

# NEWSLETTER

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### Recommendations for Managing Non-Cardiac Implantable Electrical Devices (NCIEDs) During Non-Neurologic Surgery and Procedures

by Jacqueline M. Morano, MD, FASA, and Jamie L. Uejima, MD

Anesthesia professionals are encountering patients with non-cardiac implantable electrical devices (NCIED) with increasing frequency. These devices are otherwise known as neurologic stimulators and include, but are not limited to spinal cord stimulators (SCS), deep brain stimulators (DBS), and vagal nerve stimulators (VNS). The indications for placement of NCIEDs are expanding and as such the likelihood that an anesthesia professional will encounter them during elective and emergent surgical procedures is increasing.

#### **TYPES OF NCIEDS**

#### Vagal Nerve Stimulators (VNS):

VNS are pulse generators placed in the midcervical neck, usually on the left. The left is typically chosen to avoid severe bradycardia that can occur with the right-sided vagal nerve stimulation. Indications for VNS include seizure reduction, cluster headache prevention, and refractory depression.

#### Deep Brain Stimulator (DBS):

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DBS is an implanted lead used to stimulate structures deep within the brain. The most common targets include the thalamus, globus palladium, and subthalamic nuclei. The target for the lead is dependent on the pathology being treated. It is considered to be a minimally invasive targeted neurosurgical intervention. Since its success with Parkinson's disease, its utilization has expanded to other movement disorders (tremors, tics, and dystonias), psychiatric illnesses (major depression and obsessivecompulsive disorder), chronic pain, and refractory epilepsy.

#### Spinal Cord Stimulators (SCS):

SCS inhibit chronic pain by continuously stimulating the large diameter afferent fibers in the spinal cord. The electrode itself lies in the dorsal



epidural space, and its location is determined by the location of the pain being treated.

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### Safety of Sugammadex in Pregnancy, Pediatrics, and Renal Failure

by Kevin Yang, BS; Christina Ratto, MD; Joseph Szokol, MD; and Ashley Osumi, MD

In 2023, the American Society of Anesthesiologists published practice guidelines for the monitoring and antagonism of neuromuscular blockade.<sup>1</sup> The guidelines recommended quantitative monitoring over qualitative assessment to avoid residual blockade. The guidelines also called for the use of sugammadex over neostigmine at different depths of blockade. While these guidelines provide a framework for general practice, they do not address specific considerations for special patient populations, such as those with renal failure, pregnant women, and pediatric patients.

#### SAFETY OF SUGAMMADEX IN RENAL FAILURE

Sugammadex is primarily excreted by the kidneys and poses challenges in patients with



severe renal impairment due to the risk of recurarization (Figure 1, page 7).<sup>2</sup> The recurarization, resulting in potential paralysis or residual weakness, presumably occurs because the circulating rocuronium-sugammadex complexes can disassociate. In patients with normal renal function, the elimination half-life of sugammadex is about 2 hours and the estimated plasma clearance is about 88 mL/min. Studies show over 90% of the dose is excreted within 24 hours, with 96% excreted unchanged in urine. However, in renal impairment, the half-life extends to 4, 6, and 19 hours in mild, moderate, and severe cases, respectively.<sup>2</sup>

The rocuronium-sugammadex complex is highly stable due to intermolecular (van der Waals) forces, thermodynamic (hydrogen) bonds, and hydrophobic interactions.<sup>3</sup> For every 25 million sugammadex-rocuronium complexes, only 1 complex dissociates. The complex is water-soluble and excreted in the urine in patients with normal renal function. The complex is also removed during dialysis with a high-flux filter.<sup>4</sup>

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#### **Guide for Authors**

### A more detailed Guide to Authors with specific requirements for submissions can be found online 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, and is available free of charge in digital format to other interested persons, including members of the public. The content of the Newsletter typically focuses on anesthesia related perioperative patient safety issues.

The *Newsletter* is published three times a year (February, June, and October). Deadlines for each issue are as follows:

#### November 1 for the February issue

March 1 for the June issue, and

#### July 1 for the October issue

However, authors should feel free to submit manuscript at any time for review.

Decisions regarding content and acceptance of submissions for publication are the responsibility of the editors. Some submissions may be published in future issues, even if the deadline is met. At the discretion of the editors, submissions may be considered for publication on our APSF website and social media pages earlier than the deadlines above. Articles (case reports, editorials, letters) that are intended to provide our authorship/readership with more rapid information will be posted on our online website section under "Articles between issues." These articles could be considered for *APSF Newsletter* publication at the discretion of the Editor Group and based on their importance and current relevance to perioperative patient safety.

#### **Types of Articles**

#### 1. Review article (invited or unsolicited)

- All submissions should focus on perioperative patient safety issues.
- b. Articles preferentially will focus on our top 10 APSF safety initiatives see APSF Newsletter).
- c. The articles should be limited to 2,000 words.
- d. Figures and/or tables are strongly encouraged.
- e. Please provide no more than 25 references.

#### 2. Case Reports

- a. Case reports should focus on novel perioperative patient safety cases.
- b. A case report should be limited to 750 words.

c. Please provide no more than 10 references for case reports.
 d. Authors should follow the CARE guidelines and the CARE checklist should be provided as an additional file.

#### 3. Letters to the Editor

- a. A letter to the editor can either comment on a past article or a current perioperative patient safety issue.
- b. A letter to the editor should be limited to 500 words.
- c. Please provide no more than 5 references.
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- a. The purpose of this column is to allow expeditious communication of technology-related safety concerns raised by our readers, with input and response from manufacturers and industry representatives.
- b. Please limit the word count to fewer than 1000 words.
- c. Please provide no more than 15 references.

#### 5. Editorials

- All submissions should focus on perioperative patient safety issues, preferably a recently published article.
- b. The editorial should be limited to 1,500 words.
- c. Figures and/or tables are welcomed.
- d. Please provide no more than 20 references.

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All submissions must be accompanied by the <u>author checklist</u>. Please ensure that all items in the checklist have been completed. Otherwise, your manuscript may be returned.



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# apsf newsletter

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#### From "Neurological Stimulators," Page 1

In general, low thoracic to lumbar placement is used to manage lower extremity pain and chronic low back pain and mid-cervical to high thoracic placement is used to manage upper extremity pain.

There are additional NCIEDs as well, such as the hypoglossal nerve stimulator, phrenic nerve stimulators, sacral nerve stimulators, and gastric nerve stimulators. The hypoglossal nerve stimulator, for example, helps treat obstructive sleep apnea (OSA). Obesity and OSA are on the rise and patients are growing less tolerant of traditional treatments such as continuous positive airway pressure (CPAP). This has given way to the increased utilization of the hypoglossal nerve stimulator for the treatment of OSA. Hypoglossal nerve stimulators treat OSA by sending electrical pulses to the hypoglossal nerve, controlling tongue movement and causing the tongue to move forward during sleep, thereby reducing airway collapse and possible obstruction.

#### **PREOPERATIVE CONSIDERATIONS**

In order to provide safe anesthetic care and prevent day of service delays, patients with

NCIEDs should undergo a preoperative evaluation such as in the anesthesia preoperative clinic prior to elective cases. This will help identify patients with NCIEDs in advance, allow time to contact the providers managing their devices, and inform those providing anesthetic care for these patients (Figure 1).

Prior to anesthetizing a patient with an NCIED, there are several questions that should be asked of the patient and/or the provider managing their device (Table 1, next page).<sup>1,2</sup>

It is imperative to request a recent interrogation of the device from the managing provider noting the lead impedance, as this is used to assess the electrical performance and structural integrity of the leads in the NCIED and should changes be seen in the lead impedance, the procedure may potentially need to be delayed.

In addition, the surgeon performing the procedure should be made aware the patient has an NCIED. A preoperative discussion should include special surgical needs that will be utilized the day of surgery (i.e., neuromonitoring or electrocautery) and determine whether those needs will interact with the device. During the preoperative evaluation regarding

the device, it is imperative to determine if the device should be reprogrammed to a specific setting (i.e., MRI safe mode or surgery safe mode) or turned off.

#### **DAY OF SURGERY**

Prior to case start, all individuals involved in the care of a patient with a NCIED should be aware that the patient has the device; this includes preoperative, operative, and postoperative care teams. Two commonly used intraoperative tools that can interact with NCIEDs are electrocautery and intraoperative neuromonitoring.

#### **ELECTROCAUTERY**

Electrocautery induces an electrical current within the body, and patients with NCIEDs undergoing surgery with electrocautery are at risk for harm. These risks can be mild, such as potentially reprogramming the device and changes in stimulator output. However, there is also the possibility of significant harm including thermal skin burns, damage to the electrode, failure of the generator, or thermal injury to the underlying neurologic tissue. Due to these greater risks, manufacturers of most NCIEDs recommend avoiding the use of electrocautery.<sup>3-5</sup> If electrocautery is necessary,

### PERIOPERATIVE NEUROLOGIC STIMULATOR (NCIED) MANAGEMENT

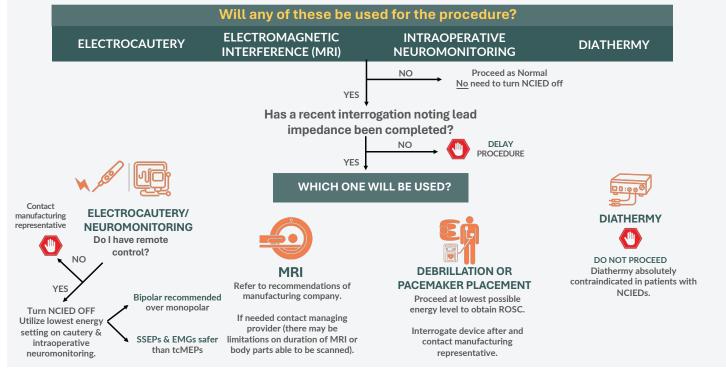


Figure 1: Potential intraoperative device interactions when patients present with NCIEDs.

NCIED: Non-cardiac implantable electrical device; MRI: Magnetic Resonance Imaging; SSEP: Somatosensory Evoked Potential; EMG: Electromyography; tcMEPs: Transcortical Motor Evoked Potential; ROSC: Return of Spontaneous Ventilation

### Bipolar Cautery Is Preferred to Unipolar/Monopolar Cautery in Patients with NCIEDs

### From "Neurological Stimulators," Preceding Page

the recommendations by most manufacturers is to first confirm the device's lead impedance with a recent interrogation and then turn the device off. If the device has a current output setting, then this should be set to the lowest setting possible or to zero prior to turning off the device. Some devices have a surgery mode available which can be another safe option.<sup>6</sup>

For many NCIEDs, a remote is used to adjust the settings. For both SCS and DBS, the remote can be utilized to turn the device off by holding it over the generator. However, VNS systems are unique in that many patients will carry their remote in the form of a wand or bracelet. Holding the remote over the generator for a specified period, usually 2-3 seconds of time generates an impulse rather than shutting the device off. How the VNS turns off varies depending on the manufacturer. Therefore, it is important to verify that the device is turned off, which can be visualized on the controller screen. Regardless of the NCIED, care must be taken to be sure the device is off or reprogrammed to the proper setting. If there is a question regarding the NCIED settings, the device representative should be contacted.<sup>4</sup>

When using electrocautery in patients with an NCIED, bipolar cautery is preferred to unipolar/monopolar cautery. With monopolar cautery, the current travels between the device tip and the return plate or grounding pad on the patient. Therefore, the risk of current traveling through the NCIED is higher. With bipolar cautery, the majority of the current travels between the tips of the bipolar cautery and is less likely to affect the NCIED. If monopolar cautery is necessary, the surgeon should utilize the lowest power setting possible. The grounding pad should be placed so that the current is least likely to travel through the NCIED and its generator, such as the contralateral distal limb. Full-length table grounding pads should be avoided. Patients should be made aware of the need to use electrocautery as part of the surgical procedure and the subsequent risks which include potential thermal injury to brain or nervous system tissue, reprogramming of the device, and potential damage to the leads.<sup>7,8</sup>

Despite these warnings, many published reports testify to the generally safe use of both monopolar and bipolar electrocautery. A survey of 167 pediatric spinal surgeons reported no complications due to the intraoperative use of electrocautery.<sup>9</sup> Most respondents reported short-term use of monopolar cautery. After a procedure involving the use of electrocautery, the provider should always

#### Table 1: General Perioperative Concerns for Patients with NCIEDs<sup>2</sup>

Identify	the type	of device,	the manufact	urer, and mo	odel. Does th	e patient have	a device
identific	cation car	d?					

Where are the leads and pulse generator located?

How is the device turned off or inactivated? Does the patient have a remote or magnet?

What symptoms develop when the device is turned off?

When was the device implanted? What is the battery status?

When was the last device check/interrogation?

What was the lead impedance on the last device check?

Determine availability of "safe modes" for surgery or for MRI.

The provider who placed the device should be contacted for perioperative device recommendations (as part of preoperative clinic assessment).

Does the surgery/procedure require neuromonitoring? If so, discuss with the provider who placed the device as certain neuromonitoring modalities may be deemed unsafe (preop. clinic provider).

Contact the device representative to determine if they need to be present on the day of surgery for pre/postoperative interrogation (preop. clinic provider).

Does the patient also have any additional implanted devices? If so, the providers managing both devices should be contacted for recommendations.

confirm that the NCIED is on and functioning properly.<sup>5,10,11</sup>

#### INTRAOPERATIVE NEUROMONITORING

Many functional neurosurgeons recommend against the use of transcortical motorevoked potentials (tcMEPs) in patients with NCIEDs. Intraoperative neuromonitoring transmits an electrical current through the patient's body. In theory, this can also be conducted along the path of the NCIED and may damage the device or cause tissue injury along the length of the leads. TcMEPs utilize a higher energy system than somatosensory-evoked potentials (SSEPs) and for this reason SSEPs are considered to be relatively safe and welltolerated in patients with these implanted devices.

