private location for the discussion.
Offer language interpreters, social workers, and clergy to be present.
Have all involved parties at the initial disclosure.
Delivery
Deliver a compassionate and unhurried explanation.
Explain the conditions under which the medical error occurred.
Discuss objectively what you know and don’t know.
Verify that the patient and family understand your explanation.
Describe the process for investigation and performance improvement.
Consider incorporating an apology for confirmed medical errors.
Follow-up
Provide frequent updates to the patient and family.
Make yourself easily accessible to the patient and family.
Facilitate discussions between risk management, the hospital, and the patient or family.

Table 1 on page 15 of the ASA Physicians Series, *Manual on Professional Liability* is reprinted with permission of the American Society of Anesthesiologists, 1061 American Lane, Schaumburg, IL 60173-4973. © November 2017 <https://www.asahq.org/standards-and-guidelines/f~/media/9bd16ced606247a19d31aa15236f842f.ashx>



## Health Care Team Members Should Be Aware of Institutional Policies That Guide Disclosure

### From “Adverse Events,” Preceding Page

Multiple articles in the patient safety literature have highlighted essential elements of disclosure to patients and their families. Suggested elements of the disclosure conversation include describing the known facts, expressing regret for what occurred, and letting patients and families know that as information becomes available, they will be kept fully informed.<sup>5</sup> The American Society of Anesthesiologists (ASA) Manual on Professional Liability has summarized key components needed for an effective disclosure of a medical error; these are summarized in Table 1.<sup>6</sup> The Anesthesia Patient Safety Foundation (APSF) has also developed an adverse event protocol for anesthesia professionals and perioperative care team members to utilize following an adverse event.<sup>7</sup>

Once it is determined that event disclosure with the patient should take place, it is important that any anesthesia professionals involved in the event collaboratively discuss with the surgical and nursing teams what is known, what remains unknown, and what steps will follow. It is ideal for the provider most centrally involved with the event to lead the discussion with the patient. Multiple specialties may need to be involved. The discussion should be rehearsed and provide a genuine and open explanation of events using terms that are understandable to the patient. Transparent communication is based on available facts and not speculation. Some institutions employ staff specifically trained to assist with disclosure and they can play a vital role in communication with patients and families, especially on an ongoing basis.

Consideration should be given to consulting with these resources prior to disclosure. Throughout this process, it is imperative that all health care team members are aware of and follow their institutional policies that guide disclosure. Physician practice groups that provide services within hospitals may also have specific guidelines to follow based on medical malpractice and insurance requirements. Furthermore, each practice setting may have specific reporting requirements for anesthesia professionals. Hospital-employed physicians should seek input from legal resources offered by the facility whenever possible. Similarly, members of independent groups and solo practitioners should consult their insurance carriers and legal counsel who represent their interests. When the adverse event is directly linked to the anesthetic care, it is critical that the anesthesia professionals are present at the initial disclosure to the family and patient. The initial discussion and relay of information provided to the patient and family is one that will be remembered and, therefore, all of the facts should be conveyed in an accurate and concise manner.

Disclosure is a process, not a single event. An empathetic expression of caring along with ongoing communication with the patient and family are foundational to successful disclosure of adverse events. Many states have adopted statutes protecting apologies and other benevolent gestures from being used as an admission of fault in the event of a lawsuit.<sup>8</sup> In addition to conveying empathy, the anesthesia professional should avoid speculation and resist any impulse to point fingers at other clinicians.

Institutions seeking to build a more robust disclosure program have a variety of established models to consider. These models originated in the public sector as well as in private and academic institutional settings. Realizing that adverse events vary in scope and severity, the Veterans Health Administration developed a three-tiered disclosure protocol consisting of a provider-driven clinical disclosure, hospital-driven institutional disclosure, and an enterprise large-scale disclosure.<sup>9</sup> The Defense Health Agency, which manages the United States military health care system, created a robust Healthcare Resolutions Program that preemptively educates clinicians, provides real-time event coaching, and supports an extensive peer-support network to assist providers throughout the disclosure process.<sup>10</sup> One of the earliest proponents of disclosure in academia was the University of Michigan, who developed an innovative approach to medical errors and disclosure called the “Michigan Model.”<sup>11</sup> In May 2016, the Agency for Healthcare Research and Quality used the “Michigan Model” results along with contributions from others including the University of Washington, the University of Illinois, and MedStar Health to develop the Communication and Optimal Resolution (CANDOR) process.<sup>12</sup> CANDOR provides a framework for hospitals to improve their response to unexpected harm events, including an online checklist to assist providers in the disclosure process (<https://www.ahrq.gov/patient-safety/capacity/candor/modules/checklist5.html>).

Through the Michigan Model and CANDOR, which are also referred to as Communication and Resolution Programs (CRPs), organizations may offer patients compensation if they determine care was not reasonable under the circumstances.<sup>13,14</sup> Organizations that have implemented this type of approach have seen a significant increase in incident reporting without an increase in claims or legal costs.<sup>7,13-15</sup> While these are positive outcomes, they may be surrogates for the laudable goals of normalizing honesty and accountability, while cultivating safety as an ethical obligation.<sup>4</sup> Notably, early adopters of CRPs have been large, integrated health systems that serve as both the medical staff’s employer and insurance carrier.<sup>16</sup> Organizations that contract with independent providers and entities may find it challenging to compensate patients during the disclosure process.

See “Adverse Events,” Next Page



# Surveys Suggest Health Care Professionals Are Negatively Impacted by Patient Harm

## From “Adverse Events,” Preceding Page

Physicians protected under traditional insurance models are typically precluded from assuming any obligation, making voluntary payments, or incurring expenses for an adverse event without the consent of the insurer. Disclosures made outside the formal peer review process are discoverable during litigation, and all parties involved in adverse events will have an interest in the investigation. This can make it difficult to conduct comprehensive investigations quickly, especially if an adverse event involves multiple providers or the extent of the injury cannot be immediately determined.

Multiple surveys have shown that health care professionals are affected when their patients experience adverse events of harm. This includes emotional distress with potential effects on performance.<sup>17-20</sup> Psychological recovery and resilience may be enhanced with structured peer support, and numerous resources exist for anesthesia professionals to learn about effective peer support programs.<sup>21-23</sup> The Joint Commission acknowledges the importance of peer support to prevent the domino effect that adverse events can have on health care worker performance.<sup>23</sup> Paramount to this process is promotion of a robust patient safety culture for learning from system defects, engaging all team members in a postevent debrief and peer-to-peer emotional support.

## CONCLUSION

The events that followed the clinical vignette illustrate key principles of authentic error disclosure that reflect a culture of safety. The error was immediately disclosed to the surgical team. Discussion and consultation ensued, resulting in a collective decision to proceed. The event was disclosed in clear and unambiguous language to the patient at a time when it could be understood and processed. The error was disclosed by all involved care team members, namely the surgeon, and anesthesia professionals. The risk management team was informed of the event and supported the process. Counseling was provided to the fearful and distraught provider. Lastly, an invitation for ongoing communication was extended by the anesthesia professional to the patient and family should questions arise in the future.

Disclosure by anesthesia professionals should occur in a timely manner, be stated in terms that the patient can understand and should provide the platform for fair and open

discussion. This may lead to subsequent conversations with the patient in consultation with risk management or other institutional entities involved in adverse event disclosure. All team members involved in the event must be supported, with numerous peer-to-peer models and disclosure programs available for institutions to emulate.<sup>11,21-23</sup>

As stewards and advocates for patient safety, anesthesia professionals play a key role in avoiding patient harm. When adverse events do occur, our response should be as principled as our commitment to patient safety. Paramount to this process is active engagement in patient-centered disclosure, authentic and ongoing communication with the patient and family, team support, and a commitment to process improvement.

*Christopher Cornelissen, DO, FASA, is an anesthesiologist at Anesthesia Service Medical Group in San Diego, CA, and clinical associate professor in the Department of Anesthesiology at Western University of Health Sciences.*

*R. Christopher Call, MD, is an assistant professor in the Department of Anesthesiology at Uniformed Services University of the Health Sciences, Bethesda, MD.*

*Monica W. Harbell, MD, FASA, is an assistant professor in the Department of Anesthesia and Perioperative Medicine at Mayo Clinic, Phoenix, AZ.*

*Anu Wadhwa, MBBS, MSc, FASA, is a clinical professor in the Department of Anesthesiology at University of California San Diego, San Diego, CA.*

*Brian Thomas, JD, is vice president, Risk Management, Preferred Physicians Medical in Overland Park, KS.*

*Barbara Gold, MD, MHCM, is a professor in the Department of Anesthesiology at University of Minnesota, Minneapolis, MN.*

*The authors have no conflicts of interest.*

## REFERENCES

1. Sentinel Event Alert 57: The essential role of leadership in developing a safety culture, The Joint Commission Sentinel Event Alert. 2017;57:1-8.
2. Patient Safety Primer Culture of Safety: An overview. <http://psnet.ahrq.gov/primer/culture-safety>. Accessed July 16, 2020.
3. Sentinel Event Alert 60: Developing a reporting culture: Learning from close calls and hazardous conditions. *The Joint Commission Sentinel Event Alert*. 2018;60:1-8.
4. Cohen JB, Patel SY. Getting to zero patient harm: from improving our existing tools to embracing a new paradigm. *Anesth Analg*. 2020;130:547-549.
5. Souter KJ, Gallagher TH. The disclosure of unanticipated outcomes of care and medical errors: what does this mean for anesthesiologists? *Anesth Analg*. 2012;114:615-621.
6. Excerpted from ASA Physicians Series, Manual on Professional Liability (3rd Edition) of the American Society of Anesthesiologists. A copy of the full text can be obtained from ASA, 1061 American Lane Schaumburg, IL 60173-4973 or online at [www.asahq.org](http://www.asahq.org). Accessed December 21, 2020.
7. Eichhorn JH. Organized response to major anesthesia accident will help limit damage. *APSF Newsletter*. 2006;21:11-13. <https://www.apsf.org/article/organized-response-to-major-anesthesia-accident-will-help-limit-damage/>. Accessed December 12, 2020.
8. National Conference of State Legislatures Medical Professional Apologies Statutes. <https://www.ncsl.org/research/financial-services-and-commerce/medical-professional-apologies-statutes.aspx>. Accessed July 16, 2020.
9. Veteran's Health Affairs (VHA) Disclosure Policy, VHA Directive 1004.08 dated 10/31/18, [https://www.ethics.va.gov/docs/policy/VHA\\_Handbook\\_1004\\_08\\_Adverse\\_Event\\_Disclosure.pdf](https://www.ethics.va.gov/docs/policy/VHA_Handbook_1004_08_Adverse_Event_Disclosure.pdf). Accessed July 16, 2020.
10. Defense Health Agency (DHA) Healthcare Resolutions, Disclosure, Clinical Conflict Management and Healthcare Provider (HCP) Resiliency and Support in the Military Health System (MHS), DHA Procedural Instruction 6025.17 dated 6/28/19, <https://health.mil/Reference-Center/Policies/2019/06/18/Healthcare-Resolutions-Disclosure-Clinical-Conflict-Management-and-HCP>. Accessed July 16, 2020.
11. University of Michigan Health website, <https://www.uofm-health.org/michigan-model-medical-malpractice-and-patient-safety-umhs>. Accessed July 16, 2020.
12. Agency for Healthcare Research and Quality, CANDOR website, <https://www.ahrq.gov/patient-safety/capacity/candor/index.html>. Accessed July 16, 2020.
13. Boothman RC, Imhoff SJ, Campbell DA. Nurturing a culture of patient safety and achieving lower malpractice risk through disclosure: lessons learned and future directions. *Front Health Serv Manage*. 2012;28:13-28.
14. Lambert BL, Centomani NM, Smith KM, et al. The "seven pillars" response to patient safety incidents: effects on medical liability processes and outcomes. *Health Serv Res*. 2016;51:2491-2515.
15. Kachalia A, Sands K, Niel MV, et al. Effects of a communication-and-resolution program on hospitals' malpractice claims and costs. *Health Aff (Millwood)*. 2018;37:1836-1844.
16. Mello MM, Boothman RC, McDonald T, et al. Communication-and-resolution programs: the challenges and lessons learned from six early adopters. *Health Aff*. 2014;33:20-29.
17. Shanafelt TD, Balch CM, Bechamps G, et al. Burnout and medical errors among american surgeons. *Ann Surg*. 2010;251:995-1000.
18. Waterman AD, Garbutt J, Hazel E, et al. The emotional impact of medical errors on practicing physicians in the United States and Canada. *J Comm J Qual Pat Saf*. 2007;33:467-476.
19. Tawfik DS, Profit J, Morgenthaler TI, et al. Physician burnout, well being, and work unit safety grades in relationship to reported medical errors. *Mayo Clinic Proc*. 2018;93:1571-1580.
20. Shapiro J, Galowitz P. Peer support for clinicians: a programmatic approach. *Academic Medicine*. 2016;91:1200-1204.
21. Edrees H, Connors C, Paine L, et al. Implementing the RISE second victim support programme at the Johns Hopkins Hospital: a case study. *BMJ Open*. 2016;6:e011708.
22. Scott SD, Hirschinger LE, Cox KR, et al. Caring for our own: deploying a systemwide second victim rapid response team. *J Comm J Qual Pat Saf*. 2010;36:233-240.
23. Supporting Second Victims. The Joint Commission. *Quick Safety*. 2018;39:1-3.



# APSF Awards 2021 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. The APSF grant program has been funding safety-related grants since 1987 and this support has been integral in the careers of many anesthesia professionals.

The 2020-21 APSF investigator-initiated grant program had 33 letters of intent (LOIs) submitted with the top 16 scoring grants undergoing statistical review as well as detailed discussion among members of the Scientific Evaluation Committee. The top five scoring grants were invited to submit full proposals for final review and were discussed via Zoom virtual meeting on October 3, 2020. Two proposals were recommended for funding to the APSF Executive Committee and Board of Directors and both received unanimous support. This year's recipients were Karen Domino, MD, from the University of Washington and May Pian-Smith, MD, from the Massachusetts General Hospital.

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



**Karen Domino, MD, MPH**

*Professor of Anesthesiology and Pain Medicine, University of Washington.*

Dr. Domino's Clinical Research submission is entitled **"Development and testing of a trigger tool to identify cases at risk of adverse events in non-operating room anesthesia (NORA)."**

**Background:** Providing anesthesia services in non-operating room anesthesia (NORA) settings is a rapidly changing and growing chal-

lenge. NORA cases in the North American Clinical Outcome Registry (NACOR) increased from 28% in 2010 to 36% in 2014.<sup>1</sup> Nearly 75% of NORA cases occurred in the outpatient setting, with sicker and older patients than those receiving anesthesia care in the operating room.<sup>1</sup> Additionally, NORA cases were more frequently started after normal working hours (17% vs. 10% of OR cases,  $p < 0.001$ ).<sup>1</sup> The combination of more procedures, patient comorbidities, suboptimal case planning, lack of standard OR equipment, isolation, and limited resources creates the high potential for adverse events (AEs) in NORA settings.<sup>2</sup> Most of the understanding of risk associated with NORA comes from retrospective registry analysis or facility-based data.<sup>3,4</sup>

Trigger tools are an important new development in detection of adverse events.<sup>5</sup> Trigger tool methodology uses surveillance algorithms to identify patients at high risk for an adverse event. The presence of risk factors identified via a preprocedure checklist could trigger a change in location, anesthetic plan, and additional staffing and equipment support to reduce potential patient harm.

**Aims:** We will adapt trigger tool technology to the NORA clinical context and to the need for *prospective* action to *prevent* patient harm. Potential triggers include patient factors (e.g., advanced age, comorbidities), anesthetic planning (e.g., lack of preoperative evaluation and preparation), procedure type and complexity, procedure site (e.g., office vs. other settings), anesthetic factors (e.g., deep sedation without ventilation monitoring; availability of equipment, supplies, and personnel), and timing of procedures (daytime hours vs. nighttime or weekend). We will develop the NORA Trigger Tool (TT) to identify cases at risk for AEs in NORA using the modified Delphi technique with an expert panel of anesthesiologists, CRNAs, NORA RNs, and proceduralists. We will utilize data from the Anesthesia Closed Claims Project with case comparison with NACOR, and a systematic literature search to inform the trigger tool. We will incorporate feedback from an expert user panel and then test user acceptance and modify the TT based results. We will prospectively test the sensitivity and specificity of the NORA TT to identify cases at risk for AEs in NORA using low-fidelity simulation.