In practice, there are several case reports that describe the use of intraoperative neuromonitoring in patients with spinal cord stimulators with no postoperative complications.<sup>9,12</sup> However, for many neurosurgeons, the potential risks of utilizing tcMEPs in patients with vagal nerve stimulators or deep brain stimulators is not worth the benefits they may provide. If intraoperative neuromonitoring is to be employed, the lowest energy level possible should be used to obtain signals regardless of the device and type of monitoring utilized.

#### DEFIBRILLATION/CARDIOVERSION

The presence of a NCIED should not impede emergent cardioversion or defibrillation. The patient with a NCIED should be cardioverted or defibrillated in the setting of a cardiac emergency per advanced cardiac life support guidelines. However, clinicians should place pads as far from the device as possible and use the lowest energy that is feasible to treat the arrhythmia. The NCIED should be interrogated afterward to evaluate function.<sup>10,13,14</sup>

#### MRI CONSIDERATIONS WHEN AN NCIED IS PRESENT

MRIs pose a potential risk of harm to the patient or damage to the device if proper precautions are not taken. It is necessary to confirm the manufacturer and the exact model of the NCIED prior to the MRI. The provider responsible for the device should also be contacted before the MRI to discuss any safety concerns. The device manual or the manufacturer's technical helpline should be consulted if there is any uncertainty regarding the specific scan requirements for the patient's system. Many newer devices are MRI conditional, meaning only part of the patient's body can now be scanned, such as the limbs, or they can only undergo scans for a specified period of time and then require a rest period. This varies from device to device and many older models are not MRI-conditional. It is imperative to confirm the specific MR-conditional components and location of the system to determine if the MRI can be safely completed.<sup>15,16</sup> In addition, prior to the MRI, lead impedance should be checked. If it is discovered that the lead impedance is outside of the acceptable range

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### Regional and Neuraxial Anesthesia Can Pose Challenges to Patients with NCIEDs

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per the manufacturer's guidelines, the MRI should not be completed.

Some devices have an MRI safe mode. This setting will turn off stimulation and detection, but allow other background processes to continue to function. The NCIED should be set to MRI safe mode prior to the patient entering the scanner and programmed back to the original settings once the MRI is completed and the patient is safely outside of the scanner. The device should be interrogated at some point after the MRI. The timing of the interrogation should be determined by the provider or the device representative.

#### REGIONAL AND NEURAXIAL APPROACHES WHEN AN NCIED IS PRESENT

Regional and neuraxial anesthesia can pose challenges in patients with NCIEDs (Table 2). Any upper extremity block in a patient with a DBS or cranial nerve stimulator/NCIED should be performed under direct visualization. Using either ultrasound or fluoroscopy, the provider needs to confirm that the needle does not come into contact or transect the NCIED wires. In addition, the use of peripheral nerve stimulation to identify the location of the brachial plexus should be avoided. If the stimulation needle comes into contact with any portion of the NCIED an electrical current can be conducted, which can travel to the implanted electrode and/or pulse generator. This, like electrocautery, has the potential to damage the NCIED. There are case reports that describe the use of upper extremity block placement with peripheral nerve simulation in patients with DBS without complications.<sup>1,17,18</sup> However, with the widespread use of ultrasound for peripheral nerve blocks, the need to perform blind peripheral nerve stimulation guided nerve blocks is unnecessary and should be avoided in patients with NCIEDs.

There is an increasing number of pregnant women with SCS. Several case reports exist of the successful use of both epidurals and spinals in patients with SCS.<sup>19</sup> However, the decision to perform neuraxial anesthesia in patients with these devices should only be made after proper review of imaging identifying the location of the leads, level of insertion, extension wires, and the internal pulse generator. The physician managing the device should also be notified as they may have additional guidance to offer considering SCS reside in the dorsal epidural space.<sup>19-21</sup>

It is imperative that the neuraxial placement occur below the level of the SCS insertion, to avoid transecting the SCS. Appropriate emphaTable 2: Key Points When Performing an Acute Pain Procedure in a Patient with a Non-cardiac Implantable Electrical Device (NCIED)

#### **REGIONAL:**

- Avoid application of electrical current across the pulse generator and lead
- Use ultrasound guidance when near NCIED

#### SPINAL:

- Not contraindicated with spinal cord stimulator
- Obtain an X-ray/imaging prior to attempt to be sure that attempt is below level of electrode

#### **EPIDURAL:**

- Special emphasis on sterility
- May only obtain a patchy or failed block due to fibrosis in the epidural space
- Fibrosis may result in the catheter being directed caudally causing compression of cauda equina

sis should be placed on sterility during neuraxial placement to avoid infection as this can result in future SCS removal. In addition, the feel of loss of resistance may be altered if the SCS electrodes are near the entry level for the epidural. Due to the development of fibrosis from the SCS, the epidural spread of local anesthetic may be impeded and result in patchy analgesia or a failed block. Moreover, fibrosis can also result in the epidural catheter being directed caudally rather than cranially or coiling locally in the epidural space, which can cause compression of the cauda equina and lumbar roots.<sup>19,21</sup>

#### ECT WHEN AN NCIED IS PRESENT

Electroconvulsive therapy (ECT) is a procedure used to treat certain psychiatric conditions including refractory depression, bipolar disorder, and catatonia. While under general anesthesia, an electrical current is applied to the brain, inducing a seizure. As aforementioned, electrical currents have the potential to cause harm to the patient or damage to the device. With ECT, there is a particular concern for patients with a DBS. While there are no existing guidelines on how to manage patients with NCIEDs who are scheduled for ECT, there are many case reports demonstrating the safe use of ECT in this patient population.<sup>22</sup> It is imperative to inform the provider managing the NCIED that the patient is being evaluated for ECT. The provider will be able to comment on the safety of proceeding with the ECT and share recommendations regarding the device prior to the ECT. Most recommendations would include reprogramming the NCIED to the lowest possible stimulation setting and then turning off the device prior to the ECT. The NCIED should be turned on immediately after the ECT, particularly DBS. Allowing only temporary interruption of the DBS for the procedure minimizes the symptoms being treated by the DBS and thus the negative impact of turning the device off. The team managing the device will decide when the NCIED should be interrogated or if any imaging is required during the course of ECT. In patients with a DBS, it is important to consider ECT electrode placement. Ideally, the electrodes would be positioned so that the ECT stimulus current path would be directed away from the DBS electrodes.<sup>23</sup> While there are no reports of adverse outcomes in patients with NCIEDs who underwent ECT, these patients should still be approached with caution as there is no evidence-based safety guidelines for this patient population.

#### **POSTOPERATIVE CONSIDERATIONS**

Prior to emergence, if the NCIED was turned off, it should be turned back on. This will prevent disease symptoms from complicating emergence and extubation. If a representative was needed to reprogram the NCIED, that person should be present for emergence and recovery. The skin around the NCIED and its generator should be examined for any thermal injuries and the patient should be evaluated for any neurologic changes.

#### CONCLUSION

The number of patients presenting with NCIEDs is increasing. The article is meant to be used as a tool in the management of these patients in the perioperative period. As these devices are constantly being improved and updated, good communication with the managing provider or manufacturing representative is paramount.

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### NCIEDs Should Be Turned Back on After the Procedure

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### Sugammadex is Superior to Neostigmine for Reversing Moderate Blockade in Renally Impaired Patients

#### From "Sugammadex," Page 1

In patients not getting dialysis, there is a theoretical concern in anuric patients that the rocuronium-sugammadex complex may persist in the plasma longer leading to higher rates of disassociation.

In clinical practice, managing patients with renal failure who necessitate paralysis poses a dilemma. The anesthesia professional can either administer neuromuscular agents and then wait until recovery of function or opt for alternative agents like a benzylisoquinolinium such as cisatracurium, which is not reversible by sugammadex. A recent prospective, randomized, blinded, controlled trial addressed this, comparing sugammadex and neostigmine for reversing moderate blockade in renally impaired patients.<sup>5</sup> The study demonstrated sugammadex's superiority, achieving Train-of-Four Ratio (TOFR) >90% significantly faster  $(3.5\pm1.6 \text{ min})$  compared to neostigmine (14.8  $\pm$ 6.1 min), without major adverse events. This suggests that the use of sugammadex to reverse moderate blockade is safe and faster than a combination of neostigmine/cisatracurium in renally impaired patients. Ideally, a quantitative neuromuscular monitor should be used to assess adequacy of reversal in these patients.

#### SAFETY OF SUGAMMADEX IN PREGNANCY

The use of sugammadex in pregnancy poses a significant dilemma for anesthesia professionals due to the lack of substantial evidence indicating its clinical dangers in this patient population. Despite the absence of definitive data demonstrating harm, the Society for Obstetric Anesthesia and Perinatology (SOAP) guidelines restrict its use, leaving clinicians with limited options. This cautious stance by SOAP reflects the broader challenge in medical practice where the scarcity of conclusive research data on drug safety in pregnancy often results in conservative recommendations, potentially impacting the optimal management of pregnant patients requiring neuromuscular blockade reversal. In this section, we evaluate the current evidence on the safety, efficacy, and side effects of sugammadex in the context of pregnancy.

Many of the potential pregnancy-related side effects of sugammadex stem from its potential to bind progesterone. The initial manufacturer's model suggested potential binding to progestin, prompting speculation about similar interactions with progesterone.<sup>6</sup> Subsequent *in vitro* studies have supported that sugammadex can in fact

bind to progesterone. In pregnant patients undergoing nonobstetric surgery, there is concern that sugammadex might decrease progesterone levels which are crucial for maintaining pregnancy. However, the current preclinical evidence on this matter is inconclusive. A single preclinical study found that administering highdose sugammadex (30 mg/kg) to first-trimester pregnant rats did not reduce endogenous progesterone levels or affect live birth or stillbirth rates.<sup>7,8</sup> Conversely, a subsequent study in which pregnant rabbits underwent general anesthesia including paralysis reversal with sugammadex showed significant decreases in progesterone levels; however, all rabbit pregnancies were successful, without early births or stillbirths.<sup>8</sup> The only currently published human evidence is a single case report that describes a pregnant patient who underwent surgery for ovarian torsion who did not experience any pregnancy-related side effects following sugammadex administration.<sup>9</sup> Large retrospective studies and a registry in which providers report on the use of sugammadex in pregnant patients could help better elucidate the effect of sugammadex on pregnancy progression.<sup>6</sup>

### Sugammadex Has Been Used Safely in the Pregnant Patient

#### From "Sugammadex," Preceding Page

While neuraxial anesthesia is preferred in the setting of obstetrics, general anesthesia is necessary under certain conditions. As such, there has been investigation on how sugammadex may effect obstetric outcomes. The possible sugammadex binding of progesterone is again of concern in this context, as decreased progesterone is associated with preterm labor and preterm premature rupture of membranes.<sup>6</sup> A case series involving 25 pregnant women who received sugammadex during the antenatal period identified no obstetric complications directly attributable to sugammadex.<sup>7,10</sup> The authors attribute the lack of complications to minimal placental transfer of sugammadex and its high affinity for rocuronium, which may prevent significant sequestration of progesterone. Given sugammadex's elimination half-life of about 2 hours, most of the medication should be cleared from the bloodstream within 48 hours, implying that any potential effects on progesterone binding would manifest shortly within that period.

In cesarean deliveries requiring general anesthesia, sugammadex has been shown to be effective and safe for reversing rocuroniuminduced neuromuscular blockade at the end of cesarean deliveries, even in cases of profound neuromuscular block.<sup>78,11</sup> However, there is limited evidence on the effectiveness of sugammadex for rescue reversal in cannot-intubate/ cannot-ventilate scenarios after rapid sequence induction.<sup>7</sup> Despite this, guidelines recommend considering high-dose sugammadex for immediate reversal in such emergencies because the sequelae of severe hypoxia could be more detrimental than the potential risks that may arise from sugammadex exposure.<sup>8</sup>

Concerns about sugammadex teratogenicity arise from cell culture studies showing it may promote neuronal apoptosis due to oxidative stress,<sup>8</sup> but this effect was not seen in mice with mature blood-brain barriers.<sup>78</sup> Combined with sevoflurane, increased neuronal apoptosis occurred in mice.<sup>7</sup> Preclinical studies found no adverse effects in pregnant rats, but high doses in New Zealand white rabbits caused decreased fetal body weight and bone ossification issues, with no malformations observed.<sup>8</sup> No evidence exists regarding these effects in humans.

Just as the large and polarized sugammadex molecules may limit the drug's ability to cross the blood-brain barrier, these biochemical properties are also thought to limit its excretion into breast milk.<sup>8</sup> Sugammadex passage into breast milk is of concern because the infant's immature metabolism and renal function may delay clear-

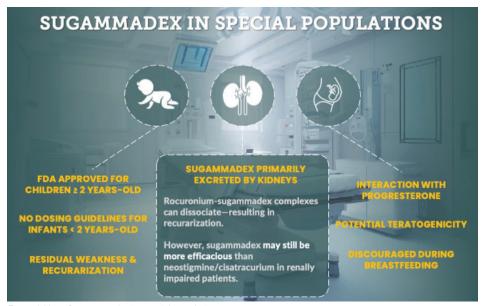


Figure 1: Use of sugammadex in special populations.

ance of the agent. An unpublished preclinical study demonstrated peak sugammadex levels in rat milk 30 minutes post-administration without adverse effects on offspring.<sup>7</sup> However, there is no evidence regarding sugammadex in human breast milk.<sup>7</sup> Given the lack of human evidence, breastfeeding immediately after received sugammadex is discouraged due to peak concentrations of sugammadex occurring around one hour postdelivery and potential increased passage into breast milk during the early postpartum period.<sup>8</sup>

While sugammadex offers critical benefits in pregnancy for rapid reversal of neuromuscular blockade, uncertainties persist regarding its interaction with progesterone, teratogenic potential, and safety during breastfeeding. Robust clinical data are needed to delineate these risks comprehensively and guide safe practices in obstetric and nonobstetric settings where its use is necessary.