**Implications:** NORA care has grown significantly over the past decade with 30–40% of anesthesia cases occurring in NORA areas. There were over 2 million NORA cases in 2019 alone, which represents only a sample of total NORA cases in the U.S. While severe AEs are

rare, given the high prevalence of NORA, even a small reduction of preventable harm with pre-procedural use of a NORA TT to result in actionable changes in the anesthetic plan, will improve patient safety for a large number of patients.

**Funding:** \$149,879 (January 1, 2021–December 30, 2022). This grant was designated as the APSF/Medtronic Research Award and was also designated the APSF Ellison Pierce, Jr., MD, Merit Award for \$5,000 of unrestricted research.

*The author has no conflicts of interest.*

## REFERENCES

1. Nagrebetsky A, Gabriel RA, Dutton RP, et al. Growth of nonoperating room anesthesia care in the United States: a contemporary trends analysis. *Anesth Analg*. 2017;124:1261–1267.
2. Chang B, Urman RD. Non-operating room anesthesia: the principles of patient assessment and preparation. *Anesthesiol Clin*. 2016;34:223–240.
3. Bhananker SM, Posner KL, Cheney FW, et al. Injury and liability associated with monitored anesthesia care. A closed claims analysis. *Anesthesiology*. 2006;104:228–34.
4. Metzner J, Posner KL, Domino KB. The risk and safety of anesthesia at remote locations: the U.S. closed claims analysis. *Curr Opin Anaesthesiol*. 2009;22:502–508.
5. Griffin FA, Resar RK. IHI Global Trigger Tool for measuring adverse events (second edition). IHI Innovation Series white paper. Institute for Healthcare Improvement, Cambridge, MA 2009 (available on [www.IHI.org](http://www.IHI.org)).



**May Pian-Smith, MD, MS**

*Associate professor of Anesthesia, Critical Care and Pain Medicine, Massachusetts General Hospital, Harvard Medical School*

Dr. Smith's Clinical Research submission is entitled: **"Trust between surgeons and anesthesiologists: developing and implementing a qualitative method to identify keys to relationship and teamwork success."**

See "2020 Grant Recipients," Next Page



## 2021 Grant Recipients

### From “2020 Grant Recipients,” Preceding Page

**Background:** Work in the operating room (OR) is characteristically complex and requires that skilled workers are both independent and interdependent. The Institute of Medicine (IOM) has called for increased trust, respect, and transparency in communication to improve the quality of care. The important impact of the surgeon-anesthesiologist dyad to set the tone for collaboration in the OR has been highlighted by Jeffrey Cooper, PhD, in his recent article in the *APSF Newsletter*.<sup>1</sup> According to relational coordination theory, colleagues can collaborate best when there is high-quality communication (frequent, timely, accurate, and problem-solving), which is enhanced by high-quality relationships (shared goals, shared knowledge, and mutual respect).<sup>2</sup>

This project is intended to gather pilot data for further study. Lingard and others have described observations of the differing perspectives between members of the OR team, but with no specific focus of that between surgeons and anesthesiologists.<sup>3</sup> Katz has written about conflict in the OR and how to manage it, but without empirical data of the type we are proposing to gather.<sup>4</sup>

**Aims:** We will build on the qualitative interview-based methodology used by Cooper et al. in the Critical Incident studies<sup>5</sup> to answer the following questions: What are key behaviors between individual anesthesiologists and surgeons that facilitate trust and collaboration or create barriers to trust and collaboration during perioperative care? Are there differences in the personal relationships between anesthesiolo-

gists and surgeons, including their perspectives and preferences, based on sex, practice setting, or whether teams are “dynamic” vs. “intact”? Are there specialty-identities and assumptions or stereotypes that individual anesthesiologists and surgeons hold toward their counterparts that may help or interfere with an effective, patient-safe working relationship?

**Implications:** We do not know the incidence of poor outcomes in the OR that are precipitated specifically by poor interactions between anesthesiologists and surgeons. Personal anecdotes about the OR and published studies on ICU interactions suggest the incidence of conflict is significant and that this is an important area for study and improvement. Studies have shown that optimizing teamwork has impact on the patient experience, and improving quality outcomes (such as length of hospital stay, and mitigating harm from errors and intra-operative adverse events). Improved relationships can enhance worker resilience, support joy and meaning in the workplace, and decrease the costs of workforce turnover.

This will be the first study to identify behaviors and characteristics that can engender “trust” across surgeon and anesthesiologist role-groups during perioperative care. This information will be important for defining professionalism within both specialties and will impact training methods and content. The results can inform and improve interdisciplinary and interprofessional team-training aimed at improving patient safety outcomes. Key behaviors can also be incorporated into a novel

assessment tool of non-technical skills of OR personnel and such tools can subsequently be used to link observed behaviors with real patient clinical outcomes.

**Funding:** \$149,601 (January 1, 2021–December 31, 2022). This grant was designated the APSF/ASA 2021 President’s Research Award.

*May Pian-Smith, MD, currently serves on the board of directors for the APSF.*

### REFERENCES

1. Cooper JB. Healthy relationships between anesthesia professionals and surgeons are vital to patient safety. *APSF Newsletter*. February 2020;35:8–9. <https://www.apsf.org/article/healthy-relationships-between-anesthesia-professionals-and-surgeons-are-vital-to-patient-safety/> Accessed December 12, 2020.
2. Gittell JH, Weinberg DB, Pfefferle S, et al. Impact of relational coordination on job satisfaction and quality outcomes: a study of nursing homes. *Human Resource Management Journal*. 2001;18:154–170.
3. Lingard L, Espin S, Whyte S, et al. Communication failures in the operating room: an observational classification of recurrent types and effects. *BMJ Qual Saf*. 2004;13(5):330–334.
4. Katz JD. Conflict and its resolution in the operating room. *J Clin Anesth*. 2007;19:152–158.
5. Cooper JB, Newbower RS, Long CD, et al. Preventable anesthesia mishaps—a human factors study. *Anesthesiology*. 1978;49:399–406.

The APSF would like to thank the above researchers and all grant applicants for their dedication to improve patient safety.

*Steven Howard, MD, is a professor of anesthesiology, perioperative and pain medicine at Stanford University School of Medicine, staff anesthesiologist at the VA Palo Alto Health Care System and the outgoing chair of the APSF’s Scientific Evaluation Committee.*

*The author has no other conflicts of interest.*



## Did you know?

**APSF accepts stock donations.** We work with our investment firm to take care of the details. You will need the following information to give to your investment advisor/broker dealer. Please let us know of your generosity by notifying Stacey Maxwell at [maxwell@apsf.org](mailto:maxwell@apsf.org) so that we may properly acknowledge your contribution.

**DTC #: 2085**

**Account Name: Anesthesia Patient Safety Foundation**  
**Account #: FBO APSF / #7561000166**

## RAPID Response

to questions from readers

## What Type of Operating Room Pressure Should We Use for Patients with SARS-COV-2 Infection?

The following articles were previously published on the APSF online portal. The present version is updated and modified by the authors for the present APSF Newsletter.

### Dear Rapid Response:

Has APSF developed definitive recommendations regarding negative pressure operating rooms for patients who are known or suspected to have SARS-COV-2 infection? If not, when will it happen?

Thank you and kind regards

Marshal B. Kaplan, M.D.

Clinical Professor

Director of Airway Management

Co-Chair Performance Improvement Committee

Department of Anesthesiology

Cedars Sinai Medical Center

The author has no conflicts of interest.

### Reply:

Dear Dr. Kaplan,

While APSF does not have definitive recommendations as you have requested, the following response from Dr. Charles Cowles, ASA liaison to the National Fire Protection Association (NFPA), details the important considerations for developing a local approach to caring for these patients.

Thank you for your inquiry.

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

The author has no conflicts of interest.

### REFERENCES:

1. Overview of NFPA codes and standards that apply to emergency power systems in healthcare facilities. <https://nfpa.org/Codes-and-Standards/Resources/Standards-in-action/NFPA-resources-for-CMS-requirements-on-NFPA-99-and-NFPA-101/Action-for-emergency-power-in-Florida> Accessed December 21, 2020.
2. Lessons learned from Hurricane Sandy and recommendations for improved healthcare and public health response and recovery for future catastrophic events. American College of Emergency Physicians, Dec 22, 2015. <https://www.acep.org/globalassets/uploads/uploaded-files/acep/by-medical-focus/disaster/lessons-learned-from-hurricane-sandy-webpage.pdf> Accessed December 21, 2020.

## Recommendations for OR Ventilation during the SARS COV-2 Pandemic—Staying Positive

by Charles Cowles, MD

Positive pressure, where the pressure in the operating room is greater than the adjacent areas, is the typical approach to OR ventilation. This approach is employed to prevent circulation of pathogens that could contaminate an open wound from entering the OR. For all patients undergoing a surgical procedure, positive pressure is an accepted infection prevention strategy. Negative pressure, where the pressure in the room is less than the adjacent areas, can be used to prevent airborne pathogens from leaving the room. While not a standard, negative pressure has been advocated for hospital rooms where a patient is known or suspected to be infected with an airborne pathogen.

What is the best strategy for OR ventilation when a COVID-19 patient, or a person under investigation (PUI), requires a procedure in the operating room? The existing approach of positive pressure ventilation is best to protect the patient coming to the OR, but how can the risk to staff and other patients from any aerosol generating procedures be minimized? The following is intended to provide the information needed to make an informed decision about the approach to OR ventilation best suited to the local conditions.

### What are the current recommendations for ventilation in the operating room?

The American Institute of Architects (AIA) recommends 15 air exchanges per hour combined with a minimum of 3 air exchanges of outside (fresh) air for operating rooms.<sup>1</sup> In addition, air flow should be designed to create positive pressure in the operating room relative to areas outside the OR to prevent the entry of common pathogens (e.g., *Staphylococcus aureus*) that could contaminate an open wound. These basic requirements are the standard for all patients receiving care in the operating room.

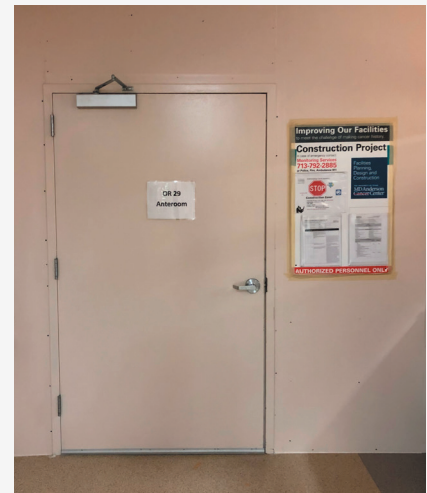


Figure 1: Depicts the creation of a temporary wall with a door to create an anteroom from an OR hallway.



Figure 2: Portable air handler inside anteroom to create negative pressure.

See "Negative Pressure," Next Page

**RAPID Response**

to questions from readers

From "Negative Pressure," Preceding Page

**Should the operating room (OR) ventilation be converted to negative pressure to protect the staff from COVID-19 exposure when caring for known or suspected COVID-19 positive patient?**

No, the American Society for Healthcare Engineering (ASHE) recommends the same strategy for COVID patients in the operating room as they do for other airborne diseases such as TB.<sup>2</sup> This includes the following, if feasible:

- Only medically necessary procedures should be scheduled "after hours."
- Minimize staff in the room and all staff involved should wear N95 or HEPA respirators.
- The door to the operating room should be kept closed throughout the procedure.
- Recovery should be accomplished in an Airborne Infection Isolation Room (AIIR).
- Terminal Cleaning should be performed after sufficient number of air changes has removed potentially infectious particles.

Pathogens such as staphylococcus can be pulled into the operating room if a negative pressure configuration is chosen.<sup>3</sup> Taking all factors in to account, negative pressure should not be instituted in operating rooms. When treating a positive COVID patient or a person under investigation (PUI) for COVID, aerosol-generating procedures (AGPs) such as intubation, should be performed in an Airborn Infection Isolation Room (AIIR), separate from the OR, if feasible.

**What exactly is an Airborne Infection Isolation Room and how does this differ from a negative pressure room?**

According to the American Institute of Architects (AIA) guidelines, AIIRs must meet several criteria for room ventilation unrelated to the pressure differential:

- At least 12 air exchanges per hour
- Inability to inadvertently change the ventilation modes from a negative mode to a positive mode
- Tightly sealed doors
- Self-closing doors
- A permanent indicator of airflow that is visible when the room is occupied and
- A filtration system with at least 90% efficiency.<sup>1</sup>

## A Remembrance: Charles Cowles, MD, MBA, FASA



Charles Cowles, MD, MBA, FASA

In the last few days before this publication was to go to press, we learned the tragic news that Charles Cowles, MD, lost his life in a car accident on a family trip. Thankfully, his wife and three children, although injured, have all survived. Charles contributed so much to APSF and our specialty throughout his career including two articles in this issue of the *Newsletter*. With heavy hearts, we offer this remembrance.

Charles possessed many qualities that made him such an effective advocate for patient safety. He possessed a wealth of knowledge gained through innate curiosity, and the discipline to pursue learning until he had a thorough understanding of the topic of interest. He had the insight to understand how to apply his knowledge to enhance patient safety and the dedication to put his efforts towards that end. Finally, he generously shared his time and energy in the pursuit of improving patient care.

As a trained firefighter, Charles worked consistently for many years in an effort to ensure that no patient is injured by fire. He provided lectures and educational material as well as representing ASA at the National Fire Prevention Association (NFPA). He was an expert on facilities and the systems needed to keep patients and providers safe. Whenever called upon for an opinion, Charles provided valuable information in a form that was accessible to the clinician.

We will never know the impact Charles would have had on future safety efforts. There is no question that APSF will need to respond to patient safety concerns where we will immediately feel the loss of his guidance. Of course, our loss pales in comparison to that of his family. Our thoughts and prayers go out to them with the hope they will find some comfort being together and holding on to his memory.

We will miss Charles Cowles greatly, hold his contributions dear, and honor his memory by continuing our work on patient safety.

—Anesthesia Patient Safety Foundation

The AIIR can be positive pressure if a negative pressure anteroom (see below) is used. The AIIR should be negative pressure in relation to the corridor in the absence of an anteroom. A negative pressure room can be created by having a return air system rate greater than the supply of air, but it is not an AIIR unless it meets the other criteria. Rooms in the ICU, PACU and repurposed spaces can be configured to meet the AIIR criteria to facilitate caring for COVID-19 patients.

**Are there other actions we can take to protect the staff and other patients if the OR does not have negative pressure?**

Creating a negative pressure anteroom to the OR can help control the movement of contaminated air and is a fairly simple modification which can either be temporarily or permanently

constructed (see Figure 1). This anteroom is a small room built adjacent to the patient entry door to the OR and contains a portable air handler that creates a negative pressure which prevents airborne particles from being pushed out of a positive pressure operating room and into a hallway or other adjacent room. Anterooms should be large enough to maneuver a bed into the OR and also hold a small air handling unit. Locating the anteroom near a return air duct simplifies the routing of the air handling duct work. These rooms can be designed in a hallway with self-closing doors which can allow personnel to walk through the area. If an anteroom is deployed, then other doors to the OR should be sealed to airflow.

See "Negative Pressure," Next Page



**RAPID Response**

to questions from readers

**From "Negative Pressure," Preceding Page**

Both the Anesthesia Patient Safety Foundation and the American Society of Anesthesiologists offer additional guidance. In the absence of a negative pressure anteroom to the OR, efforts should be made to minimize environmental contamination and staff risk during any aerosol-generating procedure. Intubating, extubating, and recovering the patient in an AIIR separate from the OR is one approach, but it requires transporting an intubated patient and the need to filter any exhaled gases during transport. If the airway is managed in the OR, staff in the room should be the minimum required to secure the airway, all must wear PPE, and other doors to the OR should remain closed. Once the airway is secured, or the patient has been extubated, other staff should not enter the OR until sufficient time has elapsed to clear the room of any airborne pathogens.<sup>4,5</sup>

**How long does it take after an aerosol-generating procedure (AGP) for the air in the room to be completely filtered?**

The CDC provides a chart which shows that at 15 air exchanges per hour, 99% of airborne contaminants can be removed in about 14 minutes.<sup>6</sup> However, these data are an estimate of fairly complex calculations for which many factors need to be taken into account. The efficiency of 99% assumes that all of the air is cycled by pushing air in a laminar flow pattern. However, large nonaerodynamic objects such as anesthesia machines, OR tables, and other equipment can result in turbulent airflow and create dead air spaces where air is not circulated. This air does not consistently participate in the 15 air exchanges, but also airborne contaminants would likely bypass these dead air spaces as they circulate from the infected source to the exhaust vents. Another factor for determining adequate time is air filtration. A High Efficiency Particulate Air (HEPA) filter is one common type of filter. Air filtration is actually rated using the Minimum Efficiency Reporting Value (MERV) system. The higher the MERV number, the more efficient the filter is at filtering small particles. Hospital ORs should have a filtration system rated 14 or greater.<sup>7</sup> A HEPA filter exceeds this MERV threshold.

**Where can I find more information on ventilation standards and recommendations?**

Every facility will have different constraints that will dictate the procedures to care for

COVID-19 patients. The availability and location of AIIRs outside of the operating room will determine where airway management can be performed and where patients should be allowed to recover. Negative pressure anterooms to the OR are useful to prevent spread of airborne pathogens outside of the OR but may not be feasible. The number of air exchanges per hour will also vary and dictate the time required for airborne pathogens to be cleared from the OR environment. Resources for currently accepted standards and recommendations include the following.

- American Society for Healthcare Engineering (ASHE)—<https://www.ashe.org/>
- American Institute of Architects (AIA)—<https://www.aia.org/>
- American Society of Heating, Refrigeration, and Air Conditioning Engineers (ASHRAE)—<https://www.ashrae.org/>
- Facilities Guidelines Institute (FGI)—<https://fgiguideinlines.org/>
- Center for Disease Control (CDC)—<https://www.cdc.gov/infectioncontrol/guidelines/environmental/appendix/air.html#tableb1>

*Charles E. Cowles, Jr., MD, MBA, FASA, was associate professor and chief safety officer at the University of Texas MD Anderson Cancer Center, Houston, TX.*

*The author has no conflicts of interest.*

**REFERENCES**

1. American Institute of Architects. 2006 American Institute of Architects (AIA) Guidelines for Design and Construction of Hospital and Health Care Facilities. 2016.
2. American Society for Healthcare Engineering. <https://www.ashe.org/covid-19-frequently-asked-questions> Accessed August 6, 2020.
3. Chow TT and Yang XY. Ventilation performance in operating theatres against airborne infection: review of research activities and practical guidance. *J Hosp Infect.* 2004;56:85–92.
4. Anesthesia Patient Safety Foundation. <https://www.apsf.org/covid-19-and-anesthesia-faq/#clinicalcare> Accessed August 10, 2020.
5. American Society of Anesthesiologists. <https://www.asahq.org/about-asahq/governance-and-committees/asa-committees/committee-on-occupational-health/coronavirus>. Accessed August 10, 2020.
6. US Health and Human Services Center for Disease Control (CDC) <https://www.cdc.gov/infectioncontrol/guidelines/environmental/appendix/air.html#tableb1> Accessed August 6, 2020.
7. Barrick JR, Holdaway RG. Mechanical Systems Handbook for Health Care Facilities. *American Society for Healthcare Engineering.* 2014.

**SUPPORT YOUR APSF****Your Donation:**

- Funds Research Grants
- Supports Your APSF Newsletter
- Promotes Important Safety Initiatives
- Facilitates Clinician-Manufacturer Interactions
- Supports the Website

Donate online  
(<https://www.apsf.org/donate/>) or  
mail to

**APSF**  
P.O. Box 6668  
Rochester, MN 55903  
U.S.A.

**Vision**

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

**& Mission**

*The APSF's mission is to improve the safety of patients during anesthesia care by:*

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

## LETTER TO EDITOR:

# The Single-Provider-Operator-Anesthetist Model for Dental Deep Sedation/Anesthesia: A Major Safety Issue for Children

by Charles J. Cote, MD, FAAP; Raeford Brown Jr, MD, FAAP; and Anna Kaplan, MD

In 2019 the American Academy of Pediatrics (AAP) published a joint statement with the American Academy of Pediatric Dentistry (AAPD) updating the AAP sedation guideline.<sup>1,2</sup> This revision was prompted by the preventable death of Caleb, a healthy 6-year-old sedated for removal of a supernumary tooth. Multiple sedating medications caused apnea and airway obstruction, the oral surgeon was unable to clear the airway, and there was no other skilled help in the office. Caleb was asystolic when the EMTs arrived and he died.<sup>3</sup> Caleb's aunt, Anna Kaplan, now a pediatric resident, worked to introduce legislation (Caleb's law)<sup>4</sup> in California that required an anesthesia-trained provider for deep sedation/anesthesia. This was opposed by the oral surgery lobby,<sup>5</sup> and the California Legislature codified the single-provider-operator-anesthetist model for oral surgeons whereby the operating dentist/oral surgeon simultaneously provides deep sedation/anesthesia and performs the dental procedure (two tasks concurrently). The single-provider-operator-anesthetist model codified in this law contradicts all known anesthesia standards.<sup>6</sup>

The 2016 AAP guideline clearly stated the skills required for administering deep sedation: The person administering/directing the sedation must be "able to provide advanced pediatric life support and capable of rescuing a child with apnea, laryngospasm, explicit or airway obstruction. Required skills include the ability to open the airway, suction secretions, provide CPAP, insert supraglottic devices (oral airway, nasal trumpet, laryngeal mask airway) and perform successful bag-valve-mask ventilation, tracheal intubation, and cardiopulmonary resuscitation."<sup>2</sup> It explicitly states that there must be an independent observer whose only responsibility is to observe the patient and is capable of assisting with or managing emergencies. The AAP model is a multiple-provider-sedation-care team whereby multiple individuals are immediately present to initiate rescue.

In response, the oral surgery community developed a Dental Anesthesia Assistant National Certification Examination (DAANCE) with no pre-examination educational requirements. It consists of 36 hours of internet study covering the following:

1. Basic sciences
2. Evaluation and preparation of patients with systemic diseases
3. Anesthetic drugs and techniques
4. Anesthesia equipment and monitoring
5. Office anesthesia emergencies.<sup>7</sup>

Individuals who pass the examination are expected to "possess the expertise to provide supportive anesthesia care safely and effectively. The Dental Anesthesia Assistant (DAA) is knowledgeable in the perioperative and emergent care management of patients undergoing office-based outpatient anesthesia. The DAA is able to effectively communicate pertinent information to patients and their escorts as well as members of the health care team."<sup>7</sup>

It is astonishing to assume that a person with no practical or clinical experience would be certified to be the independent observer with all of the skill-sets described above learned in just 36 hours of internet reading. Such an individual would likely be incapable of providing any meaningful help with a genuine life-threatening emergency as they lack hands-on medical training, are not skilled in starting an IV, and not licensed to draw up and administer life-saving medications.

Consider the patient who developed airway obstruction, with the operating dentist the only person present with any medical knowledge. He/she must recognize the problem, manage the airway to provide oxygen, and then cease airway support to administer rescue medications; the only backup is 911. The DAANCE provider may be able to inform the dentist that something is wrong, but they cannot do much to help. It is truly dangerous to substitute a DAANCE observer for a skilled anesthesia professional.

Following introduction of the DAANCE oral surgery practice model, the AAP and AAPD crafted new wording. The 2019 sedation guideline now states explicitly that deep sedation/anesthesia must be provided by an anesthesia-trained provider and the operating dentist must be currently PALS-certified to assist the anesthesia provider with an adverse event. This provides a ready-to-respond sedation team on site. The single-provider-operator-anesthetist oral surgery model must be replaced with the multiple-provider-sedation-care team AAP/AAPD model.

It is essential that patient safety advocates be informed of this significant safety issue; healthy patients continue to suffer adverse outcomes specifically because of this single-provider-operator-anesthetist oral surgery practice model. We have a professional and personal responsibility to educate parents and patients to ask their oral surgeon very specific questions: "How will I/my child be monitored and by whom? Is there an independent observer whose only responsibility is to watch me/my child, certified in and up-to-date in resuscitation and trained in the delivery of anesthetics? Is the equipment for resuscitation immediately available?" If the answer to these questions is ambiguous or "no," then patient



safety may be compromised. It is critical for health care professionals, patients, and parents to speak to their associated legislatures to oppose proposals that support the single-provider-operator-anesthesia model for oral surgeons since California's approval of this law has encouraged oral surgeons across the U.S. to propose similar legislation.

*Charles J. Cote, MD, FAAP, is professor emeritus at Harvard Medical School, Division of Pediatric Anesthesia, and at the Massachusetts General Hospital for Children in the Department of Anesthesia, Critical Care and Pain Management, Boston, MA.*

*Raeford E Brown, Jr., MD, FAAP, is professor of anesthesiology and pediatrics at the University of Kentucky/The Kentucky Children's Hospital and chair of the Section on Anesthesiology, Lexington, PA, and Pain Medicine, The American Academy of Pediatrics.*

*Anna Kaplan, MD, is a resident in pediatrics at the University of California San Francisco Benioff Children's Hospital, Oakland, CA. She is co-author of Caleb's Law.*

*The authors have no conflicts of interest.*

## REFERENCES

1. Coté CJ, Wilson S. Guidelines for monitoring and management of pediatric patients before, during, and after sedation. *Pediatrics*. 2019;143:6 e1–31.
2. Coté CJ, Wilson S, American Academy of P, American Academy of Pediatric D. Guidelines for monitoring and management of pediatric patients before, during, and after sedation for diagnostic and therapeutic procedures: Update 2016. *Pediatrics*. 2016;138(1).
3. Caleb's Parents Cs. 2018. Parental permission to discuss child's death.
4. Caleb's Law. <http://www.calebslaw.org/caleb-s-story-and-law/>. Accessed December 21, 2020.
5. Moran D. How \$3 million in political donations stands in the way of justice for this boy's death. <https://www.sacbee.com/opinion/opn-columns-blogs/dan-morain/article147407899.html2017>. Accessed December 21, 2020.
6. Gelb AW, Morris WW, Johnson W, Merry AF. International standards for a safe practice of anesthesia W. World Health Organization-World Federation of Societies of Anaesthesiologists (WHO-WFSA) international standards for a safe practice of anesthesia. *Can J Anaesth*. 2018;65:698–708.
7. Surgeons AAOaM. Dental anesthesia assistant national certification examination (DAANCE). <https://www.aaoms.org/continuing-education/certification-program-daance2018>. Accessed December 21, 2020.

# Anesthesia Machine as an ICU Ventilator—A Near Miss During the COVID-19 Pandemic

by Matthew A. Levin, MD; Garrett Burnett, MD; Joshua Villar, AS; Joshua Hamburger, MD; James B. Eisenkraft, MD; and Andrew B. Leibowitz, MD

*This article was previously published on the APSF online portal.  
The present version is updated and modified by the authors for the present APSF Newsletter.*

**Disclaimer:** Viewers of this material should review the information contained within it with appropriate medical and legal counsel and make their own determinations as to relevance to their particular practice setting and compliance with state and federal laws and regulations. The APSF has used its best efforts to provide accurate information. However, this material is provided only for informational purposes and does not constitute medical or legal advice. This response also should not be construed as representing APSF endorsement or policy (unless otherwise stated), making clinical recommendations, or substituting for the judgment of a physician and consultation with independent legal counsel.

The COVID-19 pandemic in New York City during spring 2020 resulted in an unprecedented number of patients requiring mechanical ventilation. With the need for intensive care unit (ICU) beds and ventilators exceeding supply, anesthesia machines were used as ventilators in non-OR locations, an off-label use.<sup>1</sup> The APSF/ASA document “Guidance on Purposing Anesthesia Machines as ICU Ventilators” includes “Key Points to Consider in Preparing to Use Anesthesia Machines as ICU Ventilators,” which notes that any location with high pressure air and oxygen might be acceptable.<sup>2</sup> We report the case of an anesthesia machine ventilator failure in a COVID-19 patient who was being managed in a windowless negative pressure room in a telemetry unit that had been converted to a temporary COVID-19 ICU. This case highlights that novel use of standard equipment is subject to unforeseen problems.

## THE CASE

A 66-year-old man with a history of noninsulin-dependent diabetes was admitted to a temporary COVID-19 ICU for acute respiratory failure requiring tracheal intubation and mechanical ventilation. Temporary negative pressure rooms had been created by replacing the exterior window of each room with a hard-board panel that contained a cutout for a HEPA filter/extractor fan exhaust duct (Air Shield 550 HEPA Air Scrubber, AER Industries, Irwindale, CA). Anesthesia workstations (Aisys Caresta-

tion CS<sup>2</sup>, GE Healthcare, Waukesha, WI) were being used as ventilators in this temporary ICU, managed 24/7 by a group of anesthesia professionals. The rooms had no interior or door windows, but indirect viewing was provided via a remote visual patient monitoring system (AvaSys Telesitter, Belmont, MI). Monitoring was via a central station telemetry network (GE CareScape, GE Healthcare, Waukesha, WI) to which the workstation physiologic monitor had been connected, with high volume audio alerts for abnormal rhythms and bradycardia/tachycardia, and the default low volume audio alarm for low SpO<sub>2</sub>.

On hospital day 10, an audible alarm sounded at the central station and the SpO<sub>2</sub> was noted to be 45%. The care team donned PPE, entered the patient's room and observed that mechanical ventilation had ceased, the extractor fan was off, and the room was very warm. The Aisys control screen was dark, the AC power indicator light was off, but the physiologic monitor was on and functioning. The patient was immediately disconnected from the breathing circuit, ventilated using a self-inflating manual ventilation bag, and the SpO<sub>2</sub> rapidly returned to baseline levels. It was noted that the bed (HillRom Progressa Pulmonary, HillRom, Chicago, IL) was plugged into an auxiliary outlet on the extractor fan, the fan was plugged into a floor-level electrical outlet, and the Aisys workstation was plugged into a separate floor-level outlet. The workstation was

immediately connected to a different electrical outlet, the AC power indicator light came on, and the workstation rebooted. After a pre-use check-out had been performed, the patient was reconnected to the breathing circuit and mechanical ventilation resumed normally.

The Aisys workstation was subsequently removed from the room for interrogation and replaced with a new one. Hospital engineering staff found that a circuit breaker for the room had tripped and it was reset. No problem was found with the extractor fan and it was restarted.

## ROOT CAUSE ANALYSIS

The workstation's failure was caused by interruption of its power supply due to a tripped circuit breaker. Review of the service log revealed an AC power loss, appropriate cutover to the backup battery, and eventual complete discharge of the battery. Several alarm messages had been displayed on the workstation screen beginning 28 minutes after the AC power loss progressing from “Battery Low,” “Battery V Low” to “Battery V VERY LOW” and, after 1 hour 43 minutes, to “Battery Empty.” The system shut down after 1 hour 52 minutes. The service log verified that the system operated as intended,<sup>3</sup> but these alarm messages were not visible to the staff outside the patient's room.

See “ICU Ventilator,” Next Page





## Anesthesia Ventilator Failure Caused By Loss of External Power

From "ICU Ventilator," Preceding Page

### DISCUSSION

This case illustrates some of the problems that could be encountered during the COVID-19 pandemic, namely creating a makeshift ICU on short notice and using an anesthesia workstation to ventilate a critically ill patient in a closed room, with less-than-ideal remote monitoring. During normal use of an anesthesia workstation, a qualified anesthesia professional is in constant attendance, able to view the screens, hear audible alerts, and make adjustments as necessary. The backup battery on the Aisys workstation is specified to last from 50–90 minutes depending on the model, but in this case it lasted almost two hours. In contrast, an ICU ventilator such as the Puritan Bennett 980 (Medtronic, Boulder, CO) is specified to have a one-hour backup battery.<sup>4</sup> While ventilator failure in this case was caused by loss of external electrical power, failure of a ventilator's internal power supply has also been reported.<sup>5</sup> Fortunately the physiologic monitor (CareScape b650, GE Healthcare, Waukesha, WI) had its own backup battery with a 1–2 hour run time,<sup>6</sup> and was connected to the telemetry network, thus alerting staff. The cause of the tripped circuit breaker is unknown. The electrical power supply to the room comprised two dedicated 15A circuits with white outlets, two 20A circuits that were shared with the adjacent room and also had white outlets, and one 20A emergency circuit with red outlets. The white electrical outlets had no markings to indicate to which of the circuits they were connected.