#### SAFETY OF SUGAMMADEX IN THE PEDIATRIC PATIENT

When sugammadex was introduced to the US market, FDA approval was only for use in adults. The Bridion<sup>®</sup> package insert (Merck, Rahway, NJ) outlined that the safety and effectiveness of the drug had yet to be established in patients under 17 years of age.<sup>2</sup> Compared to adult patients, pharmacokinetics and pharmacodynamic profiles vary by age group, and a high age-dependent variability has been observed in pediatric patients in response to muscle relaxants and neuromuscular blockade reversal agents.<sup>12</sup> Numerous studies and case reports have since been published, and in 2021, an updated package insert was released with FDA approval for use in patients 2 years and older. Sugammadex provides safe, effective, and predictable reversal of neuromuscular blockade in pediatrics, revolutionizing care and improving outcomes in pediatric surgical settings. This section will focus on sugammadex in different pediatric age groups, recurarization, adverse events, and use in specific pediatric populations.

#### SUGAMMADEX USAGE BY AGE GROUP

#### Children aged 2–17

Sugammadex has been FDA-approved for use in children 2 years and older with the same dosing parameters as adults for moderate and deep blockade. The dose of 16 mg/kg for immediate reversal in pediatric patients has not been studied and is not FDA-approved for use.<sup>2</sup> Compared with neostigmine, reversal of moderate blockade with 2 mg/kg sugammadex occurred significantly faster.<sup>13</sup> Within 3 minutes, over 90% of the pediatric population had a TOFR > 0.9. The time to reversal of deep neuromuscular blockade with 4 mg/kg was consistent with results found in the adult population.<sup>13</sup> Sugammadex use was associated with a significantly shorter duration from the administration of reversal agents to TOFR > 0.9 compared to acetylcholinesterase inhibitors. There is also an association with shorter interval from reversal of neuromuscular blockade to extubation compared to acetylcholinesterase inhibitors. These findings demonstrate the superiority of sugammadex for reversing neuromuscular blockade over the conventional drugs such as the acetylcholinesterase inhibitors.14

Pediatric Patients Receiving Sugammadex Do Not Have a Higher Incidence of Bradycardia Than Those Receiving Neostimine in the Operating Room

#### From "Sugammadex," Preceding Page

#### Infants (less than 2 years)

Currently, sugammadex use in infants to children under 2 years of age is considered offlabel, as safety and effectiveness data have yet to be clearly established. There still needs to be validated pediatric dosing, and inconsistencies with monitoring have led to a wide range of approaches to the use of sugammadex as a reversal drug. Infants exhibit diverse reactions to neuromuscular blocking agents because of their immature neuromuscular junctions, larger extracellular volume during development, distinct body composition, anatomy, respiratory physiology, and muscle mass, all contributing to varying responses to neuromuscular blocking agents (NMBAs).<sup>15</sup> Additionally, the morphology of acetylcholine receptors differs from that of adults, and neuromuscular transmission is immature in neonates and infants until 2 months of age. Fetal postjunctional receptors are more sensitive to neuromuscular blockers as they have prolonged opening times. Pharmacokinetics are also affected by infants' underdeveloped hepatic and renal function, which reduces NMB clearance.16

In a prospective pilot trial, a sugammadex dose of 2 mg/kg was used in children aged 1–12 months old. Similar time to recovery of TOFR in all age groups was observed with no subsequent TOFR decrease after initial TOFR recovery to 0.9.<sup>17</sup> Redosing occurred in 4.2% of the cases after an initial dose of 3.45 mg/kg in children under 2 years of age. However, in this study, the use of neuromuscular blockade monitoring was inconsistent as only 43.7% of patients received train of four monitoring.<sup>16</sup> Overall, there are no specific dosing guidelines for neonates, and further investigation is needed to determine the appropriate dose of sugammadex in children under 2 years of age.

#### **RESIDUAL WEAKNESS** AND RECURARIZATION

Postoperative residual paralysis impacts respiratory function and compromises ventilation, increasing the incidence of critical postoperative respiratory events.<sup>18</sup> The pediatric population is more vulnerable to hypoxemia due to smaller lung volumes, reduced Functional Residual Capacity (FRC), immature respiratory control and high oxygen demand, and postoperative recurrent paralysis "recurarization." While residual weakness and recurarization occur in both adult and pediatric populations, children, particularly infants, have an increased susceptibility to postoperative

respiratory complications due to anatomical airway differences when exposed to lingering effects of neuromuscular blocking agents.<sup>15</sup> The overall incidence of residual postoperative weakness has been reported as high as 28.1% in children, which may be due to inappropriate neostigmine use, as it cannot reverse deep neuromuscular block.<sup>15</sup> One of the advantages of sugammadex is the ability to reverse both moderate and profound block, and it has been shown to reduce the risk of residual neuromuscular blockade. Multiple large-scale retrospective and prospective studies reviewed sugammadex use in pediatrics, in which both recurarization was not observed, and additional doses of neuromuscular reversal agents were not required.<sup>13,17</sup> However, case reports have described recurarization events that required additional reversal. In a case series of four pediatric patients with residual weakness or recurarization, three of the patients were under the age of 2. After adequate reversal with sugammadex and extubation was executed, the patients were noted to have a decreased respiratory effort, minimal limb movement, weakness, and cyanosis. In these patients, repeated sugammadex dosing had near-immediate improvement in ventilatory effort and strength. An additional patient, age 11, was also noted to be adequately reversed and required additional sugammadex 50 minutes after the initial dose, followed by improved ventilatory effort and eye-opening.<sup>19</sup> In a different case report describing an eight-month-old with DiGeorge and Truncus Arteriosus, who was adequately reversed using TOF monitoring at the adductor pollicis muscle, the patient required a repeat sugammadex dose 20 minutes after extubation.<sup>20</sup> While uncommon, the need for additional reversal does occur, and close monitoring and awareness during the postoperative period are essential to avoid complications.

#### ADVERSE EVENTS IN PEDIATRICS

Children can experience adverse events such as recurarization or anaphylaxis. There are considerations specific to the pediatric population. In young children, cardiac output is heart rate-dependent, and dose-dependent bradycardia could have a more clinically significant hemodynamic impact.<sup>21</sup> There was no significant difference between patients receiving sugammadex 2 mg/kg, 4 mg/kg, or neostigmine in the incidence of bradycardia while in the operating room.<sup>13</sup> At the same time, a metaanalysis with trial sequential analysis noted a significantly lower incidence of bradycardia in patients receiving sugammadex compared to acetylcholinesterase inhibitors or placebo in the operating room.<sup>14</sup>

#### CONCLUSION

The evolving landscape of neuromuscular blockade reversal continues to advance clinical practice, and sugammadex has emerged as a preferred agent in many settings. It has shown efficacy and safety in many different patient populations including those with renal impairment, during pregnancy, and pediatrics. By continuing to expand clinical evidence, anesthesia professionals can optimize patient care and safety in the management of neuromuscular blockade and reversal.

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### Sugammadex is Emerging as a Preferred Agent in Many Special Populations

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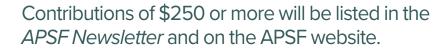
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### Battling Medical Misinformation: An Important Patient Safety Issue for Health Care Professionals

by George Tewfik, MD, MBA, FASA, and Raymond Malapero, MD, MPH, FASA,

#### PREVALENCE OF MEDICAL MISINFORMATION

Medical misinformation can have a profound impact on perioperative patient safety. With users numbering in the billions, platforms such as Facebook, Instagram, TikTok, X (formerly Twitter), Snapchat, Pinterest, Reddit, Messenger, and YouTube command an ever-increasing share of the public's time, attention, and dependence.<sup>1</sup> Consequently, they have also become primary sources of information for politics, sports, general knowledge, and news for the general public. Statistics published by Pew Research in 2022 show that adults under the age of 30 actually trust information from social media almost as much as national news outlets, and in 2023, half of US adults get news at least some of the time from social media.<sup>2,3</sup>

The relationship between medical care and information on the internet has been fraught since the early days of the internet, predating the more recent increase of medical misinformation. According to the United States Office of the Surgeon General, medical misinformation is "information that is false, inaccurate, or misleading according to the best available evidence at the time."4 The term "cyberchondria" was first coined more than two decades ago to describe heightened distress or anxiety caused by review of medical information on the internet.<sup>5</sup> One framework to explain the etiology of this distress suggests that patients with pre-existing anxiety seek out additional information on the internet for reassurance. Given the possibly unreliable nature of this information, alarm and surprise may follow, causing some patients or family members to find reassurance, whereas others do not. Those that fail to find reassurance seek out even more online health research, which often produces more anxiety and a self-perpetuating cycle takes hold.<sup>6</sup>

Misinformation can affect understanding of public health concerns, as was seen in the recent COVID pandemic when concerns were expressed regarding social distancing, mask mandates, and vaccination.<sup>7,8</sup> Perioperative medicine is no less affected. Patients presenting for labor pain may hesitate to consent for an epidural for analgesia if they consumed medical misinformation regarding potential side effects or complications. In 2022, a scoping review to assess the most common patient-reported barriers regarding epidural use in labor found that patients feared maternal side effects, fetal complications, prolonged labor, and paralysis, among other concerns.<sup>9</sup>

### Table 1: Sampling of Categories of Medical Misinformation in Anesthesiology With Associated Questions/Statements From Patients or Family Members.

Common misinformation about anesthesia	Sample patient/family concerns
	"Will I wake up during surgery?"
Intraoperative awareness	"Please don't let me wake up during surgery!"
	"I saw a movie once, and they were awake during the surgery."
	"Are you going to give me that fentanyl stuff?"
Medications given are very	"I've heard you use that stuff that killed Michael Jackson."
dangerous (propofol, fentanyl, etc.)	"Don't use that on me, are you trying to make me an addict?"
	"Matthew Perry died from ketamine. Don't give me that!"
Anesthesia changes postoperative	"Don't let me say anything stupid in there."
behavior (e.g., truth serum, seizures)	"Can you get seizures from anesthesia?"
Epidurals cause permanent damage	"Don't those things paralyze you?"
Epidurais cause permanent damage	"I know you can get bad back pain from those things."
Nerve blocks do not work	"You just want me to have that so I don't get any pain meds."
Nerve blocks do not work	"I've heard those things never work and can really hurt!"
Sedation is safer versus general	"I know sedation is so much safer—can I have that instead?"
anesthesia	"I've heard people die undergoing general anesthesia all the time."
Understanding how anosthesis	"You don't even know how that stuff works?"
Understanding how anesthesia works	"How do you give medication when you don't know what it does?"

A similar situation may present when discussing peripheral nerve block techniques for postoperative analgesia, especially if patients found medical misinformation on public health forums. These forums are often not moderated, and the personal anecdotes on these forums can influence patients, both positively and negatively. For example, there was significant public concern regarding peripheral nerve blocks following the lawsuit filed by professional American football player Sharrif Floyd against renowned orthopedic surgeon James Andrews, MD, and his colleagues. Floyd attributed his career-ending injuries to both his knee procedure and the nerve block that followed, with possible embellishments or sensationalism of the story causing panic and fear among future patients needing orthopedic surgery.<sup>10</sup> There are reliable sources of information, such as the in-depth analysis provided by journalist Michael McCann in Sports Illustrated, as well as the text of the legal complaint.<sup>11</sup> However, there are also sources of potential misinformation, such as a Reddit page featuring a robust discussion of theories regarding the case, and an X/Twitter post that also featured speculation and comments that may appear knowledge-based for members of the general public.<sup>12</sup>

Sensationalism in news stories may even cause patient fear and hesitancy when discussing medication selection (Table 1). For example, following the death of Michael Jackson, patients became very concerned with the administration of propofol, despite its high safety profile when administered by a trained anesthesia professional. Recent negative coverage regarding fentanyl and its use in illicit drugs may cause undue panic, as well.

See "Misinformation," Next Page

### Medical Misinformation May Negatively Impact Patient Safety

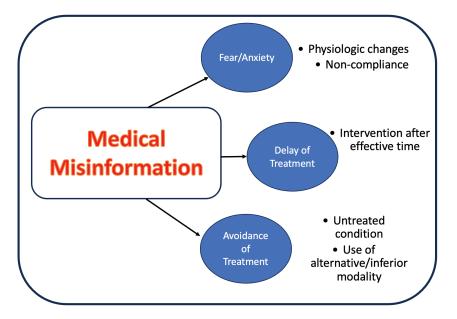


Figure 1: Potential consequences of medical misinformation in anesthesiology.

From "Misinformation," Preceding Page

#### THE IMPACT OF MEDICAL MISINFORMATION ON PATIENT SAFETY

Medical misinformation may negatively impact patient safety throughout the perioperative period. The detrimental effects of such misinformation may be grouped into three categories: fear and anxiety, delay of treatment, and avoidance of treatment (Figure 1). Fear and anxiety may cause psychological distress, which can lead to perseveration on concerns, gastrointestinal upset, sleep loss, and more. In addition, such negative feelings may provoke physiologic sequelae such as blood pressure and heart rate changes. These physical and psychological effects can further lead to patient noncompliance.

Delays in treatment may also occur. For example, if a patient initially refuses neuraxial anesthesia due to fear of labor epidurals, this may lead to last-minute epidural analgesia requests as the baby is about to deliver, leading to a rushed provider placing an epidural on an actively contracting patient. It may lead to increased risk in complicated pregnancies, such as those in patients suffering from preeclampsia. Although use of epidurals to control blood pressure in preeclampsia is controversial, early epidural placement is encouraged in parturients with preeclampsia to minimize the need for general anesthesia in the event of an emergent cesarean delivery.<sup>13,14</sup> Peripartum safety may therefore be compromised by the introduction of medical misinformation if a delay precludes safe and efficacious epidural use.

The final category is avoidance of treatment. This may affect not only the anesthetic plan

developed by the care team, but also may affect a patient's clinical course. For example, a patient with pulmonary comorbidities may not receive the most optimal perioperative care if they refuse to receive a regional anesthetic nerve block due to misinformation about the risk of paralysis or local anesthetic toxicity. The patient's pain may instead be treated with opioids, resulting in the potential for respiratory depression and airway obstruction and possible downstream complications and delayed discharge. Another example is the patient that may have benefited from a labor epidural, but instead encounters severe labor pain that remains untreated and may even develop acute stress, or even post-traumatic stress disorder, secondary to their experience during peripartum period.<sup>15</sup>

#### HOW TO MINIMIZE THE IMPACT OF MEDICAL MISINFORMATION ON PATIENT SAFETY

What can be done to combat misinformation and to ensure that it does not impact patient safety? Awareness among anesthesia professionals must be increased. Patients who ask such questions as "Will I wake up during surgery" or "Don't epidurals mess up your back forever?" may be heavily influenced by seeing a video on TikTok or reading a post on Facebook. A friend or family member may have sent them an anxiety-producing video from You-Tube in anticipation of their planned surgical procedure, leading to increased concern. Clinicians must be aware that these comments or questions are not seemingly random or fleeting thoughts, but may be deeply rooted in anxiety provoked by misinformation. It is important to consider that the genesis of these questions is fear-based, and though it may arise from incorrect information or irrational concerns, the patient will continue to suffer anxiety if these questions are not answered in a compassionate and thoughtful manner.

After facilitating awareness of this potential phenomenon, it is important to demonstrate empathy for a patient and not to be dismissive. Statements should be used such as "I'm sure this process can be very scary" or "I understand you have some concerns; let's discuss them further." Validation of one's fear, instead of dismissing their concerns as unreasonable, is a valuable first step to attenuating fear and establishing trust between the clinician and patient. Building trust with a patient during the preoperative evaluation is always an important aspect of a focused and targeted evaluation, but it gains new importance when the patient has anxiety due to misinformation.

Upon taking action to build trust, the anesthesiology professional should seek to carefully inquire regarding the patient's misinformation and to use facts to reassure the patient and their family. However, it is important to remember the importance of patient autonomy. One should not attempt to aggressively persuade a patient, especially for an elective intervention such as a regional anesthetic. Often, this will not only fail to persuade a patient, but may reinforce negative perceptions regarding health care professionals. Nonetheless, empathy, patience, and a willingness to listen to a patient's concerns are often enough to adequately address the concerns regarding anesthetic care that have been intensified by fear and anxiety due to misinformation.

Unsurprisingly, regulatory agencies and public health organizations have recognized the potentially disastrous impact on patient safety related to medical misinformation. In 2021, the United States Surgeon General released an "Advisory on Building a Healthy Information Environment."<sup>16</sup> This valuable resource offers further recommendations for health care professionals regarding false or misleading data. The recommendations include such items as proactively engaging with patients and the public regarding health information, using empathy, and accessible language. Furthermore, health care professionals are encouraged to use technology and electronic communications platforms to share accurate health information with the public at large. Finally, partnerships with community and local officials are encouraged to help develop localized messaging to address health care concerns in an accurate manner.

Verification of medical information is a complex task, especially for patients and family members who lack medical training. It is impor-See "Misinformation," Next Page

### Patients Can Be Heavily Influenced by Social Media

#### From "Misinformation," Preceding Page

tant for medical professionals who interact with a patient in the preoperative period to refer discussions regarding anesthesia (especially the choice of techniques and associated risks/benefits) to the anesthesia professional who will take care of the patient. Confusion often results when an unqualified person makes suggestions about possible techniques and medications, as well as their associated potential side effects. The preoperative evaluation and consultation with the designated anesthesia professional will be the single most important source of relevant information for a patient and their family. However, the impetus to consume information regarding anesthesia prior to a procedure is understandable, and patients should be directed (if necessary) to trusted and reputable sources of medical information on the internet, such as the APSF Patient Guide to Anesthesia and Surgery, that are designed for nonclinicians.<sup>17</sup>

It is important for anesthesia professionals to remember that medical misinformation may negatively affect patients and their families. Members of the public may seek out information prior to a surgical procedure or be sent information by loved ones. That information may be incorrect or sensationalized, thus affecting a patient's perceptions regarding anesthetic care. Utilizing empathy, patience, and facts, one may work to address medical misinformation to prevent fear and anxiety, delayed treatment, or the avoidance of appropriate medical care.

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### **APSF Initiative Against Medical Misinformation**

by Salvador Gullo Neto, MD, PhD, BCMAS, and Maria van Pelt, PhD, CRNA, CNE, CPPS, FAAN, FAANA



Technological advances, including online platforms, present both opportunities and challenges in health care communication. As the article by Tewfik and Malapero on medical misinformation describes, while these platforms enable widespread information sharing, they can also facilitate the spread of misleading and unscientific content that can negatively impact patients and their families.

As health care professionals, we have a fundamental responsibility to counter misinformation with evidence-based, scientifically accurate information from reliable sources. Since we cannot control what others post on the internet, our best strategy is to establish a strong presence in digital spaces, providing scientific evidence and medical information to help combat misinformation.

Many national organizations have established a digital presence, including the APSF who most recently launched the <u>APSF Patient Guide to</u> <u>Anesthesia & Surgery</u>, developed by the APSF Patient Engagement Working Group. Our methodology focuses on identifying and addressing the most common concerns about anesthesia side effects and surgical risk factors, as well as other frequently asked questions patients have before surgery. Since its launch last year, we have seen consistent organic growth, reaching 9,000 monthly visits to the <u>APSF Patient Guide</u> to Anesthesia & Surgery by October 2024, and demonstrating the public's desire for trustworthy medical information.

The perioperative period presents a crucial opportunity for anesthesia professionals to effectively communicate with patients. By actively listening with empathy and sensitivity, clinicians can build and strengthen trust. This relationship serves as the foundation for combating misinformation and enhancing patient safety.

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### Editorial: Euglycemic Ketoacidosis Concerns in Perioperative Use of SGLT2 Inhibitors: Re-Examining Current Recommendations

by Soyun M. Hwang, MD; Arney S. Abcejo, MD; Adam K Jacob, MD; Jesse M. Raiten, MD; and Manpreet S. Mundi, MD

Table 1: Summary of Current Notable Recommendations on Perioperative SGLT2i Use.

Over the past decade, sodium-glucose cotransporter-2 inhibitors (SGLT2i) have been well established as excellent therapeutic agents for the management of type 2 diabetes mellitus (T2DM).<sup>1</sup> Several randomized controlled trials (EMPEROR and CANVAS) have further established that SGLT2i demonstrate additional benefits in heart failure and chronic kidney disease, leading to their increased prevalence in the perioperative setting.<sup>2-4</sup> However, there has been growing concern regarding euglycemic ketoacidosis, an uncommon but life-threatening side effect associated with SGLT2i use.<sup>1</sup> SGLT2i inhibit glucose reabsorption in the proximal convoluted tubule resulting in glycosuria and reductions in serum glucose levels without an increase in insulin levels. Additionally, glucagon production can be stimulated resulting in lipolysis, ketoacid production, and, rarely, anion gap metabolic acidosis.<sup>5</sup> Since several perioperative factors (e.g., fasting state, increase in stress hormones) can exacerbate this risk, anesthesia professionals must carefully consider the risk of perioperative SGLT2i-associated ketoacidosis.

#### REVIEW OF CURRENT RECOMMENDATIONS AND CHALLENGES

Currently, there is no consensus on perioperative management of SGLT2i and many published recommendations are outdated or based on limited data (Table 1). In 2020, an article in Anesthesiology recommended continuing SGLT2i for ambulatory surgery but stopping on the morning of surgery.<sup>6</sup> However, these recommendations were extrapolated from expert opinions. In addition, they were published before United States Food and Drug Administrative (FDA) updated its recommendation to stop SGLT2i at least 3-4 days before all scheduled surgery. The FDA's current recommendations also appear to be based on limited case reports and the elimination half-life of SGLT2i.1 In 2023, the validity of the FDA recommendations were evaluated by reviewing 99 reported cases of SGLT2i associated diabetic ketoacidosis; no cases were found in patients who held SGLT2i for longer than 3 days.<sup>7</sup> Despite this being the largest systematic review to date on the subject, only 58.6% of the reviewed cases discontinued SGLT2i preoperatively, making the study further underpowered, and none of the reviewed cases discontinued SGLT2i for more than 2 days preoperatively. Despite a lack of validity, the FDA's recommendation has been adopted by several organizations. Other individual institutions have published their own rec-

<ul> <li>United States Food and Drug Administration (FDA)<sup>1</sup></li> <li>Canagliflozin, dapagliflozin, empagliflozin—hold for 3 days prior to surgery.</li> <li>Ertugliflozin—hold for 4 days prior to surgery.</li> <li>Ertugliflozin—hold for 4 days prior to surgery.</li> <li>Mo studies to date that validate its 3-4 day hold time.</li> <li>No recommendation for emer- gency surgery or other surgical considerations.</li> <li>Stop 24–48 hours prior to scheduled surgery.</li> <li>Immediate cessation for emergent surgery.</li> <li>Immediate cessation for emergent surgery.</li> <li>Initially published as position state- ment in 2016 and was re-iterated in consensus statement published in 2020, but without further updates.</li> <li>American College of Cardiology</li> <li>Endorses FDA recommendations.</li> </ul>	Organization	Perioperative Guideline	Consideration	
Clinical Endocrinologists and American College of Endocrinology (AACE/ACE) <sup>8,9</sup> scheduled surgery.reports and expert opinion.• Immediate cessation for emergent surgery.• Initially published as position state- ment in 2016 and was re-iterated in consensus statement published in 2020, but without further updates.• American Diabetes Association• Endorses FDA recommendations.• American College of• Endorses FDA recommendations.		<ul><li>empagliflozin—hold for 3 days prior to surgery.</li><li>Ertugliflozin—hold for 4 days</li></ul>	<ul> <li>of case studies and each agent's elimination half-life, which is not the same as pharmacologic half-life (SGLT2i have shown prolonged clinical effect over a week after cessation.)</li> <li>No studies to date that validate its 3-4 day hold time.</li> <li>No recommendation for emergency surgery or other surgical</li> </ul>	
Association     American College of     Endorses FDA recommendations.	Clinical Endocrinologists and American College of Endocrinology	scheduled surgery. <ul> <li>Immediate cessation for</li> </ul>	<ul> <li>reports and expert opinion.</li> <li>Initially published as position statement in 2016 and was re-iterated in consensus statement published in</li> </ul>	
		Endorses FDA recommendations.		
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ommendations, but these are still based on limited case reports and do not demonstrate consensus on hold times for SGLT2i.  $^{8-10}$ 

Several factors contribute to the current lack of evidence for perioperative management of SGLT2i. The most concerning factor is that, due to its atypical presentation, SGLT2i-associated euglycemic ketoacidosis is underreported, which makes it challenging to understand its prevalence and impact on a patient's perioperative outcome.<sup>11</sup> In fact, outside the perioperative setting, two large meta-analyses assessing 82 randomized controlled trials demonstrated that SGLT2i are not significantly associated with a higher risk of diabetic ketoacidosis compared to other hypoglycemic agents.<sup>12,13</sup> Position statements from the American Association of Clinical Endocrinologists and American College of Endocrinology also suggest that the risk of diabetic ketoacidosis associated with SGLT2i is no greater than the low levels occurring in the general diabetes population.<sup>8</sup> However, neither the meta-analyses nor position statements specifically comment on the risk of euglycemic ketoacidosis, which is marked by a different clinical presentation, diagnostic criteria, and occurrence rate. The question remains: what makes SGLT2i administration an exceptional risk factor for euglycemic ketoacidosis compared to other hypoglycemic agents during the

perioperative period? Are there other perioperative factors that affect the risk of SGLT2iassociated euglycemic ketoacidosis? Several sources repeatedly comment that these critical questions are yet to be answered, which impedes the development of evidence-based perioperative guidelines for SGLT2i.

#### RECENT UPDATES ON PERIOPERATIVE SGLT2I USE

Based on an updated review of current literature, there are new findings that elucidate the prevalence and impact of perioperative SGLT2iassociated diabetic ketoacidosis. In 2022, the first and largest population-based study examining the incidence rate of SGLT2i-associated postoperative diabetic ketoacidosis was published.<sup>14</sup> The incidence of postoperative diabetic ketoacidosis within 30 days postoperatively was six times higher in SGLT2i users compared to nonusers, which is much higher than previously suspected. SGLT2i users who developed diabetic ketoacidosis postoperatively had higher rates of complications (e.g., need for mechanical ventilation, infection, longer hospital stay) and overall increased mortality. This is the first study to establish SGLT2i as an independent risk factor for developing postoperative diabetic ketoacidosis.

### Recognition of Perioperative Euglycemic Ketoacidiosis Can Be Challenging

#### From "Re-Examination," Preceding Page

However, this population study did not have uniform diagnostic criteria for diabetic ketoacidosis and did not clarify which of them, if any, were euglycemic at presentation. This is concerning since SGLT2i can cause prolonged glycosuria and ketonemia up to 9-10 days after cessation, which can confound the diagnosis.<sup>15</sup> In fact, a 2023 single-institution retrospective analysis showed that all patients on SGLT2i, after average preoperative hold time of 1.5 days, developed some degree of ketoacidosis with mean increase in anion gap from 12.6 mmol/L preoperatively to 13.4 mmol/L postoperatively.<sup>16</sup> These findings suggest that diagnosis of clinically significant ketoacidosis is a complex clinical consideration of not just pertinent laboratory values, but also clinical symptoms and presenting circumstances. Without clear diagnostic criteria differentiating the types of ketoacidosis, we may not understand the true incidence and impact of SGLT2iassociated euglycemic ketoacidosis, which continues to hinder the development of evidence-based perioperative SGLT2i guidelines.