It is unlikely that a device in the adjacent room caused the circuit breaker to trip because that room did not lose power. The most likely explanation is that the bed, extractor fan, telemedicine monitor, and anesthesia workstation were all connected to the same 15A circuit, and the total current draw from all devices exceeded 15A. The extractor fan draws 2.5A, and the bed can draw up to 12A, leaving a very small margin before the circuit would be overloaded. Notably, in many hospitals (including ours) the circuit breaker panels are locked and can only be accessed by engineering due to security concerns. Limited accessibility can cause a delay in reinstating power.<sup>7,8</sup>

The APSF/ASA Guidance includes the recommendation that "An anesthesia professional needs to be immediately available for consultation, and to 'round' on these anesthesia machines at least every hour." During the height of the pandemic, with limited PPE, limited staff, 168 ventilated patients and 18 patients being ventilated using anesthesia workstations, hourly rounding was simply not possible. The

same problem could also have occurred with a standard ICU ventilator, since they also have limited backup power, and aside from some very new models, lack remote monitoring capability. One solution not available to us at the time is to detach the control and monitoring screens from the Aisys workstation and, using special extension cables, move them to outside the room thereby allowing control of gas flows and ventilation as well as remote monitoring.<sup>9</sup>

In conclusion, the use of an anesthesia workstation as an ICU ventilator is feasible in a crisis situation, but increased vigilance is required to recognize and manage unanticipated problems.

*Matthew A. Levin, MD, is associate professor in the Department of Anesthesiology, Perioperative and Pain Medicine, Icahn School of Medicine at Mount Sinai, New York, NY.*

*Garrett Burnett, MD, is assistant professor in the Department of Anesthesiology, Perioperative and Pain Medicine, Icahn School of Medicine at Mount Sinai, New York, NY.*

*Joshua Villar, AS, is the head anesthesia technician in the Department of Anesthesiology, Perioperative and Pain Medicine, Icahn School of Medicine at Mount Sinai, New York, NY.*

*Joshua Hamburger, MD, is assistant professor in the Department of Anesthesiology, Perioperative and Pain Medicine, Icahn School of Medicine at Mount Sinai, New York, NY.*

*James B. Eisenkraft, MD, is professor in the Department of Anesthesiology, Perioperative and Pain Medicine, Icahn School of Medicine at Mount Sinai, New York, NY.*

*Andrew B Leibowitz, MD, is professor in the Department of Anesthesiology, Perioperative*

*and Pain Medicine, Icahn School of Medicine at Mount Sinai, New York, NY.*

*Garrett Burnett, Joshua Villar, Joshua Hamburger, James Eisenkraft, and Andrew Leibowitz report no conflict of interest.*

*Matthew Levin reports having received publication fees from the McMahon Group and consultant fees from ASA PM 2020, and has filed a provisional patent for the split ventilation circuit design with the Stryker Corporation for which he received no fee or equity interest.*

### REFERENCES

1. Haina KMK Jr. Use of anesthesia machines in a critical care setting during the coronavirus disease 2019 pandemic. *A A Pract.* 2020;14:E01243. [Doi:10.1213/Xaa.0000000000001243](https://doi.org/10.1213/Xaa.0000000000001243)
2. APSF/ASA guidance on purposing anesthesia machines as ICU ventilators. <https://www.asahq.org/in-the-spotlight/coronavirus-covid-19-information/purposing-anesthesia-machines-for-ventilators> Accessed August 6, 2020.
3. GE Aisys CS2 user's reference manual. <https://www.manualslib.com/manual/1210542/ge-aisys-cs2.html> Accessed August 10, 2020.
4. Technical Specifications for U.S. Puritan Bennett™ 980 Ventilator System. Medtronic/Covidien; 2016. <https://www.medtronic.com/content/dam/covidien/library/us/en/product/acute-care-ventilation/puritan-bennett-980-ventilator-system-tech-specifications.pdf> Accessed December 21, 2020.
5. Davis AR, Kleinman B, Jellish WS. Cause of ventilator failure is unclear – Anesthesia Patient Safety Foundation. Published 2005. <https://www.apsf.org/article/cause-of-ventilator-failure-is-unclear/> Accessed August 6, 2020.
6. GE Healthcare. Carescape Monitor B650; 10/2010. <https://www.gehealthcare.com/-/jssmedia/e4c9c6ed59f43a-0b2efdba2adfe2687.pdf?la=en-us> Accessed August 10, 2020.
7. Carpenter T, Robinson ST. Response to a partial power failure in the operating room. *Anesthesia & Analgesia.* 2010;110:1644. [Doi:10.1213/Ane.0b013e3181c84c94](https://doi.org/10.1213/Ane.0b013e3181c84c94)
8. August DA. Locked out of a box and a process. *Anesth Analg.* 2011;112:1248–1249; Author Reply 1249. [Doi:10.1213/Ane.0b013e31821140e4](https://doi.org/10.1213/Ane.0b013e31821140e4)
9. Connor CW, Palmer LJ, Pentakota S. Remote control and monitoring of GE Aisys anesthesia machines repurposed as intensive care unit ventilators. *Anesthesiology.* 2020;133:477–479. [Doi:10.1097/Aln.0000000000003371](https://doi.org/10.1097/Aln.0000000000003371)



Join the #APSF Crowd!  
Donate now at <https://apsf.org/FUND>



The Anesthesia Patient Safety Foundation is launching our first-ever crowdfunding initiative, defined as raising small amounts of money from a large number of people.  
**Just \$15 can go a long way to reach our goals.**

Help support the vision that "no one shall be harmed by anesthesia care."

# Perioperative Hypersensitivity: Recognition and Evaluation to Optimize Patient Safety

by David A. Khan, MD; Kimberly G. Blumenthal, MD, MPH; and Elizabeth J. Phillips, MD

## SUMMARY

Cefazolin is currently the most commonly identified cause of anaphylaxis in the United States, occurring in 1 in 10,000 surgeries; however, it is often overlooked.<sup>1</sup> If anaphylaxis is suspected, serum tryptase drawn within 2 hours may be helpful to identify or differentiate the episode from other causes. Cefazolin is a first generation cephalosporin with R1 and R2 side chain groups that are distinct from other beta-lactams, and most patients with cefazolin allergy can tolerate penicillins and other cephalosporins.

## WHAT DOES CEFAZOLIN ANAPHYLAXIS LOOK LIKE? A REAL LIFE CASE EXAMPLE

A 50-year-old African-American woman presented to an Allergy and Immunology clinic following two suspected discrete episodes of anaphylaxis prior to an intended right hip replacement at an outside hospital. She gave no other significant past medical history. Her medication history was significant for long-standing use of rosuvastatin 20 mg orally and acetaminophen 500 mg orally as needed. On the first occasion, she received vancomycin 2g and cefazolin 1g prior to the planned joint replacement. No sedation or anesthetic agents had been given. Within minutes of the cefazolin infusion, she had skin flushing, facial and lip swelling, and hypotension. She received a single dose of epinephrine 0.3 mg intramuscularly, diphenhydramine 50 mg and hydrocortisone 125 mg both intravenously, and was transferred to the intensive care unit under observation for an additional day. Ten days later, preparation for right hip replacement was again attempted, and this time she received cefazolin 2 g (without vancomycin) and within minutes developed facial swelling and flushing; epinephrine 0.3 mg intramuscularly and diphenhydramine 50 mg intravenously were immediately given, and she was observed for several hours without recurrence. Two months later, she was seen in allergy clinic where she underwent skin prick testing to cefazolin followed by intradermal testing to penicillins, cefazolin, and ceftriaxone (Figure 1). Skin tests were weakly positive to cefazolin prick testing and strongly positive to intradermal cefazolin but negative to all other reagents. She tolerated challenges with amoxicillin and cephalexin, both 250 mg orally. Based on these data, she was diagnosed with cefazolin anaphylaxis and given advice that it was safe for her to take penicillins and cephalosporins other than cefazolin and also safe for her to take vancomycin. We emphasized that cefazolin should



Figure 1: Illustration of positive prick and intradermal skin tests to cefazolin (Cp) following two discrete episodes of anaphylaxis temporally associated with cefazolin two months prior. Prick testing to histamine (H) is positive as a control. Prick and Intradermal testing to saline is negative as a negative control. Intradermal skin tests to other reagents including ampicillin 25 mg/ml, benzyl penicillin 1000 and 10,000 IU/ml, minor determinant mixture (MDM) and major determinant (Pre-pen) were negative.

be clearly documented as a severe reaction (anaphylaxis) in all electronic health records and pharmacy records and she should wear a medic alert bracelet.

## HOW TO IDENTIFY PERIOPERATIVE HYPERSENSITIVITY?

Perioperative hypersensitivity (POH) reactions are unexpected and unpredictable events that present suddenly without warning. The severity of reactions can range from mild reactions to severe anaphylaxis, which in some cases may be fatal. The incidence of POH ranges widely and by country of origin with recent studies suggesting an incidence of 1 in 10,000.<sup>2</sup> The majority of cases of POH are thought to be allergic, caused by IgE-mediated mast cell activation. However, non-IgE-dependent mechanisms that activate mast cells may also occur in association with many drugs given perioperatively. Recently, the Mas-related G-protein-coupled receptor X2 (MRGPRX2) has been shown to be a cause of reactions to certain medications such as neuromuscular blocking agents, vancomycin, fluoroquinolones, and

opioids. Radiocontrast dyes may also cause non-IgE mediated mast cell activation.

POH reactions typically present with cardiovascular and/or respiratory involvement including signs of hypotension, tachycardia, bronchospasm, and cardiac arrest. Mucocutaneous reactions such as erythema, urticaria, or angioedema can also occur, but may be missed due to draping of the patient. Cardiorespiratory symptoms are not specific for POH and may occur for a variety of other reasons such as medications, hypovolemia, underlying respiratory disease, and multiple attempts at intubations. Recently, an expert panel of anesthesia professionals and allergists developed a clinical scoring system to assist with determining the likelihood of a reaction being due to POH (Table 1).<sup>3</sup> A weighted scale with points for or against POH are tabulated based on clinical parameters which produces a score yielding the likelihood of an immediate hypersensitivity reaction. This scoring system underwent content, criterion, and discriminant validity but has not undergone independent external validation.<sup>3</sup>

The most useful laboratory test for helping to confirm an immediate hypersensitivity reaction is a serum tryptase level. Tryptase is a protease released by mast cells during anaphylaxis and is specific for evidence of mast cell activation. A tryptase level is ideally obtained within 2 hours of a reaction and will not be affected by medications used to treat a reaction. Elevations in tryptase have high positive predictive values (82–99%) for anaphylaxis in suspected perioperative reactions.<sup>4</sup> However, patients may have anaphylaxis without an elevated tryptase level ( $> 11.4$  ng/ml). A tryptase  $> 7.35$  ng/ml has a 99% positive predictive value for POH in patients with severe cardiovascular collapse or cardiac arrest. An acute serum tryptase level greater than  $(1.2 \times \text{serum baseline tryptase}) + 2$  can help confirm anaphylaxis (especially in those with normal acute tryptase levels) and has a positive predictive value for POH of 94%. Severe reactions can occasionally occur even with non-IgE mediated mast cell activation such as with vancomycin infused rapidly.<sup>5</sup> In about 10% of cases, serum tryptase may be elevated in the setting of non-IgE mediated mast cell activation.

While there are many causes of POH, antibiotics, neuromuscular blocking agents, and disinfectants are among the most common causes documented internationally.<sup>2</sup> In the U.S., however, cefazolin is the most commonly identified

See “Hypersensitivity,” Next Page

# International Consensus Recommendations Suggest A Comprehensive Allergic Evaluation For Patients with Perioperative Allergic Reactions

## From “Hypersensitivity,” Preceding Page

cause of POH, reported to be associated with >50% of cases of POH, and may occur with the first exposure to cefazolin.<sup>6</sup> The pathway of sensitization to cefazolin has not been determined. It is important to recognize that currently most episodes of anaphylaxis to cephalosporins are thought to be related to the R1 side chains. Cefazolin has R1 and R2 side chains that are distinct and not shared with any other beta-lactams used in North America. In

keeping with this, patients allergic to cefazolin are typically not allergic to penicillin or other cephalosporins.<sup>6</sup>

## WHY IS TESTING IMPORTANT IN THE SETTING OF PERIOPERATIVE HYPERSENSITIVITY?

After a suspected allergic reaction in the perioperative setting, it is critical to use all possible diagnostic investigational tools to identify the culprit drug. First, it is possible that the event occurred prior to the surgery and the surgery

was aborted at the time of the allergic reaction, but is still needed or recommended. Second, even if that specific surgery was completed despite the reaction, most patients will require subsequent anesthesia in the future. International consensus recommendations by an expert panel of anesthesia professionals and allergists recommend a comprehensive allergy evaluation, ideally with collaboration between anesthesia professionals and allergists, for all patients with perioperative allergic reactions.<sup>7</sup>

**Table 1: Clinical scoring system for suspected perioperative hypersensitivity reactions.\***

Cardiovascular System (CVS) (Choose hypotension, severe hypotension or cardiac arrest if appropriate, then any other items that apply)	Points
Severe hypotension	6
Hypotension	4
Cardiac arrest	9
Tachycardia	2
A poor or unsustained response of hypotension to standard doses of sympathomimetics used to treat pharmacological hypotension during anaesthesia (e.g., ephedrine, phenylephrine, metaraminol)	2
A point-of-care echocardiogram showing a hyperdynamic and poorly-filled heart	2
Recurrence or worsening of hypotension after a further dose of a drug given prior to the initial event	1
<i>Cardiovascular Confounders (choose any that apply)</i>	
Excessive dose of anaesthetic drug or drugs	-2
Surgically induced hypovolemia or relative hypovolemia from prolonged fasting/dehydration	-1
Acute illness predisposing to hypotension	-1
Medications affecting cardiovascular responses during anaesthesia	-2
Neuraxial regional anaesthesia (epidural/spinal)	-1
Onset of hypotension after development of increased peak airway pressure during mechanical ventilation of the lungs	-2

Respiratory System (RS) (Choose bronchospasm or severe bronchospasm if appropriate, then any other items that apply)	Points
Bronchospasm	2
Severe Bronchospasm	4
Recurrence or worsening of bronchospasm after a further dose of a drug given prior to the initial event	1
Bronchospasm occurring before airway instrumentation (having excluded airway obstruction)	2
<i>Respiratory Confounders</i>	
Respiratory disease associated with reactive airways	-1
Prolonged or multiple attempts at tracheal intubation	-1
Inadequate dose of drugs to obtund airway responses prior to airway instrumentation	-1

Dermal/mucosal (D/M) (Choose any items that apply)	Points
Generalised urticaria	4
Angioedema	3
Generalised erythema	3
A generalised rash is itchy in the awake patient who has not received epidural/spinal opioids	1
<i>Dermal/Mucosal/Confounder</i>	
Angioedema in a patient taking an ACE inhibitor	-3

Combinations (Choose a maximum of one item)**	
CVS>2 & RS > 2	5
CVS>2 & D/M >2	5
RS>2 & D/M >2	5
CVS>2 & RS>2 & D/M >2	8

Timing (Choose a maximum of one item)	
Onset of cardiovascular or respiratory features within 5 min of possible IV trigger	7
Onset of cardiovascular or respiratory features within 15 min of possible IV trigger	3
Onset of cardiovascular or respiratory features within 60 min of possible non-IV trigger	2
Onset of cardiovascular or respiratory features more than 60 min after possible non-IV trigger	-1

Likelihood of immediate hypersensitivity reaction	Total (net) score
Almost certain	>21
Very likely	15 to 21
Likely	8 to 14
Unlikely	< 8

\*Table modified from Hopkins PM, Cooke PJ, Clarke RC, et al. Consensus clinical scoring for suspected perioperative immediate hypersensitivity reactions. *Br J Anaesth.* 2019;123(1):e29–e37.