#### PRACTICE CONSIDERATIONS AND RECOMMENDATIONS

There are several perioperative factors that should be considered when assessing the risk of SGLT2i-associated diabetic ketoacidosis (Table 2). Advanced T2DM (HgbA1c >8%) was recently reported to increase the risk by 3.1-fold.<sup>14</sup> Emergent surgery, which was previously suggested as a risk factor given its inherent stress and urgency, was also recently reported to increase the risk by 24.5-fold.<sup>14</sup> Bariatric surgery has long been considered a risk factor as perioperative SGLT2iassociated euglycemic ketoacidosis was first reported in bariatric patients, thought due to postoperative dietary changes as well as complications.<sup>7,11</sup> This concern can be expanded to consider adequate postoperative nutritional intake (to overcome postoperative catabolic state) as an indicator for when to resume SGLT2i. Such a complex variety of factors should be incorporated when developing a guideline to manage patients on SGLT2i. For example, the University of Pennsylvania recently published a comprehensive single-center guideline incorporating factors such as anticipated procedure duration, anesthesia type, preoperative HgbA1c and glucose and basic metabolic panel, and underlying patient comorbidities to better identify which patients may be at high risk of perioperative SGLT2i-associated euglycemic ketoacidosis.<sup>17</sup> While this guideline still endorses the FDA recommendation for preoperative SGLT2i cessation and needs further evidence for optimization, this is the first published approach to developing an algorithm to guide the management of high-risk euglycemic ketoacidosis cases for anesthesia providers taking care of patients on SGLT2i.

 Table 2: Factors That Can Increase the Risk of Perioperative SGLT2i-Associated

 Euglycemic Ketoacidosis.

#### Underlying comorbiditie

Underlying comorbidities			
Female sex	Suggested based on case review. <sup>7</sup>		
Advanced or poorly controlled T2DM	Previously suggested as an independent factor. <sup>7,19</sup> Recently, HgbA1c >8% reported to cause 3.1-fold increased risk. <sup>14</sup>		
Liver disease	Suggested as liver function is critical in glucose metabolism. <sup>19</sup>		
Concomitant insulin use	Recently reported to cause 2.8-fold increased risk. <sup>14</sup>		
Obesity	Suggested due to ketosis. <sup>7</sup>		
Surgical type			
Emergency	Previously suggested as an independent factor associated with as much as 25% of SGLT2-associated DKA. <sup>7,16</sup> Recently reported to cause 24.5-fold increased risk. <sup>14</sup>		
Bariatric	Supported by several systematic reviews as a prominent factor due to its postoperative nutrition management. $^{7,\!11}$		
Cardiac	Suggested through several case reports. <sup>16</sup>		
Other perioperative considerations			
Pre- and Postoperative hypovolemia	Suggested as it can mask the usual hyperglycemia induced polyuria. <sup>11</sup>		
Postoperative nutrition	Supported by current guidelines, reviews and meta-analyses; inad- equate nutrition can worsen postoperative catabolic state and worsen metabolic complications. <sup>19</sup>		
Infection/sepsis	Suggested as it can impair adequate glycemic control and cause physiological stress. <sup>7,11</sup>		
Glucocorticoid use	Suggested as it can promote hyperglycemia and insulin resistance. <sup>11</sup>		

T2DM: Type 2 Diabetes Mellitus; DKA: Diabetic Ketoacidosis

Finally, it is important to highlight that for certain patients, SGLT2i cessation in the perioperative setting may be more harmful. At the end of EMPEROR trials that demonstrated cardioprotective benefit of empagliflozin, the patients who were prospectively withdrawn from treatment had increased risk of cardiovascular death and hospitalization for heart failure within 30 days of discontinuation back to pretreatment baseline.<sup>18</sup> Given the rapid reversal of the cardioprotective benefits of SGLT2i, some advocate for early detection and treatment of ketoacidosis (e.g., intraoperative lab monitoring for acidosis and insulin infusion use) rather than perioperative discontinuation of SGLT2i in heart failure patients.<sup>19,20</sup> There also has never been a case of euglycemic ketoacidosis in patients taking SGLT2i for cardiorenal indications in the absence of T2DM, so SGLT2i should be continued in this population.<sup>17</sup>

We suggest a perioperative algorithm for patients on SGLT2i (Figure 1, next page). Given the lack of evidence in current literature, this algorithm may not apply to every case. However, we highlight the most significant perioperative considerations supported by current data, such as emergent procedures and other confounding risk factors for diabetic ketoacidosis.<sup>7,11,14,16,19</sup> For emergent or urgent procedures,

we recommend proceeding with surgery with close perioperative monitoring for acidosis and early initiation of insulin infusion, as the risk of delaying surgery may outweigh the risk of diabetic ketoacidosis. While data are lacking, the current FDA and other institutional guidelines suggest holding SGLT2i for all scheduled surgeries, including outpatient procedures with expected rapid return to preoperative state. 1,8,9 Therefore, for elective procedures, if the patient is considered high risk, we recommend rescheduling surgery, but if the patient is considered low risk, we recommend assessing other patient and surgical factors.<sup>17</sup> For nondiabetic patients taking SGLT2i for heart failure or cardiorenal protection, we do not believe this algorithm applies; based on current data, they should continue SGLT2i and are considered at low risk for diabetic ketoacidosis. However, depending on other confounding risk factors, they too may require close perioperative monitoring for acidosis.

In summary, we believe that SGLT2i pose an increased risk for diabetic ketoacidosis and other morbidities in the perioperative setting. However, the optimal preoperative hold time for SGLT2i and how cases should be handled if the hold time is not met remains controversial.

### SGLT2i Should Be Continued for Patients With Cardiorenal Indications

From "Re-Examination," Preceding Page The latter is particularly important for anesthesia professionals as many patients currently do not adhere to a universal hold time. While further research is needed, we encourage clinicians to consider the currently reported risk factors, along with other patient and surgical factors, to risk-stratify and individualize the management of patients taking SGLT2i, from case cancellation consideration to enhanced postoperative monitoring. Soyun M. Hwang is an assistant professor of anesthesiology and critical care, Mayo Clinic, Rochester, MN.

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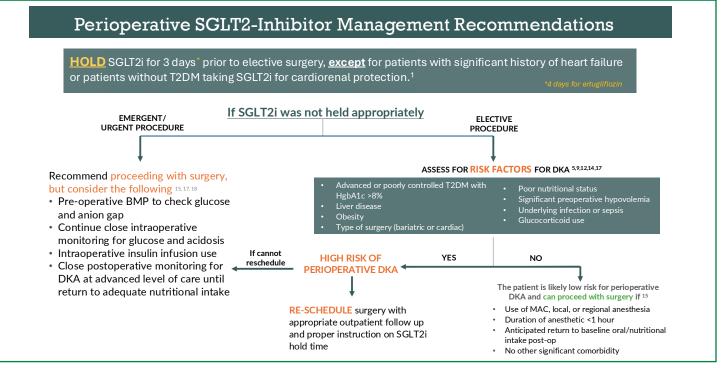


Figure 1: Recommendations for perioperative management of SGLT2i. Management pathways are influenced by the urgency of surgery and other significant patient or surgical factors that may increase risk of perioperative diabetic ketoacidosis. This algorithm does not apply to nondiabetic patients taking SGLT2i for heart failure or cardiorenal protection, as data suggest they should continue SGLT2i. Note that there are no Class 1 evidence for the perioperative management of SGLT2i. Sodium-Glucose Cotransporter-2 Inhibitor; BMP: Basic Metabolic Panel; T2DM: Type 2 Diabetes Mellitus; DKA: Diabetic Ketoacidosis; MAC: Monitored Anesthesia Care.

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Note: Donations are always welcome. Donate online (https://www.apsf.org/donate\_form.php) or mail to APSF, P.O. Box 6668, Rochester, MN 55903. (Donor list current as of December 1, 2023–December 31, 2024.)

### The Open Oximetry Project: Safe and Accurate Pulse Oximeters for All Skin Tones

by Daryl Dorsey, BS; Fekir Negussie, MPH; Elizabeth Igaga, MMed; Tyler Law, MD, MS; and Michael Lipnick, MD

Pulse oximetry has long been a cornerstone of patient safety both inside and outside the operating room. However, data emerged during the COVID pandemic revealing health care disparities that may be linked to underperformance of these essential devices. Most notably during the pandemic, patients with darker skin tones experienced delays in treatment.<sup>1</sup> This delay can lead to worse health care and health outcomes. Although these concerns have persisted for years with relatively little attention prior to the pandemic, increasing data on potential harms from inequitable device performance have renewed interest from the public and regulatory agencies.<sup>2,3</sup> There is a need to understand and address the root cause of pulse oximeter performance issues in patients with darker skin tone.

The Open Oximetry Project, spearheaded by University of California San Francisco's Hypoxia Lab and Center for Health Equity in Surgery and Anesthesia, was formed as a collaborative initiative to tackle this issue. This group's foundational goal was to uncover why some pulse oximeters underperform in patients with darker skin tone and to develop solutions to promote equitable performance. The project has multiple facets, including (1) data collection in healthy human volunteers as well as critically ill patients; (2) data sharing through an open-source data repository and open-access website (OpenOximetry.org) providing device performance data; (3) communication of best practices with health care providers, and convening a collaborative community of stakeholders from around the world (Figure 1). The Open Oximetry Collaborative Community is one of 18 entities formally recognized by the United States (US) Food and Drug Administration (FDA) (https://www.fda.gov/about-fda/cdrh-strategic-priorities-and-updates/collaborative-communities-addressing-health-care-challengestogether) that brings together clinicians, engineers, researchers, device manufacturers, regulatory agencies, and patient safety advocates, including the Anesthesia Patient Safety Foundation (APSF). This is to prevent duplication of efforts, to share knowledge, and to accelerate progress towards more equitable standards and guidelines that will serve the full spectrum of patients worldwide.

#### **EDUCATION**

One initiative that has been undertaken by the OpenOximetry.org Collaborative Community is the creation of educational content to inform clinicians on how to optimize pulse oxim-

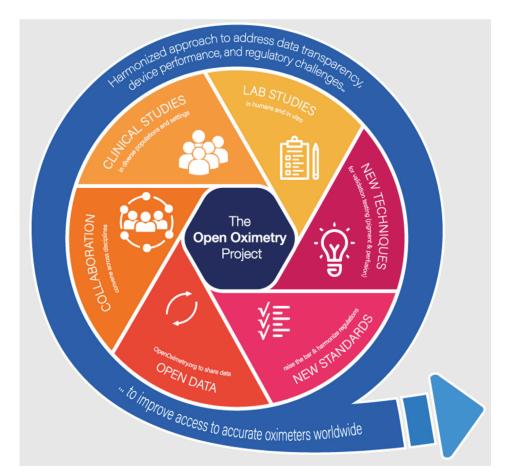


Figure 1: Key facets of the Open Oximetry Project are shown in the infographic wheel, including clinical and lab studies, new techniques, standards, open data sharing, and global collaboration to improve access to accurate oximeters. Reproduced with permission from the Open Oximetry Project. Available at: OpenOximetry.org/about.

eter use and to minimize health and health care disparities. Through a series of online stakeholder meetings and asynchronous design processes involving collaborators from numerous geographies and disciplines, the project has created a customizable infographic that outlines the best practices for pulse oximetry use. This online tool (https://openoximetry.org/infographic-builder/) allows users to download a pre-made infographic or to customize and build their own using templates created by the project team (Figure 2, next page). Users can fully customize the infographic content to address the needs and specific challenges of their institution, selecting from a range of options, each highlighting a key aspect of pulse oximetry for greater relevance to their unique context. Topics covered included "How to Place a Probe," "How to Obtain a Reliable SpO<sub>2</sub> Reading," "Known Limitations," "SpO2 for Clinical Decisions," among others.

#### LABORATORY STUDIES

Another key focus of the Open Oximetry Project involves performing validation testing for pulse oximeters in the UCSF Hypoxia Lab. The Hypoxia Lab, founded by Dr. John W. Severinghaus in 1958, has been one of the leading centers for investigating the effects of hypoxia in the body as well as the discrepancies seen in the pulse oximeter's accuracy in darker skin tones. Healthy participants volunteer in controlled desaturation studies with SaO<sub>2</sub> plateaus between 70–100%, allowing the lab to test and compare the performance of various pulse oximeters as compared to gold standard arterial blood gas analysis. The project has focused on independently testing pulse oximeters that are representative of global markets, especially those found in low and middle-income countries.

### Pulse Oximeters May Have Variable Performance in Patients with Darker Skin Tones

#### From "Open Oximetry," Preceding Page

The project has published findings for 20 devices and plans to release data on an additional 20 in the coming months (Device Update meeting). To date, these results have been mixed, demonstrating highly variable performance of devices on the market, many with positive bias in people with dark skin pigment, some with negative bias, and some without apparent bias. Of note, definitions for clinically relevant levels of bias are evolving, and the team is actively working and refining methods to optimize sample size and improve detection of biases and definitions of biases linked to skin pigment.

#### COLLABORATION WITH REGULATORY BODIES

The Open Oximetry Project also collaborates closely with regulatory agencies, including the US FDA and the International Organization for Standardization (ISO). The team actively shares data through their open data repositories with the intention of informing updated regulatory guidelines and standards that address disparities in device performance. The team has been working to develop and publish new protocols for pulse oximeter regulatory testing, and also is developing new protocols to ensure that diversity of skin pigment is included in research cohorts an element that has been lacking to date. We are hopeful that through this ongoing collaboration, we can contribute to the development of standards that ensure all pulse oximeters are rigorously tested and validated to be effective across all skin tones and clinical scenarios so that clinical decision-making is based upon the most reliable data.

#### **OUR FUTURE GOALS**

We are fortunate to work alongside partners like APSF, whose commitment to patient safety aligns perfectly with our mission. Together, we are pushing forward on the path toward more equitable health care technology and greater inclusiveness in patient monitoring. The work is

See "Open Oximetry," Next Page



Improve the use of pulse oximetry in your health facility!

We've created a simple process to help you **build your own pulse oximetry infographic.** You can choose from preset information tiles each addressing different areas of best practice so you can prioritize issues most relevant in your setting. Follow the steps below and in seconds you will have a custom infographic to download and share. (Individual images can be downloaded here). This tool is currently in beta testing. <u>Download</u> our premade infographic



### Step 1/6

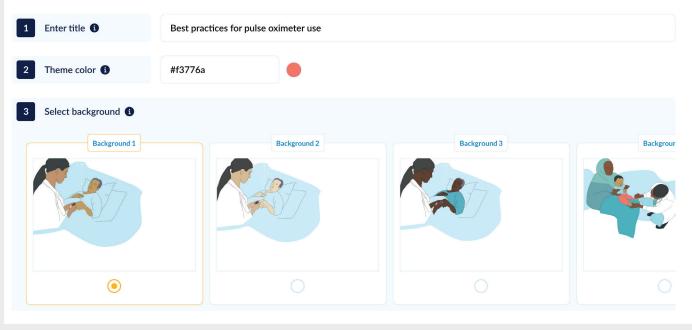


Figure 2: The Infographic Builder, an online tool developed by the Open Oximetry Project allows users to create or customize infographics on best practices for pulse oximetry use, enabling health care providers to tailor the information to their specific needs and improve clinical decision-making. Reproduced with permission from the Open Oximetry Project. Available at: <u>OpenOximetry.org/infographic-builder</u>.

### Diversity of Skin Pigment Needs to Be Included in All Research Cohorts

#### From "Open Oximetry," Preceding Page

far from over, but through continued efforts, we believe that substantial strides can be made in closing the gaps in pulse oximetry performance and ensuring that every patient receives accurate, reliable care. We plan to release performance data on an ongoing basis and are working to open a medical device development laboratory in East Africa to expand global research capacity and improve representations of diverse populations in medical device research and development. Daryl Dorsey, BS, is a medical student at the University of California, San Francisco.

Fekir Negussie, MPH, is the program manager at the Center for Health Equity in Surgery and Anesthesia at the University of California, San Francisco.

Elizabeth Igaga, MMed, is a lecturer at Makerere University, Kampala, Uganda.

Tyler Law, MD, MS, is a clinical associate professor of anesthesiology and critical care at the University of California, San Francisco, and Zuckerberg San Francisco General Hospital.

Michael Lipnick, MD, is a clinical professor of anesthesiology and critical care at the Univer-

sity of California, San Francisco, and Zuckerberg San Francisco General Hospital.

The authors have no conflicts of interest.

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### Alan G. Sieroty APSF/SOCCA Inaugural Lecture at the Annual SOCCA Meeting in Hawaii



Meghan Lane-Fall, MD, APSF Board Member

Integrating Human Factors Engineering & Implementation Science to Support Safety in Anesthesiology & Critical Carex

—With Keynote by Meghan Lane-Fall, MD

#### Saturday, March 22, 2025

from 3:30 pm—4:30 pm HST

at the Hilton Hawaiian Village Waikiki Beach Resort

### **Get Social With Us!**

The APSF is eager to connect with patient safety enthusiasts across the internet on our social media platforms. Over the past year, we have made a concerted effort to grow our audience and identify the best content for our community. We've seen increases in followers and engagement by several thousand percent, and we hope to see that trajectory continue in 2025. Please follow us on Facebook at <a href="https://www.facebook.com/APSForg/">https://www.facebook.com/APSForg/</a> and on X at <a href="https://www.facebook.com/APSForg/">https:/



In

Tube

Amy Pearson, MD, APSF Director of Digital Strategy and Social Media.

# 2024 President's Report: Improving Patient Care in Perioperative Medicine Continues as Our Purpose.

Recent data continue to confirm the epidemic of preventable harm in American health care. In 2022, the U.S. Department of Health and Human Services Office of Inspector General released a report titled "Adverse Events in Hospitals: A Quarter of Medicare Patients Experienced Harm in October 2018."<sup>1</sup> In 2023, the New England Journal of Medicine published that, "Adverse events were identified in nearly one in four admissions;" with adverse drug events accounting for 39.0% of all events, and surgical procedural events a close second at 30.4%.<sup>2</sup> Clearly, we have work to do in the perioperative space.

Not only does preventable harm exact a high human cost, but it exerts a resource and financial stress on our health care system. According to a recent report by the Organisation for Economic Co-operation and Development (OECD), "the direct cost of treating patients who have been harmed during their care approaches 13% of health spending," with most of these events deemed preventable.<sup>3</sup> One final adverse impact of harm is the erosion of trust by patients in health systems. Trust has a clear impact on health and health care outcomes. A recent publication reports that between April 2020 and January 2024, trust in physicians and hospitals decreased from 71.5% to 40.1%.<sup>4</sup>

The Anesthesia Patient Safety Foundation (APSF) approaches the challenge of preventable harm with collaborative relationships, realizing we accomplish more together than in a silo. Since inception, the APSF has included leaders from industry, regulatory agencies, other health care specialties and providers, and medicolegal and insurance companies. This broad union of forces has allowed APSF to serve as a convenor of collaborators, each working together to resolve patient safety issues that can have devastating impacts on patients, their families, and their health care providers.

While the APSF has been laser focused on our vision "that no one shall be harmed by anesthesia care," we understand that, like the strands of a strong rope, we should not unravel safety from quality. The primary goal of quality health care is to ensure that patients receive the best possible care, achieve optimal outcomes, and meet or exceed their personal health goals. Health care and our patients do not get to quality outcomes without safety. Our vision should be entrenched throughout the patient experience during the entire perioperative process, and beyond. In short, we aspire to by Dan Cole, MD



Daniel J. Cole, MD, Current APSF President

a system without preventable harm, returning patients to their baseline or an improved state of physical, cognitive, and psychological health.

#### **OUR ACTIVITIES**

The APSF serves as a strong advocate for perioperative safety, and we continue to work the levers of action by which we turn ideas into action, and action into results. They include research, education, our *Newsletter*, other communication vehicles (e.g., social media, website), collaboration with other stakeholders in patient safety, and advocacy. With limited resources, we will continue to strategically exercise these levers to make continued progress in the fight against preventable harm. Let me highlight just a few of our many activities.

- Establishment of perioperative patient safety priorities. The APSF seeks broad input and has established a list of the top perioperative patient safety priorities. These may be viewed at <u>https://www.apsf.org/patientsafety-priorities/</u>. In general, APSF's primary activities and initiatives are focused on these priority issues which include
  - 1. Culture of Safety, Teamwork, and Clinician Safety
  - 2. Clinical Deterioration
  - 3. Nonoperating Room Anesthesia
  - 4. Perioperative Brain Health
  - 5. Opioid-related Harm
  - 6. Medication Safety
  - 7. Infectious Diseases
- 8. Airway Management
- Consensus Conferences: Each year, the APSF hosts a Stoelting Consensus Conference oriented towards one of the priority

issues. These conferences bring together patient safety advocates, anesthesia and surgical professionals, and industry and regulatory leaders to address specific topics. Examples of past conferences can be found at https://www.apsf.org/past-apsf-consensusconferences-and-recommendations. The 2024 conference was titled "Transforming Anesthetic Care: A Deep Dive into Medication Errors and Opioid Safety." Medication errors continue to comprise a high percentage of the total errors in perioperative medicine. The 2024 conference was exceptional and was held in Boston in celebration of the meeting that occurred 40 years ago (https:// www.apsf.org/about-apsf/apsf-history/) that resulted in the formation of APSE in 1985. The conference was sold out with over 200 individuals signed up for virtual participation. The lectures are available online at https:// www.apsf.org/event/apsf-stoelting-conference-2024/. A manuscript with recommendations will be submitted for publication.

Next year's conference will be held in Chicago on September 3–4 and will be titled "Transforming Maternal Care: Innovations and Collaborations to Reduce Mortality."

- Our Committee on Technology has created a technology education initiative, which can be accessed at the APSF website. Two learning activities are currently available free-ofcharge and include 1) <u>Low-Flow Anesthesia</u> and 2) <u>Quantitative Neuromuscular Monitoring</u>. A course on Manual External Defibrillation, Cardioversion, and Pacing will soon be released.
- There is a new webpage dedicated to preventing and treating surgical fires. This includes a legacy video of about 18 minutes, and a new abbreviated video of 5–6 minutes available in multiple languages. <u>https://www.apsf.org/videos/preventing-surgical-fires/</u>
- A new initiative that we have been working on for over two years and was launched late last year regarding patient engagement. According to a 2023 report by the OECD on patient engagement, "Patients' and citizens' perspectives and their active engagement are critical to make health systems safer and people-centered—and are key for codesigning health services and co-producing good health with health care professionals and building trust." Way overdue in Ameri-

See "President's Report," Next Page

### The APSF Continues to Focus on Our Vision "That No One Shall Be Harmed By Anesthesia Care"

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

can health care is patient engagement in their health care. We have a new website that has been developed with significant patient input and to date has been highly utilized. We envision building out this website with a menu of options, over time, that are specific to patient-specific conditions and risks. <u>https://www.apsf.org/patient-guide/</u>

We have a deeply committed group of volunteers who I am confident will rise to the challenges of health care that will occur in the perioperative space over the next decade, and the solutions that improve patient safety and ultimately quality outcomes. We rely on your financial support to achieve our goals, and we will use our resources wisely to ensure that anesthesiology remains a leader in perioperative safety to the benefit of our patients and providers. We at the APSF will be proactive to continue our work to fulfill our vision "that no one shall be harmed by anesthesia care." It is indeed a sacred trust that we have with our patients and our goal is to further the foundation of trust on which our specialty has been built.

Dan Cole, MD, is professor of clinical anesthesiology in the Department of Anesthesiology and Perioperative Medicine David Geffen School of Medicine, University of California at Los Angeles. He is also the current president of the Anesthesia Patient Safety Foundation.

The author has no conflicts of interest.

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# SAVE THE DATE! APSF Stoelting Conference 2025 Transforming Maternal Care: Innovations and Collaborations to Reduce Morbidity and Mortality

September 3–4, 2025 The Palmer House Hilton Chicago, IL

\*This will be offered as a hybrid conference\*

For registration and conference inquiries, please contact Stacey Maxwell, APSF Administrator (maxwell@apsf.org). Registration to open Spring 2025

For information on sponsoring the 2025 Stoelting Conference, please contact Jill Maksimovich, APSF Director of Development (maksimovich@apsf.org)

### Assessing Fire Risk in Surgery: Why Limit Open Oxygen Delivery to 30%?

by Mark E. Bruley, CCE-R, FACCE, and Jeffrey Feldman, MD, MSE, FASA

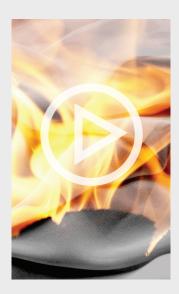
Surgical fires continue to cause preventable morbidity and mortality despite educational efforts and well-established recommendations for eliminating the risk.<sup>1-6</sup> Many medical societies and regulatory bodies recommend limiting open oxygen delivery to 30%. These include the American Society of Anesthesiologists, the American College of Surgeons, the Society of American Gastrointestinal and Endoscopic Surgeons, the Association of periOperative Registered Nurses, the Joint Commission, the Emergency Care Research Institute (ECRI), the Food and Drug Administration, and the Pennsylvania Patient Safety Authority.

The root cause of the overwhelming majority of serious fires is administration of oxygen via an open delivery source, i.e., disposable facemask or nasal cannula. For this reason, the key recommendations for preventing fires are

- Limit the delivered oxygen concentration connected to the open delivery device to 30% or less
- Control the airway if a greater concentration of oxygen is clinically indicated.

Procedures around the head, neck, and upper chest are considered high-risk for fire and intravenous sedation is often sufficient to achieve patient comfort. Oxygen is commonly delivered during sedation via an open source to "keep the patient safe." In the case of a surgical fire, oxygen becomes the root cause of patient harm rather than improving safety. Since administering oxygen can be useful for ensuring adequate oxygenation, in procedures at high risk for fire it is important to question how much oxygen can be administered to ensure patient safety without increasing the fire risk. The following information reviews the rationale for the recommendation to limit oxygen concentrations by open delivery to 30% or less. The rationale is based upon work at ECRI (www.ecri.org) by Mark Bruley and others investigating surgical fires over several decades.7

In the early days of surgical fire investigation, ECRI performed laboratory testing of the flammability of surgical drapes in the presence of oxygen at concentrations of 21% (room air) and 80%.<sup>8</sup> Other authors have done similar testing.<sup>9-12</sup> While there are no data specifically testing the flammability of surgical drapes and other materials in the presence of 30% oxygen, observations from testing at higher concentrations provided useful guidance.



A video depicting surface fiber flame propagation was created by the Royal Air Force (RAF) Institute of Aviation Medicine investigating enriched oxygen fires in aircraft.

#### Video available: https://www.sages.org/video/ fire-in-the-or-cause-and-prevention/.

The one-minute RAF video segment begins at time code 2:43. The video segment is from research and testing by the RAF Institute of Aviation Medicine. Denison D, Ernsting J, and Cresswell AW. The Fire Risks to Man of Oxygen-Rich Gas Environments. Royal Air Force (RAF) Institute of Aviation Medicine, Farnborough, England. RAF Institute of Aviation Medicine Reports 320 (April 1965) and 343 (Sept. 1965).

The 30% recommendation was derived over time from surgical fire accident investigations by ECRI in the late 1970s. During investigation testing, "surface fiber flame propagation" was observed to occur in vitro on cotton surgical towel fibers and human hair in the presence of oxygen concentrations of 50% and greater.79 This phenomenon involves the rapid spread of fire from the inciting source. In other words, the enriched oxygen concentration creates flammable conditions that otherwise would not exist (apsf.org/ORFire30). Testing revealed that when oxygen concentration was reduced below 50%, down to about 45%, flame propagation was not as likely. It is the oxygenenriched atmosphere enhanced propagation that creates the two-fold risk of easier ignition of materials and subsequent very rapid spread of flames outward from the point of ignition. When supplemental oxygen was discontinued, tests found that oxygen concentrations under drapes quickly dropped to below 30% and fire propagation was not observed.<sup>7</sup>

Discussions and collaborations with anesthesia professionals about the laboratory results subsequently focused around what would be an acceptable reduced delivered oxygen concentration via an open source (mask or nasal cannula). Fortunately, reliable pulse oximeters were introduced coincident with developing recommendations for preventing surgical fires in the late 1980s. The 30% recommendation was promoted as safe, knowing that pulse oximeter monitoring could be used to continuously estimate the resulting blood oxygenation and surface fiber flame propagation was unlikely to occur.