\*\*For a score from one of the 3 organ systems (CVS, RS, D/M) to contribute to a combinations score, the net score for that system must be > 2. The net score is the sum of scores for positive features minus the sum of scores for confounders within scores for that system.

See “Hypersensitivity,” Next Page



# Patients With Low-Risk Histories Can Safely Receive Cefazolin for Surgical Prophylaxis

## From “Hypersensitivity,” Preceding Page

The ideal time for allergy evaluation is thought to be approximately 4 weeks after the event; however, this is not evidence-based and testing up until at least 6 months after the event is still useful.<sup>8</sup> For patients allergic to cephalosporins, approximately 60–80% will lose skin test reactivity 5 years after acute anaphylaxis.<sup>9</sup>

It is important that the allergist have access to the full anesthesia record and operative note that includes timing of administration and any other detail related to potential exposures including disinfectants, latex, lubricants, contrast, dyes, gelatin sponges used for hemostasis, foreign devices, and local anesthetics and their timing in relation to the suspected allergic event. This will help guide the appropriate assessments. After a negative skin test, observed challenges whereby a full dose of a drug is given to the patient in an observed setting in 1 or 2 steps is performed to all potential culprit medications that are possible in an outpatient clinic setting. Most allergy practices do not do intravenous challenges and challenges cannot be safely performed in outpatient allergy practices to opioids, benzodiazepines, neuromuscular blocking agents, and propofol. As such, negative skin testing to agents not challenged by the allergist warrant a “test dose” to be given immediately prior to subsequent anesthesia. The best evidence to date from the U.S. suggests that we will identify at least one-third of culprits with this strategy by finding patients with positive skin tests.<sup>8</sup> Approximately 9 in 10 of the patients assessed by an allergy specialist, regardless of whether they have a positive skin test, will tolerate their subsequent anesthesia without a recurrent allergic reaction.<sup>8</sup>

Several patients presenting for surgery report allergies to penicillin or cefazolin without a formal allergist evaluation. Therefore, perioperative providers often seek alternative prophylactic antibiotics to administer to these patients. However, alternative perioperative antibiotics for surgical site infection prophylaxis can result in an increased risk of prophylaxis failure and infection.<sup>10</sup> Furthermore, perioperative clindamycin and vancomycin are associated with an increased risk of *Clostridium difficile* colitis and acute kidney injury. Additionally, a patient with a cefazolin allergy documented in their electronic health record without specific allergist guidance may avoid all beta-lactam

antibiotics, which can have additional clinical implications in the future.<sup>11</sup> If cefazolin is identified as the causative drug, tolerance to other beta-lactams can be confirmed through specialized allergy testing.

Most patients in the U.S. who are labeled as being allergic to penicillin report histories of benign rashes, remote reactions, or unknown reactions. Patients with these low-risk histories can safely receive cefazolin for surgical prophylaxis.<sup>6</sup> Recently, a multi-disciplinary group at Emory University developed a simple algorithm for administration of cefazolin or cefuroxime for perioperative antibiotic prophylaxis to patients with histories of penicillin allergy.<sup>12</sup> If patients did not have histories of severe drug reactions such as Stevens-Johnson syndrome or toxic epidermal necrolysis, drug reaction with eosinophilia and systemic symptoms, liver or kidney injury, anemia, fever, or arthritis following penicillin, they were allowed to receive cefazolin or cefuroxime. After implementation of this simple algorithm, cephalosporin use increased nearly 4-fold in penicillin allergic subjects and none of the 551 penicillin allergic patients who received a cephalosporin had an immediate allergic reaction. Another study revealed that even in patients with confirmed anaphylactic penicillin allergy, the risk of cefazolin allergy is < 1%.<sup>13</sup>

For patients with POH, we recommend a standard approach that optimizes patient safety and includes anesthesia professionals working with an allergist/immunologist to identify the culprit or compose a logical plan for subsequent anesthesia that minimizes allergic risk, while considering the importance of antibiotic prophylaxis.<sup>1</sup> If the anesthesia professional does not have an allergist to work with, allergists can be found through a professional society link (<https://allergist.aaaai.org/find/>). Additionally, with the expansion of telemedicine that accompanied the COVID-19 pandemic, virtual appointments with allergists at the major academic medical centers that routinely evaluate these patients, for formal triage and risk stratification preceding specialized testing is now possible.

In summary, POH reactions are rare events with many potential culprits with cefazolin being the most frequent in the U.S. Collaboration between anesthesia professionals and allergists can help to identify the culprit and develop a plan for safe administration of anesthesia in the future. While most patients with a label of

penicillin allergy are not truly allergic, the vast majority of patients with an unverified penicillin allergy can receive cefazolin for surgical prophylaxis without increased risk of an allergic reaction.

*David A. Khan, MD, is professor of medicine in the Division of Allergy & Immunology at the University of Texas Southwestern Medical Center, Dallas, TX.*

*Kimberly G. Blumenthal, MD, MPH, is assistant professor of Medicine at Harvard Medical School in the Division of Rheumatology, Allergy and Immunology at Massachusetts General Hospital, Boston, MA.*

*Elizabeth J. Phillips, MD, is a professor of medicine and John A. Oates Chair in Clinical Research in the Department of Medicine at Vanderbilt University Medical Center, Nashville, TN.*

*The authors have no conflicts of interest.*

## REFERENCES

1. Saager L, Turan A, Egan C, et al. Incidence of intraoperative hypersensitivity reactions: a registry analysis. *Anesthesiology*. 2015;122:551–559.
2. Mertes PM, Ebo DG, Garcez T, et al. Comparative epidemiology of suspected perioperative hypersensitivity reactions. *Br J Anaesth*. 2019;123:e16–e28.
3. Hopkins PM, Cooke PJ, Clarke RC, et al. Consensus clinical scoring for suspected perioperative immediate hypersensitivity reactions. *Br J Anaesth*. 2019;123:e29–e37.
4. Volcheck GW, Hepner DL. Identification and management of perioperative anaphylaxis. *J Allergy Clin Immunol Pract*. 2019;7:2134–2142.
5. Alvarez-Arango S, Yerneni S, Tang O, et al. Vancomycin hypersensitivity reactions documented in electronic health records. *J Allergy Clin Immunol Pract*. 2020.
6. Khan DA, Banerji A, Bernstein JA, et al. Cephalosporin allergy: current understanding and future challenges. *J Allergy Clin Immunol Pract*. 2019;7:2105–2114.
7. Garvey LH, Dewachter P, Hepner DL, et al. Management of suspected immediate perioperative allergic reactions: an international overview and consensus recommendations. *Br J Anaesth*. 2019;123:e50–e64.
8. Banerji A, Bhattacharya G, Huebner E, et al. Perioperative allergic reactions: allergy assessment and subsequent anesthesia. *J Allergy Clin Immunol Pract*. 2020;S2213–2198.
9. Romano A, Gaeta F, Valluzzi RL, et al. Natural evolution of skin-test sensitivity in patients with IgE-mediated hypersensitivity to cephalosporins. *Allergy*. 2014;69:806–809.
10. Berrios-Torres SI, Umscheid CA, Bratzler DW, et al. Centers for Disease Control and prevention guideline for the prevention of surgical site infection, 2017. *JAMA Surg*. 2017;152:784–791.
11. Blumenthal KG, Peter JG, Trubiano JA, Phillips EJ. Antibiotic allergy. *Lancet*. 2019;393:183–198.
12. Kuruvilla M, Sexton M, Wiley Z, et al. A streamlined approach to optimize perioperative antibiotic prophylaxis in the setting of penicillin allergy labels. *J Allergy Clin Immunol Pract*. 2020;8:1316–1322.
13. Romano A, Valluzzi RL, Caruso C, et al. Tolerability of cefazolin and cefibuten in patients with IgE-mediated ampicillin allergy. *J Allergy Clin Immunol Pract*. 2020;8:1989–1993.e1982.

## RAPID Response

to questions from readers

## Unanticipated Movement of Skytron Operating Room Tables

by Stephen D. Weston, MD; Claudia Benkwitz, MD, PhD; and Richard J. Fechter

A 4.3kg 6-week-old patient was in the operating room (OR) for repair of a ventricular septal defect. After a minor adjustment in table height using the pendant (hand controller), our Skytron 3602 OR table continued to rise on its own until it reached its full height. The bed's motion could be paused by continuously pressing any of the other buttons on the pendant, but only while the button remained depressed. As the bed went to full height, we ensured our lines and monitors were not under tension. The ventilator circuit only just reached the patient's endotracheal tube. Our clinical engineering team changed out the bed control pendant, and we regained normal control of the bed. Fortunately, this event happened after the surgery was complete and the dressing on; had the bed malfunction occurred during cardiopulmonary bypass, decannulation and exsanguination could easily have resulted.

Our biomedical engineering group was familiar with the problem, diagnosing a stuck button on the pendant. Our hospital first noticed the same problem in May of 2019, when unanticipated upward movement of a Skytron bed occurred during a robotic hernia repair. Fortunately, the robot was not docked, as this would have the potential to do catastrophic damage to the patient. Since then, we have documented 4 additional incidents at our institution, 3 with Skytron 3602 and 1 with Skytron 6701 beds. The motion in each case was upward vertical motion. Two of these incidents were the subject of prior Medwatch reports to the FDA.<sup>1</sup>

We queried the U.S. Food and Drug Administration Manufacturer and User Facility Device Experience (MAUDE) database from 2015 to the present for unintended movement in Skytron OR tables. Although the level of detail in the MAUDE database is not deep, we were able to exclude some reports that pointed to different etiologies, such as sudden movement consistent with a component failure, or other electro-mechanical failures indicated by visible smoke or leaking hydraulic fluid. We also excluded bed movements that could not be



achieved by a single stuck button on the hand controller. We found 4 reports that are at least suggestive of experiences similar to ours. Two were reports of unintended vertical motion, one of which bundled four separate incidents.<sup>2</sup> The other 2 reports are of unintentional airplaning.<sup>3</sup>

Investigation by one of our biomedical engineers suggested the cause of the unintended motion was a stuck button. There is a disk-shaped piece of plastic underneath the button overlay the operator presses. This piece interfaces with the actual switch behind it. With just the right (or wrong) vector of force applied to the button, the plastic disk can jam into the switch, resulting in continuous bed movement. While difficult, it has been possible to recreate the fault in our lab.

All of the buttons on this pendant style share the same design, suggesting that any of them could trigger this kind of fault. We suspect that because the table up button is frequently used for its table lock function, that particular button may be more prone to wear, explaining why all of our cases have involved vertical motion. But the role of component wear is unclear, since the failure leading to unintended motion appears to be inherent in the pendant design. Our events have occurred with pendants that are less than 5 years old. We understand that a pendant bed control with a different underlying design is

under development, but the time-line for release is unclear.

Skytron's examination of our pendant showed evidence of fluid invasion, most likely related to overly wet cleaning cloths used during room turnovers. In addition, Skytron's testing leads them to posit a different mechanism for the fault, one more directly related to component wear over many uses. The authors of this letter are unable to adjudicate the most likely mechanism of the unanticipated movement.

Our institution has implemented a program of training and review for our hospitality staff to ensure cleaning processes that reduce the risk of leaving the pendant wet beyond the necessary dwell time of our cleaning agents. We have also undertaken a program of education for every member of the OR team. If a Skytron OR table is moving when no button is being pressed:

1. Press any other button on the bed controller to arrest the table's motion.
2. If time and clinical circumstances allow, try pressing the activated button to see if it will unstick.
3. Have someone go under the OR table to press the red emergency stop button.

See "OR Tables" Next Page

## RAPID Response

to questions from readers

# Operating Room Table Control Can Lose Functionality When Immersed in Liquids

### From “OR Tables,” Preceding Page

It is now our policy to turn off the OR table once final positioning is achieved for robotic cases. However, there are many cases, such as those with cardiopulmonary bypass, for which intermittent bed repositioning is required throughout the case, yet where large unintended changes in patient position could have catastrophic results. Turning off the bed for the duration of surgery is rarely a viable solution, nor even a broadly applicable band-aid.

*Stephen Weston, MD, is associate professor in the Department of Anesthesia and Perioperative Care at the University of California, San Francisco.*

*Claudia Benkwitz, MD, PhD, is associate professor in the Department of Anesthesia and Perioperative Care at the University of California, San Francisco.*

*Richard Fechter is a clinical engineer at the University of California, San Francisco.*

*The authors have no conflicts of interest.*

### REFERENCES:

1. Food and Drug Administration, MAUDE (Manufacturer and User Facility Device Experience) Database. Reports 8619119 and 9409491. <https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfmaude/search.cfm> Accessed June 4, 2020.
2. Food and Drug Administration, Manufacturer and User Facility Device Experience Database. Reports 8752471, 8939952. <https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfmaude/search.cfm> Accessed June 4, 2020.
3. Food and Drug Administration, Manufacturer and User Facility Device Experience Database. Reports 9340635, 6081727. <https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfmaude/search.cfm> Accessed June 4, 2020.

### Response:

This letter follows up a comprehensive investigation and review by Skytron and its manufacturer, Mizuho, of reported UCSF pendant control concerns regarding inadvertent table movement, and responds to your request for information dated September 14, 2020. Skytron and Mizuho have concluded their investigation of the UCSF pendant controls, which included extensive physical examination and testing of the UCSF controls. As discussed in a meeting with the UCSF team on Friday, September 4, 2020, the returned UCSF pendant controls exhibited a high degree of atypical

### Pendant Control Cleaning

**CAUTION**

**DO NOT** submerge the pendant control in any water or cleaning solutions!

1. Apply cleaning solutions to the pendant control and cord.
2. Using a clean, damp, lint-free cloth, wipe the pendant control to remove the cleaning solution.
3. Using a clean, dry, lint-free cloth, wipe the pendant control and cord to remove all moisture.



*Figure 1: Pendant Control Cleaning.*

cal use and uncommonly displayed both external and internal damage, along with resulting loss of functionality. Specifically, the damage and observed loss of functionality in the 22 UCSF returned units included:

- 20 Units with fluid ingress
- 10 Units with corrosion related to fluid ingress
- 5 Units backlight failure
- 22 Units physical damage to cover
- 2 Units inconsistent or failed battery on/off function
- 1 Unit continuous table up movement
- 9 Units with damage to button face

Thus, over 90% of the UCSF units revealed internal evidence of fluid ingress to the electronic components (consistent with dipping of the controls and/or other improper cleaning techniques), and 50% of the units exhibited corrosion to the circuit boards and/or wiring. One control with fluid ingress and external damage was also found to have internal physical damage to the button resulting in a continuous table up movement. Skytron has concluded that the reported issues with the UCSF controls were caused by a combination of fluid ingress and atypical use and force applied to the pendants.

The use and maintenance of the pendant controls contributed to the malfunction experienced by UCSF. Skytron understands and appreciates the challenges of the clinical environment and strives to ensure that its products are sufficiently robust to meet such challenges. With respect to maintenance of pendants, however, Skytron's manual and cleaning

instructions are clear. Skytron specifically cautions against immersing pendant controls in liquids and allowing fluid entry into electrical connectors:

When properly maintained, the pendant controls are sufficiently robust and operate safely and reliably. To be sure, as part of the investigation, Skytron and its manufacturer examined the entire history of complaint data and MDR reports for the pendants across all user facilities, taking into consideration the frequency of occurrence and the number of tables in distribution. The data demonstrated an extremely low complaint rate, and do not indicate a failure of the device design or suggested maintenance procedures.

The experience of the UCSF team, however, is being considered as we develop future product design enhancements and continuing education of our customers regarding proper maintenance of the pendants. Skytron's focus remains on understanding and meeting the specific needs of our users as we develop products that ensure patient safety and customer satisfaction.

Skytron continues to work with UCSF to meet its user needs and ensure product satisfaction, including reinforcement of proper maintenance, cleaning, and inspection protocols.

Please call or email me if you have any further questions.