Current recommendations for preventing fires clearly describe that no more than 30% oxygen be delivered by an open source and that the airway be managed using a supraglottic airway or endotracheal tube if a greater concentration of oxygen is required to keep the patient safe.<sup>1,3,4,6,8,9</sup> Most patients have normal lung function, and, therefore, 30% oxygen should be sufficient to prevent hypoxemia if spontaneous ventilation is maintained and airway obstruction managed. Previous recommendations to reduce the delivered oxygen concentration prior to activating a potential ignition source (e.g., electrosurgical probe, electrocautery probe, or surgical laser) do not seem advisable if the patient is sedated to the point that a greater oxygen concentration is required to prevent hypoxemia. Therefore, controlling the airway when an oxygen concentration of greater than 30% is required becomes an important part of the fire prevention strategy.

Many anesthetizing locations only provide a source of 100% oxygen for open delivery devices. While it is possible to use the anesthesia machine to deliver a reduced oxygen concentration during sedation, incorporating an oxygen blender (Figure 1) into the

### Oxygen Concentrations Should Be Limited to 30% or Less to Minimize Surgical Fires in High-Risk Patients

From "Oxygen Limit," Preceding Page



Figure 1: Oxygen blender device for titration of oxygen concentration. Photo courtesy of Fisher Paykel Healthcare.

anesthesia workspace for the open delivery devices will facilitate safe practice.

In summary, laboratory testing has shown that common materials in the surgical field become flammable and can rapidly propagate fire when oxygen is delivered by open source at concentrations of 50% or more. During procedures at high risk for fire, the oxygen concentration delivered using an open source should be limited to 30% or less.

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*Mr.* Bruley has no conflicts of interest. Dr. Feldman is a consultant for Medtronic and Micropore and Becton-Dickinson.

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Additional information on fire prevention including educational videos can be found at https://www.apsf.org/videos/preventing-surgical-fires/.



Anesthesia professionals are routinely

**Risk factors** 

Age

Male gender

Patient condition

Higher APACHE score

Emergent transport

Obesity

### Intrahospital Patient Transport: Checklists, Adverse Events, and Other **Considerations for the Anesthesia Professional**

by Caroline Andrew, MD, and Michael Fitzsimons, MD

#### Table 1: Adverse Events and Risk Factors Associated With Patient Transport.

involved in the transport of patients throughout Adverse event (AE) **Potential complications** the hospital (intrahospital transport). Studies on classification the outcomes of patients undergoing perioper-General<sup>1,4,7-8,11,14,16</sup> Staff musculoskeletal injury ative transport by anesthesia professionals are General patient instability rare, as most literature involves nurses or other care providers and rarely focuses on the perioperative population. Thus, we must learn from reports published in critical care or emergency medicine. The incidence of intrahospital adverse events (ITAEs) during transport or within 24 hours of transport approaches 80% in some studies.<sup>1,2</sup> The frequency of patients requiring medical intervention from ITAEs has been reported to range from 4 to 9%.<sup>2-4</sup> Production pressure, reduction in support personnel, and increased patient acuity may heighten the risk of peri-operative transport.<sup>1,5</sup> As such, now is the time to ask, "Is our approach to perioperative patient transport right and are we doing it safely?" We review the current literature to understand the incidence and contributing factors leading to ITAEs as well as practices from other areas that can be applied to our field. The variability in the incidence of ITAEs may be partially attributed to the lack of consensus regarding what an adverse event entails during transport. It can be defined as "any unintended event or outcome, which may have or did reduce the safety margin for the patient." <sup>5</sup> Or, it can be any observation that fell outside of some predefined threshold (e.g., hypotension with SBP < 100 mmHg, hypertension with SBP > 160 mmHg).<sup>6</sup> A meta-analysis describing the incidence of ITAEs commented on the high heterogeneity among studies making it difficult to accurately report a range of frequencies.<sup>7</sup> For instance, many studies did not clearly define an ITAE while others defined one based on author team consensus. Additionally, there was no method for distinguishing whether patient changes were indeed ITAEs or merely represent physiologic variability that just happened to occur during transport.

Despite the heterogeneity in the literature regarding the incidence and types of ITAEs, common themes prevail. ITAEs are often classified as respiratory, cardiovascular, neurological, and equipment related.<sup>7</sup> Commonly reported individual events included hypertension, hypotension, arrythmias (including cardiac arrest), decreased arterial saturation, and agitation.<sup>7</sup> Equipment-related problems included malfunction, accidental dislodgement of lines, tubes, and catheters,

		Emergent transport Longer transport time Acidosis Elevated PaCO <sub>2</sub> Reduced pH Higher ASA status
System <sup>2,5,7-8,13</sup>	Loss of information Transport to wrong location Failure to respond to crisis Improper management of devices Care delay	Less experienced transport team Resident rather than attending directed transport Lack of checklists
Respiratory and airway <sup>1,4,7,14,16</sup>	Hypoventilation Pneumothorax Hypoxemia Accidental extubation or ETT displacement	Mechanical ventilation Manual ventilation Need for PEEP
Cardiovascular <sup>1,7,14,16</sup>	Hypertension Hypotension Arrhythmias Central line displacement Arterial line displacement Cardiac arrest	Use of vasopressors or inotropic agents
Neurologic <sup>1,3,8,13-14</sup>	Agitation Intracranial hypertension Reduction in GCS Seizures Secondary brain injury Patient discomfort	Higher levels of sedation Inadequate monitoring during transport
Equipment <sup>1,5,7,13-14</sup>	Nonfunctioning ventilator Battery depletion Oxygen depletion Fluid depletion Infusion pump failure Equipment disconnection Monitor incompatibility Monitor disconnection	Higher number of monitors Poor preparation Inexperienced transport team Inadequate monitor inspection prior to transport

ETT, endotracheal tube: GCS: Glasgow Coma Scale. and empty oxygen cylinders. A recent

multicenter prospective study reported similar findings.<sup>8</sup> Among 102 ITAEs identified in the multicenter study, cardiac (30.3%), airway and/ or respiratory (17.6%), neurologic (16.6%), and equipment problems (12.7%) were the most

### Critically Ill Patients Are at High Risk for Experiencing an Intrahospital Transport Adverse Event

#### From "Intrahospital Transport," Preceding Page

common.<sup>8</sup> The association between the physiologic changes and transport itself was difficult to determine. Regardless, equipment-related adverse events continue to be prominent with some studies attributing over one-third of ITAEs to problems with tools and technology, including unreliable functioning of transport equipment and errant management of such equipment by health care providers.<sup>9</sup>

Patient transport may also subject anesthesia professionals to physical harm due to ergonomic factors. Transport stretchers or beds may weigh as little as 100 pounds up to as much as 700 pounds.<sup>10</sup> Bed width and length may be challenging to maneuver while simultaneously managing an airway or performing an intervention during ITAE. Anesthesia professionals report a high rate of work-related musculoskeletal disorders with a large percentage reporting the need for analgesics while over 40% report sick leave associated with such injuries.<sup>11</sup>

Numerous studies have evaluated risk factors for complications during transport (Table 1, preceding page).<sup>1,4-7,2-14</sup> Risk factors may be classified as patient-specific, equipmentrelated, or systematic. Patient-specific factors associated with higher rates of complications include higher severity of illness scores, older age, the need for pharmacologic support (specifically, sedative medications and/or vasopressors), mechanical ventilation (specifically, PEEP > 6 cm H<sub>2</sub>O), obesity, and compromised arterial oxygen saturation before transport.<sup>1,3-4,712,15</sup> In general, the literature suggests that critically ill



Figure 1: Example of unsafe environmental factors. A chest tube wrapped around a bed post in a cluttered hallway.

#### Table 2: Perioperative Intrahospital Patient Transport Checklist

System	Critical Points	
	Identification bracket on patient	
Identification/	Chart with patient	
Information	Necessary consents present	
	Confirm ICU / PACU / OR prepared for patient	
	Endotracheal tube secured	
	Airway precautions necessary	
Airway	Manual resuscitator (Bag-valve-mask) present	
	Emergency airway management equipment necessary / available	
	Mode of delivery of oxygen confirmed	
Dreathing	Oxygen supply adequate	
Breathing	Transport ventilator charged/ functioning	
	Patient on ventilator	
	Intravenous line identified for resuscitation	
	Emergency medications necessary / available	
Circulation	Infusion pumps and monitor adequately charged	
	Hemodynamic alarms set	
	Defibrillator necessary / present	
Neurologic	Sedation / pain control adequate	
	Spinal precautions necessary	
	Patient stable / safe for movement	
Extras/Precautions	Personal protective equipment present	
EXILOS/FIECAULIONS	Lines, tubes, drains secured	
	Rails raised	
	Connect monitors	
Final	Plug in bed	
	Perform comprehensive hand-off	

patients in particular are at increased risk for ITAEs. Equipment-related risk factors include the use of mechanical ventilation and increasing number of monitors utilized during transport.<sup>5,6,14</sup> System or situational risk factors include longer duration of transport (> 60 minutes outside of the ICU), poor hand-off communication, urgent or emergency transport, staffing shortages, and the use of less experienced health care or transport providers.<sup>2,5,6,13,16,17</sup> Factors not identified in studies but a subject of discussion are cluttered hallways and focus of a care provider on the act of physically moving a bed which may limit their ability to observe obstacles which threaten safe transport (Figure 1).

The American College of Critical Care Medicine and the Society of Critical Care Medicine have established guidelines for intrahospital transport of critically ill patients to and from the ICU, which provide a foundation for improving our perioperative practice.<sup>17</sup> The SCCM guidelines focus on four critical components of transport: communication, personnel, equipment, and monitoring.<sup>17</sup> Communication includes providerto-provider handoff when the receiving location assumes management of the patient and conveys information to other disciplines such as respiratory care regarding the timing of transport and equipment required.<sup>17</sup> In terms of personnel, the guidelines recommend a minimum of two

### Standardized Checklists May Help Decrease Intrahospital Transport Adverse Events

#### From "Intrahospital Transport," Preceding Page

people accompany a critically ill patient during transport. A provider with expertise in airway management and advanced cardiac life support is strongly recommended to accompany volatile patients. Basic monitors including blood pressure, pulse oximetry, and EKG should accompany every critically ill patient during transport without exception. The level of monitoring should not be reduced during transport. Medications necessary for resuscitation should be readily available. Equipment should be fully charged and capable of functioning for the entirety of the transport duration. The American Society of Anesthesiologists provides additional guidelines on the transport of patients from the operating room (OR) to the postanesthesia care unit (PACU).<sup>18</sup> The ASA guidelines on PACU transport state that a patient who has received general anesthesia, regional anesthesia, or monitored anesthesia "shall be accompanied by a member of the anesthesia care team who is knowledgeable about the patient's clinical condition."18 During transport, the patient should be consistently assessed and treated with levels of monitoring and/or support that are suitable for the patient's clinical condition based on the anesthesia professionals' clinical judgment.<sup>18</sup> Other actions that may limit adverse effects during transport include regular patient/equipment checks, meticulous patient preparation, correct use of protocols, and transport locations that are within easy reach.<sup>5,19,20</sup> Some studies have also found reductions in ITAEs and increased compliance with guidelines by incorporating standardized transport checklists into their practice.<sup>21-22</sup>

Perioperative transport of seriously ill patients should remain under the guidance of the anesthesia care team. As patient acuity, production pressure, and care volume continue to increase, anesthesia professionals must be proactive in efforts to increase transport safety for our patients while maintaining our wellbeing. We offer several recommendations that may help us achieve those goals:

- Patient assessment before transport should include the identification of risk factors associated with ITAEs.
- All anesthesia team members as well as others involved in patient movement should be educated on the potential harm of intrahospital transport and on proven practices that minimize these harms (e.g., guidelines, and the use of checklists during transport).

- 3. The use of perioperative patient transport checklists may be beneficial to assure that patients are prepared, equipment is functioning with back-up power supply, records are present, and communication has occurred (Table 2, preceding page). Such checklists should be used at initiation of transport, during hand-off at the receiving location, and upon return to the original location.
- 4. Anesthesia professionals should participate in system design when patient transport is involved. Factors to consider are uncluttered hallways, easily maneuverable beds and stretchers, and team formation that allows the anesthesia professional to observe the patient and intervene without distraction while other team members assume primary responsibility for patient physical bed movement.
- 5. Perioperative transport by anesthesia professionals should be promoted as an important focus of academic study.

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The authors have no conflicts of interest.

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### **APSF Awards 2025 Grant Recipients**

The APSF grant programs are key to the mission of APSF to support and advance anesthesia patient safety culture, knowledge, and learning. The programs have played an essential role in establishing and enhancing the careers of many anesthesia and other professionals in conducting safety research and education. Since 1987, APSF has supported more than 130 anesthesiologists and other researchers with more than \$15 million in funding. The 2024-2025 APSF investigator-initiated research (IIR) grant program received 24 letters of intent from 18 organizations in the United States and Canada. The multidisciplinary Scientific Evaluation Committee (SEC) reviewed and discussed these letters, with the assistance of external statistical reviewers. The top five scoring projects were invited to submit full proposals, which were reviewed and discussed by the SEC for their potential impact on anesthesia patient safety and scientific rigor. Three proposals were recommended for funding to the APSF Board of Directors and received unanimous support. This year's recipients are Rodney A. Gabriel, MD, MAS, from the University of California, San Diego; Kelly Michaelsen, MD, PhD, from the University of Washington; and Elizabeth Mahanna-Gabrielli, MD, from the University of Miami. In addition, the 2024 Mentored Research Training Grant (MRTG) program, jointly funded with the Foundation for Anesthesia Education and Research (FAER), received seven letters of intent from six organizations. Full proposals were requested from three principal investigators. After reviewing, the recipient was Caoimhe Duffy, MD, MSc, from the University of Pennsylvania. The principal investigators provided the following description of their proposed work.



Rodney A. Gabriel, MD, MAS

Associate Professor of Anesthesiology, University of California, San Diego - Health Sciences by Yan Xiao, PhD

Dr. Gabriel's project is titled "PLATO (Perioperative Learning using Artificial intelligence for <u>Timely surgical Optimization</u>)—An Automated Approach for Triaging Surgical Patients for Preoperative Care Clinics."

Background: Effective use of preoperative care clinics have demonstrated reductions in surgical cancellations, unneeded testing, hospital length of stay, and postoperative complications.<sup>1,2</sup> However, with the rise in surgical volume, the expansion of electronic health record (EHR) data management, and limited resources to keep up with these demands, care needs may outstrip clinic capacity. Using artificial intelligence (AI) to help automate the triaging process for preoperative care clinics have many patient safety-related benefits. While it may directly reduce production pressure, the primary goal of these automated processes is to optimize the thoroughness of the preoperative evaluation of every patient, especially among those who are high risk for postoperative complications.

Aim: The primary goal of our proposal is to develop tools that may reduce risk of major post-surgical complications, specifically cardiac-related events, by improving our ability, within a preoperative care clinic, for identifying high-risk patients prior to surgery. The objective of our proposal is to leverage AI modalities<sup>3</sup> such as machine learning and large language models to process unstructured and structured data-to develop PLATO, which will process preoperative EHR data to calculate a patient's Revised Cardiac Risk Index<sup>4</sup> (RCRI) and summarize relevant clinical history to assess cardiac risk (Aim 1). PLATO will process unstructured data (e.g., clinical notes) and structured data (e.g., laboratory values, medications, diagnosis codes) to determine patient risk factors and, subsequently, to calculate 30-day risk of death, MI, or cardiac arrest. We hypothesize that we will be able to develop PLATO such that it will identify which RCRI components each patient has and thus calculate their preoperative cardiac risk. This information can then be used by the preoperative anesthesia care clinics to triage preoperative evaluation needs. In addition, risks for postoperative outcomes including cardiac complications, pneumonia, surgical site infections, urinary tract infections, venous thromboembolism, renal failure, unplanned reintubation, and mortality can be predicted (Aim 2).

**Implications:** Preoperative care clinics are associated with improved patient outcomes.

The objective of our proposal is to leverage Al to develop PLATO, which will process structured and unstructured EHR data to identify postoperative risk based on the preoperative RCRI score as well as predict probability of various postsurgical complications. Such an approach may provide an automated tool to screen high-risk patients so that preoperative clinics may more effectively triage available resources for preoperative evaluations (e.g., patients identified as high risk from PLATO may be allocated to in-person preoperative clinic visits while those who are low risk may be allocated to either day of surgery or phone call evaluation).

**Funding:** \$150,000 (January 1, 2025–December 31, 2026). The grant was designated as the APSF/American Society of Anesthesiologists (ASA) President's Research Award.

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Kelly Michaelsen, MD, PhD

Assistant Professor of Anesthesiology, University of Washington

Dr. Michaelsen's project is titled "An Integrated, Centralized Anesthesia Alarm System Based on Aviation Alarm Systems Principles."

**Background:** Medical equipment alarms are widely recognized as a dysfunctional system that produces a cacophony of distracting

### **APSF Has Awarded Over 15 Million Dollars in Funding to Researchers**

#### From "2025 Grants," Preceding Page

sounds that lead to "alarm fatigue" and can jeopardize patient safety.<sup>1</sup> Equipment alarms frequently occur in operating rooms, and the majority of alarms do not have any clinical significance and do not require immediate action.<sup>2,3</sup> The Joint Commission has recognized the problem of medical alarms since 2013 and still considers the safe use of alarms to be a National Patient Safety Goal in 2024.<sup>4</sup> This project proposes a shift in the philosophy of anesthesia equipment alarms by applying design best practices from the aviation industry. Unlike medical alarms, flight deck alarms are centralized. When an alarm from any aircraft system or sensor is triggered, the condition is displayed on a central panel according to a hierarchy of importance, with alarms requiring an immediate response at the top of the hierarchy. Attention is drawn to the most important conditions with a red "master warning" light and a distinct persistent tone. In a few instances of the most important alarms, they will be accompanied by an audible announcement (CRITICAL alarms). Alarms that have lesser priority are presented with a yellow "master caution" light and a single tone (WARNINGS and CAUTIONS), or no tone at all (ADVISORIES), along with the condition message on the display.

Aims: We aim to create a proof-of-concept version of a centralized anesthesia alarm system with a commercial aviation-style architecture adapted to the anesthesia setting. We will test the proof-of-concept system in a full-size operating room simulator environment. Our hypothesis is that our alarm system will result in rare CRITI-CAL alarms, few WARNINGS, and mostly lowerlevel, unobtrusive messages. We further hypothesize that our system will provide caregivers with a simple, intuitive, central source of alarm information that reliably presents alarms in priorities that match caregiver's expectations and needs, to best support their actions in the interest of patient safety.

Implications: The key novel aspect of this design is a centralized system that pulls information from all the anesthesia-related monitors and devices in the operating room, including the patient monitor and the anesthesia machine, into a single system that presents alarms and status messages from all of the devices. This design will integrate and replace all aural and visual alarms with a single, prioritized scheme including a master alarm light, two different aural alarms (reserved for WARNING and CAUTION), and in rare instances, a voice aural alarm for CRITICAL

alarms that require immediate action, and a centralized alarm screen display with detailed information about active alarms. Ultimately, the centralized anesthesia alarm system could integrate data from all anesthesia-related devices. A similar system could be designed for other environments such as the emergency room and intensive care units.

Funding: \$150,000 (January 1, 2025-December 31, 2026). The grant was designated as the APSF/Medtronic Research Award, and was also designated as the APSF Ellison C. Pierce, Jr., MD, Merit Award with \$10,000 unrestricted research support.

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#### Elizabeth Mahanna-Gabrielli, MD

Associate Professor of Anesthesiology, Miller School of Medicine of the University of Miami

Dr. Mahanna-Gabrielli's project is titled "Does ongoing comprehensive geriatric assessment reduce the incidence of postoperative delirium in older, frail patients undergoing elective inpatient surgery?"

Background: Frail, older patients have 2-3 times the odds of postoperative delirium (POD) as compared to robust counterparts.<sup>1</sup> Frailty is a syndrome of comorbidities, weakness, and poor resilience to recover from stressors. Comprehensive Geriatric Assessment (CGA) evaluates the complex interaction of frailty, comorbidities, and risk factors for POD. Expert consensus has recommended CGA in at-risk

patients.<sup>2,3</sup> However, equipoise exists as to whether CGA reduces older patients' risk of POD, possibly due to the inclusion of robust, older patients in prior studies.<sup>4</sup> We hypothesize that postoperative assessment and individualized recommendations, including adherence to delirium prevention strategies, provided by a dedicated geriatric medicine service ("CGA") will be superior to simple EHR frailty identification, anesthetic guidelines, and generic recommendations for reducing POD ("standard care") in frail, older patients,  $\geq$  60 years old, who are scheduled for elective inpatient surgery ( $\geq 2$  day anticipated length of stay).

Aims: 1. To determine if CGA is superior to standard care with respect to reducing POD. 2. To explore if CGA is superior to standard care with respect to discharge to the same or a lower preoperative level of care. 3. To explore if CGA differs from standard care with respect to prolonged length of stay.

Implication: Delirium is a serious, common, preventable patient safety problem occurring across surgical subspecialties with significant associated morbidity, mortality and cost.<sup>5</sup> Evidence-based delirium prevention is often poorly followed.<sup>2</sup> CGA is a proposed strategy to reduce POD with current equipoise in the literature.<sup>4</sup> Models of CGA can vary and need not be comprised of only geriatricians, but rather providers with in-depth knowledge of geriatric best practices, including geriatric anesthesiologists. This proposal includes only frail, older patients with a high risk of POD and thus more potential to demonstrate benefit than robust patients. If superiority is shown, this will be strong evidence supporting postoperative CGA over EHR frailty identification and generic recommendations to reduce POD.

Funding: \$150,000 (January 1, 2025-December 31, 2026).

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### The 2024-2025 APSF Grant Program Received 24 Letters of Intent Among 18 Different Organizations

#### From "2025 Grants," Preceding Page

 Gou RY, Hshieh TT, Marcantonio ER, et al. One-year Medicare costs associated with delirium in older patients undergoing major elective surgery. JAMA Surg. 2021;156:490–442. PMID: <u>33625501</u>



Caoimhe Duffy, MD, MSc

Assistant Professor of Anesthesia and Critical Care Medicine, University of Pennsylvania, Perelman School of Medicine

#### Dr. Duffy's project is titled: "Resilience training to prevent intubation harm: the One Safe Act-Airway study."

**Background:** Over 15 million tracheal intubations are performed each year in the United States.<sup>1</sup> This practice, commonly perceived as routine, represents a high-risk medical intervention since major airway complications contribute to 25% of anesthesia-related deaths.<sup>2</sup> Neither technologic advancement nor continuous guideline refinement have successfully decreased airway-associated adverse events over the past two decades.<sup>3</sup> The largest study of airway complications to date, National Audit Project 4 (NAP4), highlighted a causal link between cognitive errors and adverse airway events.<sup>2</sup> Lapses in decision-making arise when subconscious processes and mental shortcuts are inappropriately applied. These lapses have been implicated in up to 80% of anesthetic critical incidents, yet actionable targets for improving anesthesia safety remain relatively underexamined.<sup>4,5</sup>

Cognitive error-mitigation techniques, dubbed "forcing strategies," leverage metacognitive (thinking about thinking) promotion of structured preprocedural planning and decision-making self-assessment.<sup>6</sup>

Our proposed intervention, One Safe Act-Airway (OSA-A), will address this gap and build on our prior pilot study that demonstrated that OSA-A prompts consideration of proactive safety behaviors among clinicians.<sup>7</sup> Aligning with the Safety-II approach, OSA-A promotes consideration of why processes succeed rather than the traditional focus on debriefing failures. Through this emphasis, OSA-A shifts clinicians' focus from just-in-time error mitigation towards deliberate, planned error prevention. OSA-A simply, efficiently, and seamlessly integrates into existing workflows to improve safety without significant costs.

**Aim:** To evaluate whether OSA-A can reduce errors during tracheal intubation through enhancement of clinicians' metacognition and resilience. Specifically, we will assess whether participation in this intervention leads to a reduction in hypoxic events during tracheal intubation and improves clinicians' perceptions of successful and safe intubation practices.

**Implications:** The outcomes of this project will lay the foundation for implementing proactive error-prevention behaviors in airway manage-

ment. It will offer valuable insights into cognitive techniques related to intubation, as well as demonstrate the implementation and sustainment of the OSA-A. Future work will focus on identifying proactive behaviors in clinical practice and subsequently disseminating these strategies to further enhance safe airway management.

**Funding:** \$300,000 as 2024 APSF/FAER Mentored Research Training Grant (MRTG).

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Yan Xiao, PhD, is a professor at the University of Texas at Arlington College of Nursing and Health Innovation, and the chair of the APSF's Scientific Evaluation Committee.

The author has no conflicts of interest.



### APSF Newsletter Podcast Now Available Online @ 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. If you have suggestions for future episodes, please email us at <u>podcast@APSF.org</u>. You can also find the Anesthesia Patient Safety Podcast on Apple Podcasts or *Spotify* or anywhere that you listen to podcasts. Visit us at <u>APSF.org/podcast</u> and at @APSF.org on *X*, *Facebook*, and *Instagram*.



Allison Bechtel, MD APSF Podcast Director

### **SPOTLIGHT** on Legacy Society Members

#### Drs. Alex and Carol Hannenberg



The groundbreaking improvements in clinical outcomes and patient safety for which the specialty of anesthesiology is known—above all other disciplines has been a profound source of pride for me. To call myself an anesthesiolog ist and be

associated with the work and achievements of so many I admire deeply is a privilege. The APSF is the home of these people and this work and its commitment to ceaselessly capture opportunities to protect our patients deserves our support.

Carol and I are delighted to provide for ongoing support of APSF in our estate planning and encourage others to do so.

#### Drs. Joy L. Hawkins and Randall M. Clark



We are very pleased to be part of the APSF Legacy Society. A foundation like APSF that focuses on the safety of patients is an essential part of our identity as anesthesiologists. As others before us have correctly observed, the safety of our patients is at the center of everything we do as physicians.

Joy and Randy are both professors of Anesthesiology at the University of Colorado School of Medicine in Denver. Joy is the head of obstetric anesthesia for the Department of Anesthesiology and University Hospital. She has previously served as president and chair of the Board of Directors for the Foundation for Anesthesia Education and Research. Randy is a pediatric cardiac anesthesiologist at Children's Hospital Colorado. In October 2019, Randy became ASA first vice president and then president in 2021. Randy and Joy have two daughters, Catherine and Victoria, both of whom are in graduate school.

### David Gaba, MD, and Deanna Mann

Our two careers in health care were dedicated to the provision of safe patient care. David's academic mission centered on patient safety—both on its theoretical basis and on a number of practical avenues to bring it to fruition around the world. Without APSF's support of these efforts, and those of countless others, patient safety as a specific, targetable goal would never have come to the fore. That "no one shall be harmed by anesthesia care" is a vision that we believe should continue in perpetuity.

Deanna Mann, RN, BSN, RNP, MSN, is a registered nurse and women's health nurse practitioner specializing in obstetrics and gynecology. She has worked in both hospital and community clinic settings, giving care to patients of diverse economic and cultural backgrounds. David Gaba, MD, is an anesthesiologist at Stanford School of Medicine and at VA Palo Alto Health Care System. He has served as



a director of the APSF continuously from 1990 through 2019, as well as a member of its Executive Committee, and secretary, at various times in this period. He was also a founding member of the American Society of Anesthesiologists' Simulation Editorial Board. He was a founding board member of the Society for Simulation in Healthcare and the founding editor-in-chief of its peer-reviewed journal, *Simulation in Healthcare*.

### 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 Jill Maksimovich, APSF Director of Development at <u>maksimovich@</u> <u>apsf.org</u>.

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