*Sincerely,*

*Erin Woolf*

*Quality Manager, Skytron*



# Drug-Induced MH-like Syndromes in the Perioperative Period

by Charles Watson, MD; Stanley N. Caroff, MD; and Henry Rosenberg, MD

## MALIGNANT HYPERTHERMIA VS. DRUG-INDUCED MH-LIKE SYNDROMES

Anesthesia professionals recognize malignant hyperthermia (MH) in the perioperative period as a rapidly progressing, life-threatening, hypermetabolic syndrome that's triggered in the muscle of genetically susceptible individuals by potent inhalational anesthetic agents and/or succinylcholine. Unless recognized and treated expeditiously by withdrawal of the triggering agent(s), intravenous dantrolene sodium and other supportive measures, MH crisis has a high morbidity and mortality. Evolving signs of MH include rapidly rising temperature, heart rate (HR), CO<sub>2</sub> production, end-tidal CO<sub>2</sub>, respiratory rate (RR), spontaneous or required minute ventilation, increased muscle tone with rigidity, and multiple organ system failure (MOSF). Muscle injury can lead to renal failure, even when the MH crisis is treated effectively. Fever with unmet metabolic demand together with cardiac and microcirculatory failure can lead to coagulopathy, hepatic dysfunction, other MOSF, and death.<sup>1,2</sup>

MH is best known by anesthesia professionals because it is triggered by anesthetic drugs. Since anesthesia intervention causes an MH crisis, it has become an anesthetic-related problem. But there are other drug-induced hypermetabolic conditions that are caused by abnormal central nervous system (CNS) activity and have signs resembling those of an MH crisis (See Table 1).<sup>3</sup> Moreover, anesthetic drugs or interventions may contribute to or precipitate these. Such CNS crises can present in the extended perioperative period with MH-like signs of hypermetabolism (elevated HR, RR, temperature, and carbon dioxide production), abnormal motor activity, abnormal mentation, and progressive cardiorespiratory failure. Although these drug-induced crises are more commonly seen by emergency medicine, neurology, psychiatry, and critical care providers as evolving medical emergencies, they can also present around the time of surgery. Central drug-related hypermetabolic conditions are important to anesthesia professionals because they can be seen in the perioperative period, are not MH (although they may resemble MH), and may have different management requirements if morbidity and mortality are to be avoided. Although these are not caused primarily by anesthetic drugs, some can be precipitated by drugs commonly given or withheld in the perioperative period. Fever associated with MH crisis and these central hypermetabolic conditions respond poorly to antipyretic drugs. Anticholinergic and antipsychotic drugs with

anticholinergic effects are relatively contraindicated because they inhibit heat dissipation and sweating.<sup>4</sup> Dantrolene sodium is a specific antidote to the MH crisis because of its direct action on muscle, but it may also be helpful in controlling fever caused by muscle hyperactivity and heat production caused by these CNS and other problems.<sup>5-8</sup>

The volunteer MH Hotline that is supported by donations and the Malignant Hyperthermia Association of the United States [MHAUS] receive calls from anesthesia and surgical practitioners, perioperative nursing staff, and others with questions about the recognition and management of MH crises, post-crisis management, and other conditions that resemble MH. (<https://www.mhaus.org>) Review of MH Hotline calls shows that some of these calls are associated with MH-like conditions that are drug- or toxin-induced (unpublished data-author's personal communication with MHAUS Hotline Database).

Drug-induced, MH-like syndromes include Neuroleptic Malignant Syndrome (NMS), Parkinsonism/Hyperthermia Syndrome (PHS), Serotonin Syndrome (SS), baclofen withdrawal, intoxication caused by stimulants like amphetamine, MDMA and cocaine, and psychoactive drugs like phencyclidine (PCP, "angel dust") and lysergic acid diethylamide (LSD) (see Table 2). While the clinical setting of these is most often not perioperative and the presentation may not be so fulminant as classic MH, these conditions also can pose life-threatening medical problems that the anesthesia and surgical team have to address intra- and postoperatively. And, of course, these evolving drug-induced problems should be differentiated from inflammatory and central neurologic effects of organic conditions like encephalitis, sepsis, CNS abscess, tumor, head trauma, and some strokes. Also, confusion, together with hypermetabolism is seen with thyrotoxicosis, heat-stroke, and untreated lethal catatonia.

## NEUROLEPTIC-MALIGNANT SYNDROME (NMS)

NMS is a relatively rare condition associated with administration of chronic or increasing doses of neuroleptic drugs that block dopaminergic activity in the brain. Neuroleptics are given for sedation, behavioral control, and management of psychotic disorders. Postoperatively they may be used for behavioral control during emergence delirium, for antiemetic properties, or in the ICU following surgery. Individuals who take these drugs, and are ill, dehydrated, agitated, or catatonic are more susceptible to NMS. "Occult" neuroleptics like

prochlorperazine can also trigger NMS. These are often given perioperatively for nausea or nausea prophylaxis. The onset of hypermetabolic signs with fever, abnormal muscle activity (including rigidity), and abnormal mentation can be seen within hours and up to one or two weeks after neuroleptics are started. Progression of these signs is usually reversed over time when the causative agents are discontinued, but unrecognized NMS can progress to muscle injury, cardiorespiratory failure, and death. Primary treatment requires early diagnosis, neuroleptic withdrawal, and supportive medical care. In the absence of randomized controlled trials, benzodiazepines, dopaminergic drugs like bromocriptine or amantadine, dantrolene, and ECT (electroconvulsive therapy) have been employed with varying success. Neither laboratory tests nor presenting symptoms make the diagnosis of NMS. Diagnosis requires a thorough medical history and examination together with elimination of other organic or drug-induced conditions.<sup>9,10</sup> If NMS is suspected, the Neuroleptic Malignant Syndrome Information Service (NMSIS) sponsored by MHAUS provides literature, and email and telephone support through its website ([www.NMSIS.org](http://www.NMSIS.org))

## PARKINSONISM-HYPERTHERMIA SYNDROME (PHS)

PHS is caused by withdrawal of centrally acting dopaminergic drugs that control the muscle rigidity, motor retardation, and other symptoms of Parkinson's disease. Symptoms often fluctuate and drug dosing may vary because patients can become relatively insensitive to dopaminergic drugs. Dopaminergic drugs are sometimes stopped during acute hospitalization for medical or surgical conditions or preoperatively in order to minimize their autonomic side effects. PHS, a semi-acute condition that resembles NMS and MH, may follow sudden withdrawal of Parkinsonian drug therapy. It is reported in up to 4% of patients in whom dopaminergic drugs are acutely discontinued and approximately a third of patients who develop the syndrome have long-term sequelae.<sup>11</sup> Fever, abnormal muscle activity, and other signs of hypermetabolism together with autonomic instability are seen. PHS may be facilitated by dehydration, infection, and other system stresses, or following administration of central dopamine-blocking drugs like droperidol or neuroleptics like haloperidol. It can also be induced in Parkinson's patients after sudden loss of deep brain stimulation (DBS) for Parkinson's disease or following

See "MH-like Syndromes," Next Page

## MH-like Syndromes (Cont.)

### From “MH-like Syndromes,” Preceding Page

implantation of electrodes for DBS.<sup>12,13</sup> While NMS is a life-threatening condition caused by drugs that block central dopamine, PHS is caused by withdrawal of dopaminergic therapy. For this reason, complete discontinuation of dopaminergic therapy in the perioperative period should be avoided, if at all possible. Also, those patients who have had their Parkinsonian drugs discontinued in the perioperative period, should restart therapy as soon as possible.<sup>14</sup>

### SEROTONIN SYNDROME (SS)

SS is usually seen when several drugs that increase central serotonin levels are given concomitantly, but it may also occur following a single dose or overdose of one or more serotonergic drugs. Serotonin or 5-hydroxytryptamine, a monoamine derived from tryptophan, is a neurotransmitter in the brain, gut, and on

**Table 1: MH-Like Signs and Symptoms.**

Rising Temperature
Tachycardia
Tachypnea
Increasing Hypercarbia—Especially with Fixed, Controlled Ventilation
Confusion, Agitation, Altered Mentation
Muscle Rigidity, Cramping, Tremor, Spasms
Hypertension/Hypotension
Cardiac Arrhythmia

platelets. Serotonin modulates a broad array of central and peripheral actions that include regulation of mood, appetite, sleep, some cognitive functions, platelet aggregation, and smooth muscle contraction of uterus, bronchi, and small

blood vessels.<sup>15</sup> Consequently, a number of antidepressant drugs have been designed to manipulate CNS serotonin levels. These include the Selective Serotonin Reuptake Inhibitors (SSRIs), Selective Norepinephrine Reuptake Inhibitors (SNRIs), tricyclic antidepressants, and monoamine oxidase inhibitors (MAOIs). The incidence of SS has been reported as 0.9–2% of patients on chronic therapy and as high as 14–16% after overdose.<sup>16</sup> SSRIs and SNRIs are most commonly associated with SS. Commonly used anesthetic adjuvant drugs and other major classes of drugs—including some sold without prescription—may contribute to or precipitate SS (see Table 3).<sup>17-20</sup>

SS may present with altered mental status, autonomic dysfunction, hypotension, neuromuscular rigidity, agitation, ocular and peripheral clonus, diaphoresis, and fever.

**Table 2: Drug-Induced MH Look-Alike Conditions.**

Syndrome Drug	Probable Cause	Implicated Drugs	Factors	Onset	Signs & Symptoms
NMS	CNS dopamine deficit	Neuroleptics like haloperidol. Dopamine blocking antiemetics like metoclopramide & prochlorperazine	Dehydration, overdose, increasing or mixed drug doses	1–2 weeks	Fever, hypermetabolism, rigidity, shivering, abnormal CNS, unstable BP, rising creatinine kinase, MOSF
PHS	Dopamine deficit	Parkinsonian dopaminergic withdrawal	Abrupt discontinuation, dehydration & stress	Hours to days	As above
SS	CNS & peripheral serotonin excess	SSRIs, SNRIs, triptans, MAOIs, TCAs, some anesthetic adjuvants, methylene blue, some OTC drugs like loperamide, dextromethorphan	Overdose or increasing doses, multidrug interactions	1–24 hours	As above & myoclonus, agitation, confusion, dilated pupils, GI symptoms, evolving MOSF
Baclofen	Withdrawal	Baclofen	Pump failure, prescription stop	Hours to days	Hypertension, rigidity, dysautonomia, depressed CNS, coagulopathy, & MOSF
Amphetamines & CNS stimulants	Direct CNS & peripheral effects	Amphetamines, dexamphetamine, MDMA, cocaine	Dehydration, stress, other illness	Hours	Hyperdynamic circulation, fever, sweating, pupillary dilatation, cardiorespiratory, & MOSF
PCP	Direct CNS & peripheral effects	PCP or “angel dust”	Dehydration, stress, other illness	Hours	Slurred speech, abnormal gait, rigidity, sweating, hypersalivation, convulsions, coma, MOSF
LSD	Direct CNS & peripheral effects	LSD & LSD preparations	Dehydration, major stress, intercurrent illness	Hours	Hallucinations, rigidity, psychosis, CNS depression, respiratory arrest, coagulopathy, MOSF

**Table Abbreviations:** NMS (neuroleptic malignant syndrome), CNS (Central Nervous System), MOSF (multiple organ system failure), PHS (Parkinsonism-Hyperpyrexia Syndrome), SS (Serotonin Syndrome), SSRIs (selective serotonin reuptake inhibitors), SNRIs (selective norepinephrine reuptake inhibitors), Triptans (a class of Triptamine-based drugs used to abort migraines & cluster headaches), TCAs (tricyclic antidepressants), MAOIs (Monoamine Oxidase Inhibitors), OTC (sold without prescription “over the counter”), GI (gastrointestinal), MDMA (3,4-methylenedioxy-methamphetamine or “ecstasy”), PCP (phenylcyclidine or “angel dust”), LSD (lysergic acid diethylamide).

See “MH-like Syndromes,” Next Page

# Drug-Induced Hypermetabolic Syndromes May Present in the Perioperative Setting

## From “MH-like Syndromes,” Preceding Page

Onset can be abrupt following drug administration or overdose. SS can present as a hyperthermic, hypermetabolic syndrome that’s difficult to distinguish from NMS, PHS, and MH. As with NMS and PHS, progression of symptoms may lead to cardiorespiratory failure, muscle damage, multiple organ injury, and death. The incidence of SS may be underestimated, possibly because of mild cases that are overlooked or because more serious presentations can mimic other causes. Hence it may be that SS is more common in the perioperative period than we know. It is important for anesthesia practitioners to remember that a number of anesthetic adjuvant drugs we commonly use can precipitate or increase risk of SS. Treatment requires cessation of all drugs that contribute to serotonin excess together with supportive therapy.<sup>15,16</sup> Although unproven, some authorities recommend use of the central 5-hydroxytryptamine 2a receptor blocker, cyproheptadine, because the 5 hydroxytryptamine 2a receptor is thought to be one of the primary central activators of hyperthermia in SS.<sup>16,21,22</sup>

## BACLOFEN WITHDRAWAL

NMS and MH-like reactions have been reported following baclofen withdrawal. Baclofen enhances the central effects of gamma-aminobutyric acid (GABA), an inhibitory central nervous system (CNS) neurotransmitter.

Baclofen is commonly given orally or by direct injection/infusion into cerebrospinal fluid by anesthesia and other pain specialists to control spasticity seen following CNS damage in conditions like cerebral palsy, spinal cord injury, and dystonia. Since anesthesia pain specialists use baclofen, it isn’t that uncommon for other anesthesia practitioners to become involved in pump refills, assessment of a malfunctioning baclofen pump, or a baclofen prescription for a colleague. Hence it’s important for members of the anesthesia care team to know that the MH-like syndrome following acute baclofen withdrawal, with relative CNS deficiency of GABA, can be dramatic with fever, abnormal mentation, autonomic hyperactivity, respiratory distress, rhabdomyolysis, and coagulopathy. Treatment involves supportive medical care and reinstitution of baclofen therapy.<sup>23</sup>

## RECREATIONAL DRUGS

Selected CNS stimulants used for “recreation” or in overdose cause hypermetabolic conditions that may resemble MH crisis through direct peripheral and CNS effects. These include amphetamines, dextroamphetamine, methamphetamine, MDMA (methylene-dioxy-methamphetamine), cocaine, and psychoactive drugs like PCP and LSD. Although a drug history and toxicology screening usually identify such problems before emergency surgery for trauma or other acute conditions, “recreational” use may be encountered in patients scheduled

for elective surgery. Just as some patients pre-medicate themselves with alcohol or “medical” marijuana prior to surgery in order to control anxiety, habitual users of these psychoactive drugs may do the same. While initial subjective symptoms vary as each of these drugs takes effect, all may produce signs of sympathetic hyperactivity, abnormal motor activity, fever, and hypermetabolism with cardiorespiratory and MOSF in the perioperative period. Patients presenting for surgery with abnormal mentation, signs of sympathetic hyperactivity, and other unusual symptoms that are not caused by their primary medical problem should have toxicology screening if at all possible.

## CONCLUSION:

While anesthesia professionals know MH as a perioperative crisis, it is important to be aware of other drug-induced hypermetabolic syndromes that may be seen in the perioperative setting. Indeed, commonly used anesthetic adjuvant drugs may contribute to or precipitate some of these. Dantrolene sodium is the critical drug for treatment of MH crisis, but it is non-specific in that it may ameliorate some of the hypermetabolic signs of other conditions. Because these can closely mimic the MH crisis and dantrolene may control some of the symptoms, misdiagnosis as MH could delay or prevent other effective treatment.

Charles Watson, MD, is a volunteer MH Hotline Consultant for the Malignant Hyperthermia Association of the United States (MHAUS), Sherburne, NY.

Stanley Caroff, MD, is professor of psychiatry at the University of Pennsylvania School of Medicine and director of the Neuroleptic Malignant Syndrome Information Service (NMSIS) and an officer of MHAUS.

Henry Rosenberg, MD, is the president of MHAUS.

Drs. Watson and Rosenberg have no conflicts of interest.

Dr. Caroff is a consultant for Neurocrine Biosciences, Teva Pharmaceuticals. He has also received research grants from Neurocrine Biosciences, Osmotica Pharmaceuticals, Eagle Pharmaceuticals.

## REFERENCES

- Rosenberg H, Davis M, James D, et al. Malignant hyperthermia. *Orphanet Journal of Rare Diseases*. 2007;2:21.
- Rosenberg H, Hall D, Rosenbaum H. Malignant hyperthermia. In: Brendt J, ed. *Critical Care Toxicology*. Elsevier-Mosby; 2005:291–304.

Table 3: Some Drugs that Cause or Potentiate Serotonin Syndrome.

Antidepressants	Triptans	Anesthesia Adjuvants	Miscellaneous
<b>SSRIs</b> Citalopram Fluoxetine Fluvoxamine Paroxetine Trazodone	Almotriptan Eletriptan Frovatriptan Naratriptan Rizatriptan Sumatriptan Zolmitriptan	Cocaine Meperidine Methadone Ondansetron Tramadol Fentanyl	Buspirone Cyclobenzaprine Dextromethorphan Ergot 5-hydroxytryptophan Linezolid Loperamide Methylene blue St. John’s wort
<b>SNRIs</b> Duloxetine Sibutramine Venlafaxine Tricyclics			
<b>MAOIs</b> Phenelzine Tranylcypromine			

Abbreviations: SSRIs (selective serotonin reuptake inhibitors), SNRIs (selective norepinephrine reuptake inhibitors), MAOIs (monoamine oxidase inhibitors).



## MH-like Syndromes (Cont.-References)

### From “MH-like Syndromes,” Preceding Page

3. Parness J, Rosenberg H, Caroff SN. Malignant hyperthermia and related conditions. In: Kellum JA, Fortenberry JD, Fuchs BD & Shaw A, eds. *Clinical Decision Support: Critical Care Medicine*. Wilmington, Delaware: Decision Support in Medicine, LLC: 1913.
4. Mann SC. Thermoregulatory mechanisms and antipsychotic drug-related heatstroke. In: Mann SC, Caroff SN, Keck PE, Lazarus A, eds. *Neuroleptic Malignant Syndrome and Related Conditions*. 2nd Ed. Washington, DC: American Psychiatric Publishing; 2003:45–74.
5. Goulon M, de Rohan-Chabot P, Elkharrat D, et al. Beneficial effects of dantrolene in the treatment of neuroleptic malignant syndrome: a report of two cases. *Neurology*. 1983;33:516–518.
6. Pawat SC, Rosenberg H, Adamson R, et al. Dantrolene in the treatment of refractory hyperthermic conditions in critical care: a multicenter retrospective study. *Open Journal of Anesthesiology*. 2015;5:63–71.
7. Hadad E, Cohen-Sivan Y, Heled Y, et al. Clinical review: treatment of heat stroke: should dantrolene be considered? *Crit Care*. 2005;9:86–91.
8. Shih TH, Chen KH, Pao SC, et al. Low dose dantrolene is effective in treating hyperthermia and hypercapnea, and seems not to affect recovery of the allograft after liver transplantation: case report. *Transplantation Proceedings*. 2010; 42:858–860.
9. Caroff SN, Rosenberg H, Mann SC, et al. Neuroleptic malignant syndrome in the perioperative setting. *Am J Anesthesiology*. 2001; 28: 387–393.
10. Caroff SN. Neuroleptic malignant syndrome. In: Mann SC, Caroff SN, Keck PE, Lazarus A, eds. *Neuroleptic Malignant Syndrome and Related Conditions*. 2nd Ed. Washington, DC: American Psychiatric Publishing; 2003:1–44.
11. Newman EJ, Grosset DG, Kennedy, PGE. The parkinsonism-hyperpyrexia syndrome. *Neurocrit Care* 2009;10:136–140.
12. Artusi CA, Merola A, Espay AJ, et al. Parkinsonism-hyperpyrexia syndrome and deep brain stimulation. *J Neurol*. 2015; 262:2780–2782.
13. Caroff SN. Parkinsonism-hyperthermia syndrome and deep brain stimulation. *Can J Anaesth*. 2017;64:675–676.
14. Newman EJ, Grosset DG, Kennedy PG. The parkinsonism-hyperpyrexia syndrome. *Neurocrit Care*. 2009;10:136–140.
15. Frazer A, Hensler JG. Serotonin involvement in physiological function and behavior. In: Siegel GJ, Agranoff BW, Albers RW, et al., editors. *Basic Neurochemistry: Molecular, Cellular and Medical Aspects*. 6th edition. Philadelphia: Lippincott-Raven; 1999. Available from: <https://www.ncbi.nlm.nih.gov/books/NBK27940/> Accessed December 12, 2020.
16. Francescangeli J, Karamchandani K, Powell M, et al. The serotonin syndrome: from molecular mechanisms to clinical practice. *Int J Mol Sci*. 2019;20:2288.
17. Nguyen H, Pan A, Smollin C, et al. An 11-year retrospective review of cyproheptadine. *J Clin Pharm Ther*. 2019;44:327–334. doi: 10.1111/jcpt.12796
18. Basta MN. Postoperative serotonin syndrome following methylene blue administration for vasoplegia after cardiac surgery: a case report and review of the literature. *Semin Cardiothoracic Vasc Anes*. 2020: 1089253220960255. (pre-pub)
19. Orlova Y, Rizzoli P, Loder E. Association of coprescription of triptan antimigraine drugs and selective serotonin reuptake inhibitor or selective norepinephrine reuptake inhibitor antidepressants with serotonin syndrome. *JAMA Neurol*. 2018;75:566–572.
20. Boyer EW, Shannon M. The serotonin syndrome. *N Engl J Med*. 2005;352:1112–1120.
21. Simon L, Kennaghan M. Serotonin syndrome [review]. StatPearls. NCBI Bookshelf. 2020;5. Published Jan 2020, Accessed October 2020.
22. Nguyen H, Pan A, Smollin C, et al. An 11-year retrospective review of cyproheptadine use in serotonin syndrome cases reported to the California Poison Control System. *J Clin Pharm Ther*. 2019;44:327–334.
23. Coffey RJ, Edgar TS, Francisco GE, et al. Abrupt withdrawal from intrathecal baclofen: recognition and management of a potentially life-threatening syndrome. *Arch Phys Med Rehabil*. 2002;83:735–741.

## Postoperative Anterior Neck Hematoma (ANH): Timely Intervention is Vital

by Madina Gerasimov, MD, MS; Brent Lee, MD, MPH, FASA; and Edward A. Bittner, MD, PhD

### INTRODUCTION

An Anterior Neck Hematoma (ANH) can quickly progress to an airway obstruction that can occur at any time following a surgical intervention of the neck. Typically, most patients present within 24 hours of their original procedure.<sup>1</sup> Patients with an ANH need swift interventions to mitigate any life-threatening emergencies. We illustrate this important surgical complication and its associated challenges with a specific case of ANH.

### CASE STUDY

A 49-year-old man underwent a total thyroidectomy for the diagnosis of thyroid cancer. His past medical history included transient ischemic attacks, hypertension, chronic obstructive pulmonary disease/asthma. He was a current heavy smoker whose preoperative medications included aspirin (81 mg) and an albuterol inhaler, which he took as needed. His labs were all within normal limits. After an uneventful surgery, the patient was discharged from the postanesthesia care unit after five hours of observation and transferred to a surgical ward. The following day he complained of neck swelling, associated with pain, dysphagia, and odynophagia. He denied voice changes and difficulty breathing.

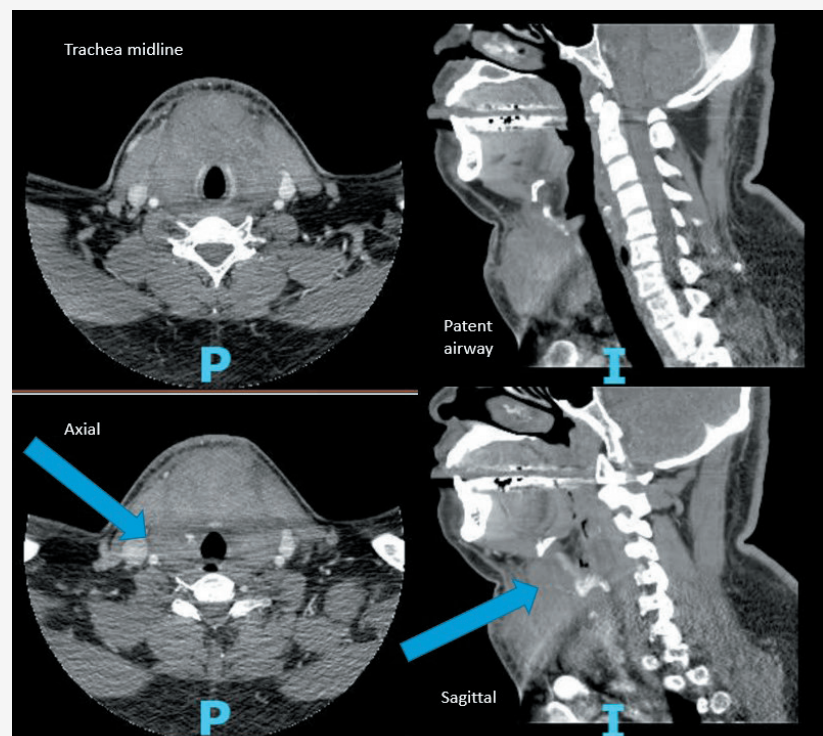


Figure 1: Arrows indicate active contrast extravasation from superior thyroid artery to the right of cricoid cartilage with hematoma formation anterior to the trachea. (P and I are not relevant to this illustration.)

See “Neck Hematoma,” Next Page

# Anesthesia Professionals Should Understand the Signs and Symptoms of Anterior Neck Hematomas

## From “Neck Hematoma,” Preceding Page

On initial exam he appeared in no acute distress, exhibited no drooling or stridor, and was alert and oriented. His vitals were 98% on room air, blood pressure 167/97, heart rate 70, respiratory rate 18, T 37.2°C, Weight 123 kg, body mass index 36. After removing the dressing, a fluctuant swelling of the anterior neck compartment measuring approximately 8 cm in diameter was appreciated. Physical exam demonstrated limited mouth opening when compared to pre-operative examination due to pain, a large tongue, and Mallampati Class 4 airway.

Based on these findings the difficult airway equipment cart was brought to the bedside. An urgent anesthesia consult was called and the patient was taken to the radiology department for a computerized tomography angiography of the neck to evaluate for a potential source of bleeding. The imaging revealed significant anterior neck swelling, trachea midline, patent airway, and active contrast extravasation to the right of cricoid cartilage (Figure 1).

The decision was made for immediate transport to the operating room (OR) to secure the airway. Topicalization of the airway was performed with lidocaine 4% administered via a nebulizer for five minutes. Shortly after administration, the patient became anxious, agitated, and less cooperative. Several attempts were made at oral fiberoptic intubation but were unsuccessful secondary to friable edematous mucosa and bleeding interfering with visualization.

After phone consultation with the trauma surgeon, the sutures were opened along the wound by the anesthesia professional and general anesthesia was induced with propofol. An l-gel laryngeal mask airway was inserted to provide immediate ventilation. The platysma closure was opened using blunt dissection, as instructed by the surgeon, exposing the trachea. Hematoma and clots were partially extruded. An endotracheal tube (ETT) 6.0 was advanced through the LMA into the trachea and correct placement was confirmed initially by direct palpation of the trachea and presence of end tidal CO<sub>2</sub>. The patient remained hemodynamically stable throughout. The trauma surgeon arrived after intubation and evacuated the remaining hematoma. The patient remained intubated postoperatively for concern of airway edema and was successfully extubated the following day.

## DISCUSSION

An anesthesia professional can encounter patients with ANH in many different clinical set-

tings including the postanesthesia care unit, operating room, intensive care unit, emergency department, or on a hospital ward. The true incidence of ANH is hard to estimate, as these cases are likely under-reported in the current literature.<sup>2</sup> Closed-claims data obtained from medical malpractice insurance carriers is informative, but represents only a fraction of all clinically significant cases. Proposed factors contributing to ANH may be associated with the procedure, patient's characteristics, or underlying conditions (Table 1).

## PATHOPHYSIOLOGY

When considering the potential source of bleeding, one should keep in mind that venous bleeding is often more complex in distribution and more difficult to isolate the site of origin. Arterial bleeds conversely are more obvious and amenable to different interventions, including embolization. A recent case series and review points out that arterial bleeding from the superior thyroid artery can present up to 16 days postoperatively.<sup>3,4</sup>

Contrary to common belief, the pathophysiology of ANH leading to airway compromise and difficulty in securing the airway is only partially related to the direct effect of the hematoma compression resulting in tracheal deviation, pharyngeal airway obstruction, or posterior tracheal compression where bony support is lacking.

A major cause of airway compromise is hematoma-induced interference with venous and lymphatic drainage.<sup>5</sup> These low-pressure capacitance vessels are easily compressed by the expanding hematoma while the arterial vessels continue to pump blood into the laryngeal soft tissue, tongue, and posterior pharynx. As the back pressure increases, plasma leaks out of these vessels and diffuses into the surrounding tissues, which further accelerates the compression of the veins and lymphatics in a rapidly worsening feedback loop. It is important to note that the degree of edema does not necessarily correlate with the degree of external swelling and may not resolve immediately upon clot evacuation, making diagnosis and treatment more challenging.<sup>5</sup>

Finally, communicating neck spaces promote the expansion of the bleeding with worsening edema secondary to blood dissection along tissue planes.<sup>5</sup> Thus, when evaluating a patient with ANH, it is important to keep in mind that sudden and catastrophic airway compromise can occur without warning. It is, therefore, paramount to be ready with difficult airway, suture removal, and tracheotomy equipment.

**Table 1: Procedure-Specific Risk Factors.**

Procedure-Specific Risk Factors
<b>Anterior Discectomy<sup>10</sup></b> <ul style="list-style-type: none"> <li>• Exposure of &gt;3 vertebral bodies</li> <li>• Excessive retraction</li> <li>• Blood loss &gt;300 ml</li> <li>• Exposure of upper cervical levels</li> <li>• Operative time &gt;5 hours</li> </ul>
<b>Thyroidectomy/Parathyroidectomy<sup>11-15*</sup></b> <ul style="list-style-type: none"> <li>• Retching and vomiting during recovery</li> <li>• Postoperative hypertension</li> <li>• Constipation</li> <li>• Bilateral/total (vs. unilateral/partial)*</li> </ul>
<b>Carotid Endarterectomy<sup>16</sup></b> <ul style="list-style-type: none"> <li>• Incomplete reversal of heparin</li> <li>• Intraoperative hypotension</li> <li>• General anesthesia</li> <li>• Preoperative antiplatelet medications</li> <li>• Inadequate hemostasis</li> <li>• Placement of carotid shunt</li> </ul>
<b>Neck Dissection (radical or partial)</b> <ul style="list-style-type: none"> <li>• Excessive tissue retraction<sup>17</sup></li> </ul>
<b>Central Line Placement<sup>18,19</sup></b> <ul style="list-style-type: none"> <li>• Multiple attempts</li> <li>• Use of anatomical landmarks (vs. ultrasound guided)</li> </ul>
<b>Nerve blocks<sup>20</sup></b>
<b>Patient-Associated Risk Factors<sup>2</sup></b> <ul style="list-style-type: none"> <li>• Coagulopathy</li> <li>• Male gender</li> <li>• Black race</li> <li>• ≥4 comorbidities (e.g., renal insufficiency, diabetes, coronary disease, hypertension)</li> </ul>

\*Data regarding the prevalence of bilateral/total thyroidectomy vs. unilateral/partial is still inconsistent; however, the presence of radiation therapy and extent of resection, as well as the degree of dissection, has been implicated.

Although the patient in the case presented was sent to CT scan for evaluation, this practice may not be advisable given the lack of close monitoring of the patient while in the scanner and the delays that may result from transport and imaging time. Use of bedside ultrasound may be a better alternative as it is often more accessible and familiar to anesthesia professionals to assess the internal structures of the neck for size and location of hematoma, degree of tissue edema, and patency of the airway.<sup>17</sup>

See “Neck Hematoma,” Next Page

# Anesthesia Professionals Should Understand the Signs and Symptoms of Anterior Neck Hematomas

From “Neck Hematoma,” Preceding Page

Timely recognition and intervention of a developing ANH is potentially lifesaving. All providers caring for such patients should, therefore, be well versed in understanding the signs and symptoms of ANH leading to airway obstruction (Table 2) and be trained to intervene rapidly. Several factors that may contribute to a delay in making the diagnosis include opaque dressing, C-collar, infrequent exams, and overall lack of vigilance and/or awareness.

## MANAGEMENT

To assist with prompt clinical management of the ANH patient we have developed an algorithm which in our opinion proposes a care pathway for patients with ANH (Figure 2). This algorithm has not yet been published or clinically validated.

Prompt notification and evaluation by the surgical team should occur as soon as ANH is suspected. Prior to more invasive interventions, supportive measures such as head elevation, administration of 100% oxygen or Heliox, intravenous steroids, and/or inhaled racemic epinephrine may be beneficial.<sup>5</sup>

Flexible fiberoptic nasopharyngo-video-laryngoscopy using a 6 mm scope (for adults) or 1.99 mm (pediatrics) can be useful to identify displacement of the larynx, degree of laryngeal edema, location, and size of any mass.

Caution must be exercised, however, when performing any procedure on these patients, as similar to patients with epiglottitis, ANH patients are susceptible to full airway collapse.<sup>18</sup> In those patients with a very narrow airway lumen and high air flow resistance (breathing through a narrowed orifice), the work of breathing may be significantly increased, resulting in hypoventilation and elevated carbon dioxide levels. As a result, any actions that increase pain and/or anxiety and, therefore, elevate blood pressure, heart rate, or oxygen consumption can lead to respiratory arrest.

As exhibited by the patient in the case study presented here, new onset of anxiety and agitation may also be signs of hypercarbia and/or hypoxia and, therefore, impending airway compromise. If a surgeon is not immediately available, an anesthesia professional may be called upon to evacuate the hematoma and secure the airway while waiting for a surgeon to arrive. In the absence of a surgeon, opening the suture line and evacuating the hematoma may be the only recourse to prevent and/or relieve total airway obstruction.

**Table 2: Anterior Neck Hematoma—Signs & Symptoms**

EARLY	LATE
Increased neck pain	Difficulty or painful swallowing/drooling
Asymmetry of neck	Facial edema
Change in neck circumference	Enlarged tongue
Change in drain output	Tracheal deviation
Tightness of neck	Convexity of neck
Hypertension	Shortness of breath/tachypnea
Discoloration of neck	Stridor
	Agitation
	Tachycardia
	Voice change

## Anterior Neck Hematoma: Airway Management Pathway

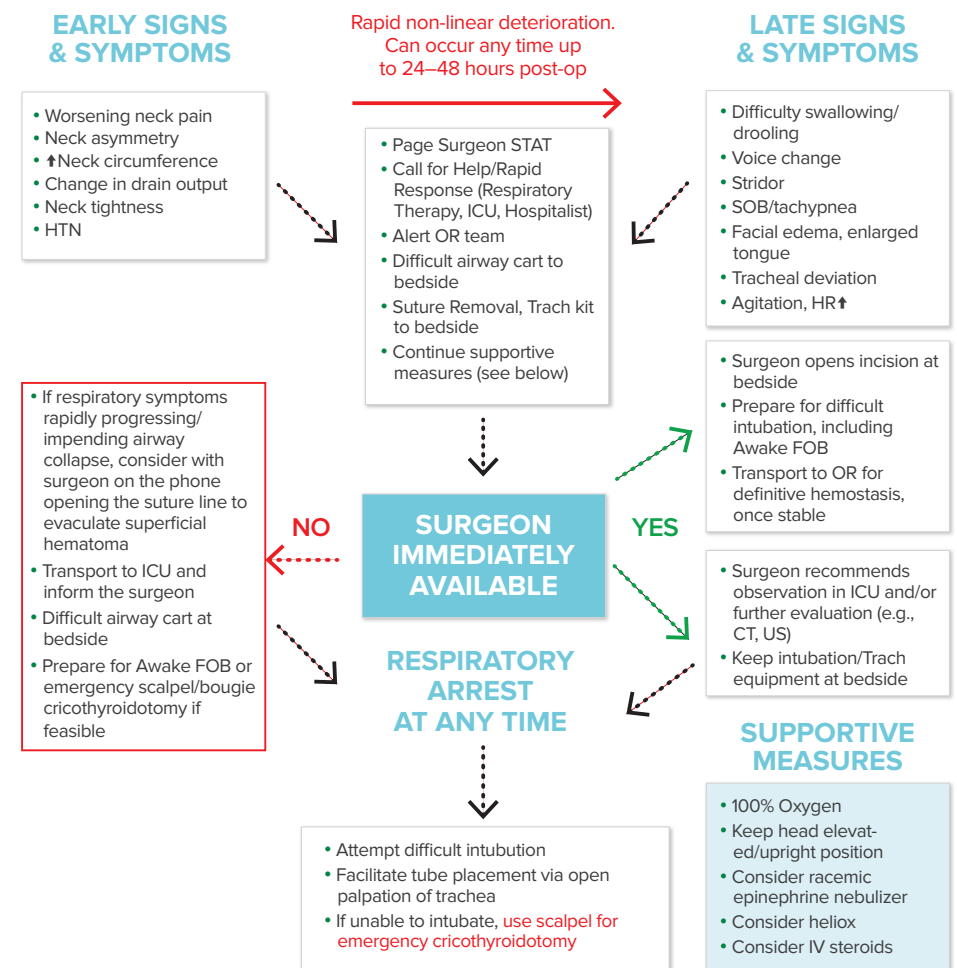


Figure 2: Anterior Neck Hematoma: Airway Management Pathway.

**Abbreviations:** CT (Computed tomography), FOB (Fiberoptic bronchoscopy), ICU (Intensive Care Unit), IV (Intravenous), HTN (Hypertension), HR (Heart Rate), OR (Operating Room), SOB (Shortness of breath), US (Ultrasound).

See “Neck Hematoma,” Next Page



# Complete Airway Obstruction from ANH Can be Rapid and Without Warning

From “Neck Hematoma,” Preceding Page

Furthermore, in the event of total airway collapse, a percutaneous (needle) cricothyroidotomy may not be sufficient to reestablish a patent airway due to anatomic distortion. In such a circumstance, a surgical cricothyroidotomy may be the only effective means to reestablish an airway, due to a completely swollen neck with distorted landmarks.<sup>1,4,8</sup>

We recognize that anesthesia professionals may not be comfortable performing these invasive surgical procedures, and, therefore, we recommend simulation training and other hands-on education be undertaken proactively. Based on our experience, in emergency situations such as this, omission bias may be an obstacle resulting in delayed care.<sup>9</sup> The following two suggestions may bolster one's level of confidence, overcome omission bias, and empower the anesthesia professional to perform these lifesaving interventions:

- call for help from an in-house physician, preferably someone with some form of airway expertise
- have the surgeon on the phone while one performs such maneuvers for guidance and support.

Depending on the clinical presentation of the patient, a decision must be made as to whether invasive interventions are needed immediately, or whether one has time to observe and/or wait for a surgeon to arrive and evaluate.

## The following questions should be asked:

- Should the suture line be opened or a more aggressive hematoma evacuation be performed?
- Should a more definitive airway be placed, such as an endotracheal tube? And, if so, should this be done with the patient awake or asleep?

Given that total airway collapse can occur at any time, one must always be prepared to establish a surgical airway.<sup>8</sup> Plans need to be weighed carefully and communicated to everyone involved (Table 3).

## CONCLUSION

Complete airway obstruction of an ANH can be rapid and without warning, with non-linear and unpredictable progression. To deliver safe patient care, a clear understanding of the pathophysiology of ANH by all providers caring for patients undergoing procedures of the neck are key to prompt and appropriate management of this insidious and potentially fatal clinical complication. Anesthesia professionals should

Table 3:

QUESTIONS	OPTIONS
WHAT?	<ul style="list-style-type: none"> <li>Open suture line</li> <li>Evacuate hematoma</li> <li>Intubate</li> <li>Awake fiberoptic bronchoscopic evaluation of airway</li> </ul>
WHEN?	<ul style="list-style-type: none"> <li>Await arrival of surgeon</li> <li>Act without delay</li> </ul>
WHERE?	<ul style="list-style-type: none"> <li>Operating room</li> <li>ICU</li> <li>Emergency Department</li> <li>Bedside on the ward</li> </ul>
HOW?	<ul style="list-style-type: none"> <li>Awake vs. under general anesthesia?</li> <li>If asleep:               <ul style="list-style-type: none"> <li>Intravenous vs. inhalational induction?</li> </ul> </li> </ul>

be prepared to intervene in such cases when a surgeon is not immediately available, and, therefore, should be familiar with and train to perform surgical techniques that generally fall outside of our usual skill sets.

*Madina Gerasimov, MD, MS, is assistant professor at the Donald and Barbara Zucker School of Medicine at Hofstra/Northwell; site director, Quality Assurance, North Shore University Hospital, Manhasset, NY.*

*Brent Lee, MD, MPH, FASA, is director of Clinical Excellence and Performance Improvement, North American Partners in Anesthesia (NAPA).*

*Edward A. Bittner, MD, PhD, is associate professor of anesthesiology, Harvard Medical School, Massachusetts General Hospital, Boston, MA, and is associate editor of the APSF Newsletter.*

*The authors have no conflict of interest.*

## REFERENCES

- Hung O, Murphy M. Airway management of the patient with a neck hematoma. In: Hung's Difficult and Failed Airway Management. [online] New York: McGraw Hill, 3rd ed. 2018.
- Shah-Becker S, Greenleaf EK, Boltz MM, et al. Neck hematoma after major head and neck surgery: risk factors, costs, and resource utilization. *Head Neck*. 2018;40:1219–1227.
- Zhang X, Du W, Fang Q. Risk factors for postoperative haemorrhage after total thyroidectomy: clinical results based on 2,678 patients. *Sci Rep*. 2017;1:7075.
- Bittner EA. Silent pain in the neck. [online] USDOH Patient Safety Network. <https://psnet.ahrq.gov/webmm/case/235/Silent-Pain-in-the-Neck>. Accessed December 12, 2020.
- Law J. Chapter 55. Management of the patient with a neck hematoma. In: Hung O, Murphy MF. Eds. Management of the Difficult and Failed Airway, 2e. McGraw-Hill; <https://accessanesthesiology.mhmedical.com/content.aspx?bookid=519&sectionid=41048448> Accessed November 17, 2020.
- Baribeau Y, Sharkey A, Chaudhary O, et al. Handheld point-of-care ultrasound probes: the new generation of POCUS. *J Cardiothorac Vasc Anesth*. 2020;34:3139–3145.
- Lichter JL, Rodriguez M0R, Aaronson NL, et al. Epiglottitis: it hasn't gone away. *Anesthesiology*. 2016;124:1404–1407.
- Heymans F, Feigl G, Graber S, et al. Emergency cricothyrotomy performed by surgical airway—naïve medical personnel. *Anesthesiology*. 2016;125:295–303.
- Stiegler MP, Neelankavil JP, Canales C, et al. Cognitive errors detected in anesthesiology: a literature review and pilot study. *Br J Anaesth*. 2012;108:229.
- Sagi HC, Beutler W, Carroll E, et al. Airway complications associated with surgery on the anterior cervical spine. *Spine*. 2002;27:949–953.
- Bononi M, Amore Bonapasta S, Vari A, et al. Incidence and circumstances of cervical hematoma complicating thyroidectomy and its relationship to postoperative vomiting. *Head Neck*. 2010;32:1173–1177.
- Shun-Yu C, Kun-Chou H, Shyr-Ming S-C, et al. A prospective randomized comparison of bilateral subtotal thyroidectomy versus unilateral total and contralateral subtotal thyroidectomy for Graves' Disease. *World Journal of Surgery*. 2005;29:160–163.
- Yu NH, Jahng TA, Kim CH, Chung CK. Life-threatening late hemorrhage due to superior thyroid artery dissection after anterior cervical discectomy and fusion. *Spine (Phila Pa 1976)*. 2010;35:E739–742.
- Dehal A, Abbas A, Hussain F, et al. Risk factors for neck hematoma after thyroid or parathyroid surgery: ten-year analysis of the nationwide inpatient sample database. *Perm J*. 2015 Winter;19:22–28.
- Rosenbaum MA, Haridas M, McHenry CR. Life-threatening neck hematoma complicating thyroid and parathyroid surgery. *Am J Surg*. 2008;195:339–343.
- Self DD, Bryson GL, Sullivan PJ. Risk factors for post-carotid endarterectomy hematoma formation. *Can J Anaesth*. 1999;46:635–640.
- Kua JS, Tan IK. Airway obstruction following internal jugular vein cannulation. *Anaesthesia*. 1997;52:776–780.
- Yu NH, Jahng TA, Kim CH, Chung CK. Life-threatening late hemorrhage due to superior thyroid artery dissection after anterior cervical discectomy and fusion. *Spine (Phila Pa 1976)*. 2010;35:E739–742.
- Pei-Ju W, Siu-Wah C, I-Cheng L et al. Delayed airway obstruction after internal jugular venous catheterization in a patient with anticoagulant therapy. *Case Rep Anesthesiol*. 2011;2011:359867.
- Mishio M, Matsumoto T, Okuda Y, et al. Delayed severe airway obstruction due to hematoma following stellate ganglion block. *Reg Anesth Pain Med*. 1998;23:516–519.

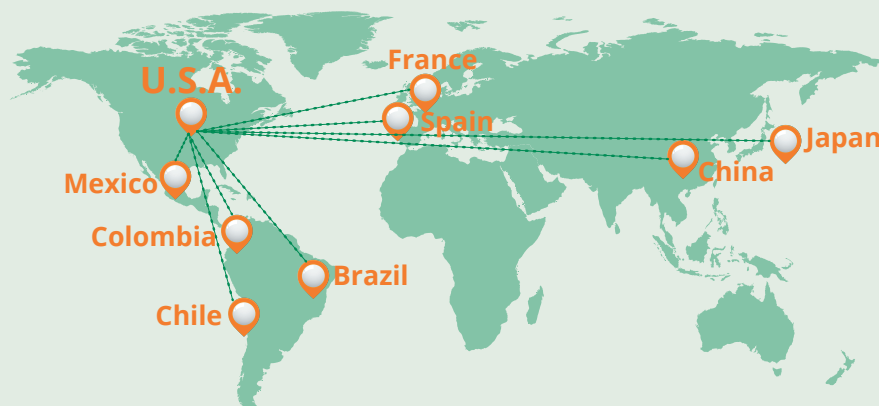
## YOUR CONTRIBUTION PROVIDES FUNDING FOR IMPORTANT PROGRAMS:

Over **\$13.5 million**  
in research grants awarded



**19** APSF Consensus  
Conferences  
conducted to date  
(no registration fees)

➤ **apsf.org**  
**over 1 million**  
visitors per year



The *APSF Newsletter* is now translated into Mandarin, French, Japanese, Portuguese, and Spanish.

## What do all of these individuals have in common?



Dan and  
Cristine Cole



Karma and  
Jeffrey Cooper



Burton A. Dole, Jr.



Dr. John H. and  
Mrs. Marsha Eichhorn



David Gaba, MD, and  
Deanna Mann



Drs. Alex and Carol  
Hannenberg



Drs. Joy L. Hawkins and  
Randall M. Clark



Dr. Eric and Marjorie Ho



Drs. Michael and  
Georgia Olympio



Dr. Ephraim S. (Rick)  
and Eileen Siker



Robert K.  
Stoelting, MD



Mary Ellen and  
Mark Warner



Matthew B. Weinger, MD,  
and Lisa Price

**Join us!**

[www.apsf.org/donate/](http://www.apsf.org/donate/)

[legacy-society/](http://legacy-society/)

An abiding belief in safeguarding the future of anesthesiology. Established in 2019, the **APSF Legacy Society** honors those who make a gift to the foundation through their estates, wills, or trusts, thus ensuring that patient safety research and education will continue on behalf of the profession about which we are so deeply passionate.

APSF recognizes and thanks these inaugural members who have generously supported APSF through an estate or legacy gift.

For more information about planned giving, please contact Sara Moser, APSF Director of Development at: [moser@apsf.org](mailto:moser@apsf.org).

